OFFICE OF STATE COURTS ADMINISTRATOR
P.O. Box 104480
2112 Industrial Drive
Jefferson City, MO 65110-4480

RFP NO. OSCA 11-029-00
AMENDMENT: 001
TITLE: Drug/Alcohol Testing Equipment & Services
ISSUE DATE: January 28, 2011

CONTACT: Russell Rottmann
PHONE NO.: (573) 522-6766
E-MAIL: osca.contracts@courts.mo.gov

RETURN PROPOSAL NO LATER THAN: February 10, 2011 AT 5:00 PM

MAILING INSTRUCTIONS: Print or type **RFP Number** and **Return Due Date** on the lower left hand corner of the envelope or package.

RETURN PROPOSAL TO:

(U.S. Mail)
Office of State Courts Administrator
Contracts Unit
PO Box 104480
Jefferson City Mo 65110 - 4480

or

(Courier Service)
Office of State Courts Administrator
Contracts Unit
2112 Industrial Dr
Jefferson City Mo 65109

CONTRACT PERIOD: JULY 1, 2011 THROUGH JUNE 30, 2012

DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:

MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI

The vendor hereby declares understanding, agreement and certification of compliance to provide the items and/or services, at the prices quoted, in accordance with all requirements and specifications contained herein and the Terms and Conditions Request for Proposal. The vendor further agrees that the language of this RFP shall govern in the event of a conflict with his/her proposal. The vendor further agrees that upon receipt of an authorized purchase order from the Office of State Courts Administrator or when this RFP is countersigned by an authorized official of the Office of State Courts Administrator, a binding contract shall exist between the vendor and the Office of State Courts Administrator.

SIGNATURE REQUIRED

AUTHORIZED SIGNATURE		DATE 02/09/11
PRINTED NAME Barry C. Chapman		TITLE Chief Financial Officer
COMPANY NAME Redwood Toxicology Laboratory, Incl		
MAILING ADDRESS 3650 Westwind Boulevard		
CITY, STATE, ZIP Santa Rosa, CA 95403		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 68-0332937
PHONE NO. 800.255.2159	FAX NO. 707.569.0121	E-MAIL ADDRESS smcintosh@redwoodtoxicology.com

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS: IN ITS ENTIRETY AS SUBMITTED		
CONTRACT NO. OSCA 11-029-14		CONTRACT PERIOD July 1, 2011 through JUNE 30, 2012
CONTACTS COORDINATOR Robert J. Conner	DATE 2-23-2011	STATE COURTS ADMINISTRATOR

February 9, 2011

Mr. Russell Rottmann
Office of State Courts Administrator
State of Missouri
2112 Industrial Drive
PO Box 104480
Jefferson City, MO 65110

Reference: RFP NO. OSCA 11-029-00
Drug/Alcohol Testing Equipment & Services

Dear Mr. Rottmann:

Redwood Toxicology Laboratory, Inc. (RTL) currently provides the State of Missouri Drug Courts with contracted laboratory and on-site drug testing services. If chosen as the vendor on this RFP, RTL will continue to provide excellent products and services for all aspects of the State's Drug Court drug testing needs.

RTL specializes in assisting agencies nationwide with implementing easy and cost effective drug-testing programs. Current customers include thousands of drug court, probation, correctional, behavioral health and mental health agencies. As outlined in this bid, RTL is serious about providing our services and products to the State. This is indicated not only in our pricing, but in our comprehensive line of support services.

We will work closely with the individual Drug Courts to develop the easiest and most comprehensive drug testing program available. We are confident that the Drug courts will be impressed with our attention to detail and dedication to customer services. As such, the entire RTL Team is dedicated to ensuring the Drug Courts' 100% satisfaction.

RTL looks forward to continuing our working relationship with the State's Drug Courts by offering new and varied drug testing options. Please feel free to contact me at any time regarding this proposal response at (800) 255-2159, ext. 4342, or by email at smcintosh@redwoodtoxicology.com.

Sincerely,

Sonja McIntosh
Sales Operations Manager

REDWOOD TOXICOLOGY LABORATORY™ | The confidence of scientific confirmation.

Third Party Government Insurance Billing

FREQUENTLY ASKED QUESTIONS

Why Redwood Toxicology Laboratory?
Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state of the art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 clients.

RTL offers numerous advantages to your agency, including the following:

- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse,
- Highly qualified scientific staff,
- State of the art instrumentation for the detection of alcohol and drugs of abuse,
- Excellent client services, and;
- Extensive quality assurance and quality control procedures that help to ensure accurate results.

Does Redwood Toxicology Laboratory (RTL) provide third party government insurance billing?
Yes. Redwood Toxicology Laboratory (RTL) gladly provides third party government insurance billing services for its drug testing to qualifying clients. This service includes billing to Medicaid, Medi-Cal and Medicare.

What information should I provide to RTL to process this billing?
The following is required by law for RTL to process client Medicaid/Medicare billing:

- Each drug screen must be ordered by a licensed practitioner (or a person designated by the licensed practitioner) within their scope of practice.
- The laboratory is required to have written verification on file in the form of a Signature Sheet.
- Each month, a Standing Order will be mailed to your agency listing all of the specimens processed for the month. The cover letter accompanying the Standing Order must be signed by one of the persons listed on the Signature Sheet and returned to RTL via fax at (707) 569-1442.

What type of patient information should I provide?
To include a patient in the billing process, fax a copy of their Medicaid/Medicare card to (707) 569-1442, Attention: Insurance Billing Department. The copy should include your agency's RTL account number and all of the following patient information:

- Patient's Full Name
- Medicaid Identification Number
- Date of Birth
- Specimen Identification (if not Name or Social Security Number)

These items only need to be provided once for each patient. It is important to maintain the same specimen identification on each sample sent to RTL for testing. This allows RTL to bill in a timely manner. Failure to do this may cause the patient's charges to appear on your agency bill.

How can I remain compliant with privacy laws (HIPAA) and still provide patient information?
RTL requires the provision of the patient's Medicaid/Medicare information from the health care provider. We request that you, as the health care provider, obtain client authorization to disclose Medicaid/Medicare information for the purpose of billing.

In general, California law (Civil Code 56.10) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), permit the disclosure of health information without authorization to the extent necessary for treatment, payment and health care operations. Furthermore, the provisions of 42 CFR Part 2 require client authorization for the disclosure of health information for payment.

Is there a maximum amount of tests/screens that can be performed per patient?
Each state generally places a limit on the number of tests/screens your agency may perform and bill for a given patient.

1. Most states consider a screening test frequency that averages one per week to be the "maximum utilization," except for a few states that allow for a specific number per year.
2. Only one screen can be processed per patient, per day.
3. More than one screen per day can be ordered if needed, but the excess screens will be billed by RTL to your account.

What if the patient is covered by Medicare and Medicaid?
Medicaid is always the last payer. If the patient is covered by Medicare and Medicaid, please provide information for both at time of patient set-up.

What if the patient is covered by a health insurance plan?
If the patient has insurance coverage, the specimen is usually tested by the laboratory contracted by that insurance. Coverage may include:

- Managed Care
- Pre-Paid Health Plan
- Health Maintenance Organization (HMO)
- Contracted Plan (such as Kaiser)

RTL will test the specimen(s) your agency sends in, but will bill the charge(s) to your RTL account.

How will I know which tests are being paid by Medicaid/ Medicare? What if RTL bills me for a test that should be paid by Medicaid/Medicare?
Your agency will receive a monthly invoice for all services that are not billable to Medicaid/Medicare. If any charges appear on the invoice, but should be billed to Medicaid/Medicare, mark these charges on the invoice and return it to RTL via fax at (707) 569-1442 with copies of the Medicaid/Medicare Identification cards. The appropriate adjustments will be made.

Please Note: RTL must receive any adjustment requests within four months of the date of service.

HOW MAY WE ASSIST YOU?
Redwood Toxicology laboratory, Inc. is dedicated to providing the most prompt, courteous and professional customer support in the industry. Please contact RTL's Insurance Billing Department with any questions:

Address: 3650 Westwind Blvd., Santa Rosa, CA 95403
Phone: (800) 255-2159, ext. 4331
Fax: (707) 284-1172
Email: tcampbell@redwoodtoxicology.com
Web: www.redwoodtoxicology.com

REDWOOD TOXICOLOGY LABORATORY

3650 Westwind Blvd., Santa Rosa, CA 95403
Phone: 707-577-7959 / 800-255-2159
Fax: 707-577-0365
www.redwoodtoxicology.com

ACCOUNT NUMBER	ACCESSION NUMBER
0000	010206-06530

IDENTIFICATION
JOHN DOE 123

ORDERED BY
SAMPLE AGENCY T152

NOTES
(707) 555-5555

COLLECTED
1/2/2006 by MS

RECEIVED	REPORTED
1/3/2006	1/4/2006

Sample Agency
300 Sample Road
Santa Rosa, CA 95403

POSITIVES	TEST NAME	RESULT
	Amphetamines	None Detected
	Opiates	None Detected
	Barbiturates	None Detected
	Cocaine (Benzoylecgonine)	None Detected
	Benzodiazepines	None Detected
	Alcohol (Ethanol)	None Detected
POS--------->	THC (Marijuana) Confirmed by RIA.	300
	Creatinine	50.0 mg/dL
	THC/Creatinine Ratio Normalized THC Value for comparison purposes only.	600 ng THC/mg Creat

Final Results reviewed by Chief Toxicologist: WR
Certification of Compliance with Standard Operating Procedures: WR

FINAL REPORT

010206-06530 1/4/2006 05:32:11

Laboratory Directors:
MARK J. DeMEO, M.D.
RICHARD R. WILBER, M.D.

Specimen disposition: Specimens will be disposed of as follows: Negatives: destroyed within 2 days; Positives: destroyed after 6 months; all methadone maintenance urines after 2 months.

SEE REVERSE SIDE FOR CERTIFICATION & TECHNICAL INFORMATION

REDWOOD TOXICOLOGY LABORATORY
3650 Westwind Blvd., Santa Rosa, CA 95403 Phone: 707-577-7959 / 800-255-2159 Fax: 707-577-0365

TOXICOLOGY SUMMARY REPORT

Client: 1 SAMPLE AGENCY

Print Date: 02/08/2008

Date Received: 02/08/2008

Accession # /Req #	Identification	Collected	Alc	Amp	Barbs	Benzo	Coc	EtG	EtS	Op	THC	THC/CR	Creat	Other/Comments
080208-00001	SAMPLE 1	02/07/2008 RAS	-	-	-	-	-			-	-		133.0	
080208-00002	SAMPLE 2	02/07/2008 RAS	-	-	-	-	-			-	-		89.0	
080208-00003	SAMPLE 3	02/06/2008 RAS	-	-	-	-	-			-	240 RIA	444	54.0	[THC/CR] Normalized THC Value for comparison purposes only. [THC] Confirmed by RIA.
080208-00004	SAMPLE 4	02/06/2008 RAS						485 LCM	230 LCM					[EtG] Cutoff = 100 ng/mL [EtG] Confirmed by LC/MS/MS [EtS] Cutoff = 25 ng/mL [EtS] Confirmed by LC/MS/MS
080208-00005	SAMPLE 5	02/06/2008 RAS	-	-	-	-	POS RIA			-	-		288.0	[Coc] Confirmed by RIA.
080208-00006	SAMPLE 6	02/07/2008 RAS						-						[EtG] Cutoff = 100 ng/mL [EtG] Confirmed by LC/MS/MS
080208-00007	SAMPLE 7	02/07/2008 RAS	-	POS TLC	-	-	POS RIA			-	-		231.0	[Coc] Confirmed by RIA. [Amp] Confirmed as Methamphetamine and Amphetamine by TLC.

SAMPLE SUMMARY REPORT

REDWOOD TOXICOLOGY LABORATORY

Random Testing Client Setup

Use this form to setup random testing for a client. This form should be stored in T:\Random Testing\Setups.

PREPARED BY:	DATE:

Requestor Information

ACCOUNT NUMBER:		ACCOUNT NAME:	
CONTACT PERSON'S NAME:		CONTACT PERSON'S PHONE NUMBER:	

Random Testing Information

FREQUENCY:	☐ On demand	☐ Recurring:
PERCENT SELECTED:		
STARTING DATE:		
ENDING DATE:	☐ No ending date	☐ Ending date:

E-mail Recipients

List the e-mail addresses that will receive the random selection results.

Laboratory Drug Test

test requisition / custody form

REDWOOD TOXICOLOGY LABORATORY™
an inverness medical company

10284477

Agency Number: 600000

Agency Name:	Web Demo Agency
Address:	3650 Westwind Blvd
City, State and Zip:	Santa Rosa, CA 95403
Agency Phone:	(800)255-2159
Agency Fax:	

DONOR INFORMATION

Donor Name:	John Doe	**Tests Requested:**
Donor Unique Id:	42698	647 - Ethylglucuronide (EtG)
Specimen Type:	URINE	P08 - Screen 7 with Creatinine
Specimen Temperature:	97F	
Test Reason:	New Intake	

DONOR CERTIFICATION

I certify that I provided my specimen to the collector and that I have not adulterated it in any manner. The specimen was sealed in my presence with a tamper-evident seal. The information provided on this form and on the label affixed to the specimen container is correct. I authorize Redwood Toxicology Laboratory to perform the tests listed and to release the results of this test to WEB DEMO AGENCY.

X	John Doe	11/22/2010
Donor's Signature	*Donor's Name*	*Date*

COLLECTOR VERIFICATION

I certify that this specimen was collected from the above person following established protocols, and the specimen has been properly sealed and labeled.

X	Jane Doe	11/22/2010	01:14 PM
Collector's Signature	*Collector's Name*	*Collection Date*	*Collection Time*

Place Over Cap

Security Seal

Donor Initials _____

Date: 11/22/2010

Place Over Cap

REDWOOD TOXICOLOGY LABORATORY

Label usage example
1. Tighten cap.
2. Place security seal across the lid as shown.
3. Place patient I.D. label around bottle as shown.

Req #: 1028 4477
Agency: 600000 - Web Demo Agency
ID: 42698 John Doe
Collector: Jane Doe
Collected: 11/22/2010 01:14 PM
Tests: 647, P08

Redwood Toxicology Laboratory // 3650 Westwind Blvd. Santa Rosa, CA 95403 | (800) 255-2159

LABORATORY STAFF ONLY

RECEIVED AT LAB:	X _____ Received By (initial)	_____ Date	Seal Intact? ☐ Yes ☐ No	Labels Match? ☐ Yes ☐ No

11 000 3360 REV 1

Tear off and provide to Donor

11 000 3313 REV1

AGENCY INFO:
Web Demo Agency
3650 Westwind Blvd
Santa Rosa, CA 95403
Phone: (800)255-2159
Fax:

COLLECTION INFORMATION:
Donor Name: John Doe
Requisition #: 1028 4477
Test Reason: New Intake
Collection Date: 11/22/2010
Collection Time: 01:14 PM

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

REQUEST

Specimen Date _____

ID _____

Collector _____

Client

SAMPLE ONLY

CHAIN OF CUSTODY

DATE	INITIALS	COMMENTS

REDWOOD TOXICOLOGY LABORATORY
P.O. BOX 5680, SANTA ROSA, CA 95402
1-800-255-2159

Urine Drug Test

Laboratory test requisition

Client ID:

URINE TEST REQUISITION

URINE DRUG SCREEN TYPE

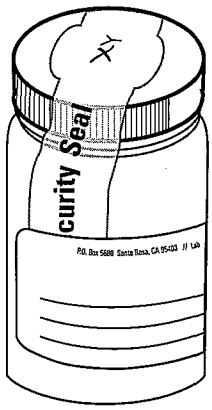
☐ Pre-Employment ☐ Periodic Medical ☐ Random ☐ Other
☐ Post-Accident ☐ Reasonable Cause ☐ Baseline

Chain of Custody: ☐ Yes ☐ No

Specimen temperature within range: ☐ Yes, 90°-100°F (32°-38°C) ☐ No, record specimen temperature here _____

LABELING AND TESTS ORDERED

Label usage example



1. Tighten cap.
2. Place security seal across lid as shown.
3. Place patient I.D. label around bottle as shown.

PEEL OFF

(Donor's Initials)

Security Seal

REDWOOD TOXICOLOGY LABORATORY

Redwood Toxicology Laboratory // P.O. Box 5680 Santa Rosa, CA 95402 // Laboratory phone: 800-255-2159

SAMPLE ONLY

PEEL OFF

DONOR CERTIFICATION (To be completed by donor)

I certify, that I provided my urine specimen to the collector and that I have not adulterated it in any manner. The specimen was sealed in my presence with a tamper-evident seal and the information provided on this form and on the label affixed to the specimen tube is correct. I authorize Redwood Toxicology Laboratory to perform the tests listed and to release the results of this test to:

Donor's signature:

Donor's name as listed above (please print):

Donor's ID (SSN OR DL#):

COLLECTOR VERIFICATION (To be completed by collection station personnel)

I certify, that this specimen was collected from the above person following established protocols, and the specimen has been properly sealed and labeled.

Collector's signature:

Date and time of collection: __ / __ / ____ __ : __ ☐AM ☐PM

Collector's name as listed above (please print):

Collection site phone: ___ – ___ – ____

RECEIVING (To be completed by laboratory):

Specimen received by:

Date received:

Seal intact? ☐ Yes ☐ No

Labels match? ☐ Yes ☐ No

REDWOOD TOXICOLOGY LABORATORY

3650 Westwind Blvd. Santa Rosa, CA 95403 // Laboratory: 800-255-2159 // Screening Devices: 877-444-0049
Local: 707-577-7959 // Fax: 707-577-0365 // www.redwoodtoxicology.com

Urine Drug Test

Client ID:

URINE TEST REQUISITION

Laboratory test requisition

URINE DRUG SCREEN TYPE

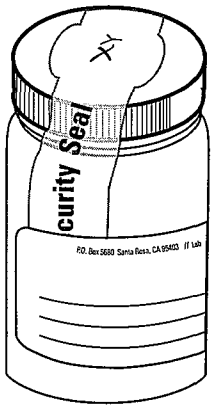
☐ Pre-Employment ☐ Periodic Medical ☐ Random ☐ Other
☐ Post-Accident ☐ Reasonable Cause ☐ Baseline

Chain of Custody: ☐ Yes ☐ No

Specimen temperature within range: ☐ Yes, 90°-100°F (32°-38°C) ☐ No, record specimen temperature here _____

LABELING AND TESTS ORDERED

Label usage example



1. Tighten cap.
2. Place security seal across lid as shown.
3. Place patient I.D. label around bottle as shown.

PEEL OFF

(Donor's Initials)

Security Seal _____ **REDWOOD TOXICOLOGY LABORATORY**

Redwood Toxicology Laboratory // P.O. Box 5680 Santa Rosa, CA 95402 // Laboratory phone: 800-255-2159

SAMPLE ONLY

PEEL OFF

DONOR CERTIFICATION (To be completed by donor)

I certify, that I provided my urine specimen to the collector and that I have not adulterated it in any manner. The specimen was sealed in my presence with a tamper-evident seal and the information provided on this form and on the label affixed to the specimen tube is correct. I authorize Redwood Toxicology Laboratory to perform the tests listed and to release the results of this test to:

Donor's signature:

Donor's name as listed above (please print):

Donor's ID (SSN OR DL#):

COLLECTOR VERIFICATION (To be completed by collection station personnel)

I certify, that this specimen was collected from the above person following established protocols, and the specimen has been properly sealed and labeled.

Collector's signature:

Date and time of collection: __ / __ / ____ __ : __ ☐AM ☐PM

Collector's name as listed above (please print):

Collection site phone: ___ – ___ – ____

RECEIVING (To be completed by laboratory):

Specimen received by:

Date received:

Seal intact? ☐ Yes ☐ No

Labels match? ☐ Yes ☐ No

REDWOOD TOXICOLOGY LABORATORY

3650 Westwind Blvd. Santa Rosa, CA 95403 // Laboratory: 800-255-2159 // Screening Devices: 877-444-0049
Local: 707-577-7959 // Fax: 707-577-0365 // www.redwoodtoxicology.com

drugs of abuse testing–*saliva*

LABORATORY SERVICES

Are they abusing? We'll find out.

Detect recent substance abuse with RTL-Oral. Oral fluid testing allows for unobtrusive collections and reliable results from the experts at Redwood Toxicology Laboratory.

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY ORAL FLUID TESTING

Oral fluid testing is gaining popularity with many programs that require convenient, gender-neutral specimen collection combined with the accuracy of lab testing. RTL–Oral is an easy and affordable lab-based testing solution for the detection of drugs of abuse in oral fluid.

RTL–Oral is ideal for drug testing in a variety of arenas, including: random, pre-employment, corrections, probation/parole, return to duty, post accident (insurance), reasonable cause, schools and methadone programs.

Redwood Toxicology Laboratory, Inc. (RTL) utilizes the most sophisticated, sensitive and specific equipment and technology available to screen, confirm and quantitate drugs (GC/MS) in oral fluid. As with all of RTL's testing options, full customer support is provided. Turn to RTL for confidence in testing—we'll find out.

BENEFITS INCLUDE:

- *Gender-neutral collection with no exposure to specimen*
- *Better indicator of recent usage as compared to urine samples*
- *Minimal chance of specimen adulteration—no need to worry about dilute specimens*
- *Collection device with volume adequacy indicator—no guesswork needed*
- *Increased THC recovery and stability*
- *Fast turn-around time from receipt of specimen (48 hours[1] negative, 72 hours positive)*

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/3275

REDWOOD TOXICOLOGY LABORATORY

an inverness medical company

FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com

Why should I implement the RTL-Oral Solution at my facility?
Not only does oral fluid testing save your agency time and money in collection fees, it offers the convenience of testing for drugs of abuse anywhere, at any time.

What are the testing and confirmation methodologies?
Specimens collected with the RTL-Oral collection device are sent to RTL for screening by Enzyme-Linked Immunosorbent Assay (ELISA). Positive screens are confirmed by gas chromatography/mass spectrometry (GC/MS)[2]. The analytical methods used by RTL for the detection of drugs of abuse are scientifically accepted and approved by the U.S. Department of Health and Human Services.

Screening Cut-off Levels by Procedure *Cut-off levels updated periodically*

Drug	ELISA
Amphetamine	50 ng/mL
Barbiturates	50 ng/mL
Benzodiazepines	20 ng/mL
Cocaine Metabolite (Benzoylecgonine)	20 ng/mL
Methamphetamine	50 ng/mL
Opiates (hydrocodone, hydromorphone, oxycodone, 6-monoacetylmorphine)	40 ng/mL
Phencyclidine	10 ng/mL
THC (Cannabinoids)	4 ng/mL
Methadone	50 ng/mL

Confirmation Cut-off Levels by Procedure *Levels updated periodically*

Drug	GC/MS
Amphetamine	15 ng/mL
Barbiturates	20 ng/mL
Benzodiazepines	15 ng/mL
Cocaine Metabolite (Benzoylecgonine)	8 ng/mL
Methamphetamine	15 ng/mL
Opiates (Morphine and Codeine)	25 ng/mL
Phencyclidine	5 ng/mL
THC (Cannabinoids)	1 ng/mL
Methadone	10 ng/mL

1. Excludes specimens received Saturday
2. Positive on methadone panels are confirmed by GC/MS upon request.

I suspect that my donor just used a substance of abuse, how long should I wait before collecting the specimen?
Depending on the drug and dosage, drugs may be detected in oral fluid in as little as a few minutes or up to approximately 2 hours from the time of use.

How do I collect the oral fluid specimen?
Instructions for use are included with your first order of RTL-Oral devices. Please read these instructions carefully. RTL offers telephonic training. If you have questions, please call (800) 255-2159.

Can I ship my oral fluid specimens with my urine specimens?
RTL will accept both oral fluid and urine specimens in the same lab pack when sending five or more specimens (e.g. three oral fluid specimens and two urine specimens). The specimens cannot, however, be mixed in the postage-paid mailer boxes due to U.S. Postal Service regulations.

What are the oral fluid drug detection times?
The drug detection times in oral fluid closely parallel those in blood.

Oral Fluid Detection Times

Drug	Detection Time
Amphetamine	From minutes up to 48 hours
Barbiturates	From minutes up to 48 hours
Benzodiazepines	From minutes up to 48 hours
Cocaine Metabolite (Benzoylecgonine)	From minutes up to 48 hours
Methamphetamine	From minutes up to 48 hours
Marijuana	From minutes up to 48 hours
Phencyclidine	From minutes up to 48 hours
THC (Cannabinoids)	From minutes up to 24 hours
Methadone	From minutes up to 48 hours

11 000 3275 REV4

REDWOOD TOXICOLOGY LABORATORY™

800-255-2159
Laboratory: 800-255-2159 // Screening Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

RTL-ORAL OVERVIEW

Oral fluid testing is popular with many agencies that require convenient, gender-neutral specimen collection combined with the accuracy of lab testing. Redwood Toxicology Laboratory, Inc. (RTL) provides an easy and affordable *lab-based testing* solution for the detection of *drugs of abuse in oral fluid*: *RTL-Oral*.

To provide the highest standard in testing, we offer two oral fluid panels that are confirmed by gas chromatography/mass spectrometry (GC/MS) at no additional fee. We also offer two methadone screen-only panels with GC/MS upon request. Due to customer demand, RTL now offers two new RTL-Oral lab panels with Benzodiazepines!

Two enticing offers are now available to get you up and running with our RTL-Oral solution. Call today to take advantage of both opportunities.

1. **Get a free lab test! Send in one oral fluid specimen for a** complimentary oral fluid lab test **with the purchase of five or more RTL- Oral collection devices. *New RTL-Oral accounts only*.**

2. **Purchase the RTL-Oral specimen collection devices in boxes of five (instead of 25) to allow your agency the opportunity to try this program with minimal financial obligation.**

The numerous benefits of the RTL-Oral solution include:

- Gender-neutral collection with no exposure to specimen
- Better indicator of recent usage as compared to urine samples
- Collection device with volume adequacy indicator – no guesswork needed
- Minimal chance of specimen adulteration – no need to worry about dilute specimens
- Forty-eight hour turnaround time from receipt of specimen with internet, fax or mailed results
- Toll-free training and technical support
- Expert witness services and litigation packages

Implementing the RTL-Oral Solution at your facility is as easy as one, two, three...

1. **Choose your panel and purchase your collection devices**. We will set up your account according to your specific needs. Call us toll-free at (800) 255-2159.

2. **Collect the specimen.** For quick and easy specimen collection, follow the instructions on the RTL-Oral collection device or call us to arrange a telephonic training session.

3. **Send the RTL-Oral collection device to RTL**. Package the RTL-Oral collection device and send to RTL in your pre-paid shipping container. When the specimen is received, it is tested and results are reported by internet, fax or mail within twenty-four to forty-eight hours.

REDWOOD TOXICOLOGY LABORATORY

Laboratory: 800-255-2159 // On-site Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

Oral Fluid Drug Test

laboratory test requisition

Client ID:

ORAL FLUID TEST REQUISITION

ORAL FLUID DRUG SCREEN TYPE

☐ Pre-Employment ☐ Periodic Medical ☐ Random ☐ Other

☐ Post-Accident ☐ Reasonable Cause ☐ Baseline

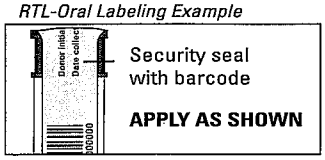
Chain of Custody: ☐ Yes ☐ No

ORAL FLUID SPECIMEN LABELING

LAB BASED COLLECTOR INSTRUCTIONS:

Ensure red cap is tightly fastened. Place the center of the security seal over the top of the red cap. Be sure that the barcode runs lengthwise/vertically on the collection tube.

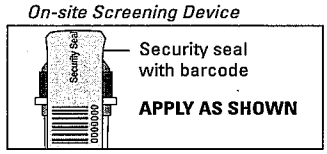
RTL-Oral Labeling Example



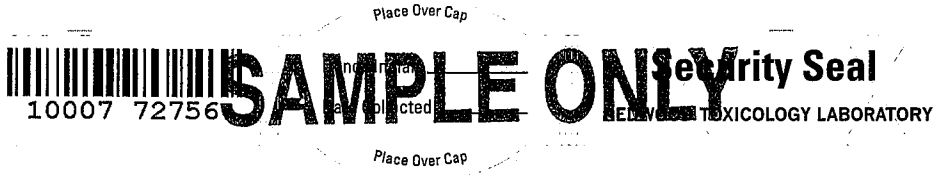
ON-SITE SCREENING DEVICE EXAMPLE:

Ensure the screw cap is tightly fastened. Write the drug(s) to be confirmed on the GC/MS confirm line above. Place the center of the security seal over the top of the cap. Be sure that the barcode runs lengthwise/vertically on the collection tube.

On-site Screening Device



10007 72756



NOTE: Place the center of this label over the cap of the screening device or collection device.

DONOR CERTIFICATION (To be completed by donor)

I certify that I provided my oral fluid specimen to the collector and that I have not adulterated it in any manner. The specimen was sealed in my presence with a tamper-evident seal and the information provided on this form and on the label affixed to the specimen tube is correct. I authorize Redwood Toxicology Laboratory to perform the tests listed and to release the results of this test to:

Donor's signature:

Donor's name as listed above (please print):

Donor's ID (SSN OR DL #):

COLLECTOR VERIFICATION (To be completed by collection station personnel)

I certify that this specimen was collected from the above person following collection site protocols, and the specimen has been properly sealed and labeled.

Collector's signature:

Date and time of collection: / / : ☐AM ☐PM

Collector's name as listed above (please print):

Collection site phone: – –

RECEIVING (To be completed by laboratory):

Specimen received by:

Date received:

Seal intact? ☐ Yes ☐ No

Labels match? ☐ Yes ☐ No

REDWOOD TOXICOLOGY LABORATORY

3650 Westwind Blvd. Santa Rosa, CA 95403 // Laboratory: 800-255-2159 // Screening Devices: 877-444-0049
Local: 707-577-7959 // Fax: 707-577-0365 // www.redwoodtoxicology.com

ghb testing

LABORATORY SERVICES

Were they drugged? We'll find out.

Gamma-Hydroxybutyric acid (GHB) testing from Redwood Toxicology Laboratory detects "date rape" drug presence in urine.

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY GHB TESTING

There are increasing reports of Gamma-Hydroxybutyric acid (GHB) being used recreationally as a euphoriant at "rave" type parties. GHB is typically associated with sexual assault or as a "date rape" drug due to its severe hypnotic and sedative effect at higher dosages. Typical illicit use of GHB involves dissolving 2 - 3 grams of powder in beverages.

Redwood Toxicology Laboratory, Inc. (RTL) utilizes the most sophisticated, sensitive and specific equipment and technology available (GC/MS - gas chromatography/mass spectrometry), to confirm and quantitate GHB. This methodology provides highly accurate results.

As with all of RTL's testing options, full customer support and training is provided. Turn to RTL for confidence in testing—we'll find out.

BENEFITS INCLUDE:

- *Strong indicator of GHB ingestion within 12 hours*
- *Expert witness services provided in court, telephonically and by written affidavit*
- *Results available via internet, fax and/or U.S. mail*
- *Fast turn-around time from receipt of specimen (48 hours[1] negative, 72 hours positive)*
- *Toll-free customer support services with access to board certified toxicologists*
- *Affordable pricing*

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/3273

REDWOOD TOXICOLOGY LABORATORY™

an inverness medical company

FREQUENTLY ASKED QUESTIONS

What is GHB?
Gamma-Hydroxybutyric Acid (GHB) was first developed as an anesthetic, but was discontinued for use due to its adverse and unpredictable effects. However, GHB is readily available and used in Europe as a sedative. The salt form of GHB has been marketed in gymnasiums and health food stores for the past few years as a steroid alternative for body-building and as a tryptophan replacement for sedation.

How is GHB used?
Typical illicit use of GHB involves dissolving 2 - 3 grams of powder in water or other beverages. Onset of effects occur within 10 - 30 minutes of ingestion and include euphoria, increased libido, drowsiness, reduced inhibitions, dizziness, nausea and may persist for 2 - 5 hours. Toxic effects include hypotension, respiratory depression, seizure, unconsciousness, and coma. Deaths have been reported when GHB is used alone or in conjunction with ethanol, heroin, or ketamine.

How is GHB metabolized?
GHB is thought to be extensively metabolized by alcohol dehydrogenase and/or succinic semialdehyde dehydrogenase. Metabolic precursors to GHB, gamma-butyrolactone (GBL) and 1,4 butanediol are also readily available as substances of abuse. Endogenous GHB is also a product of GABA metabolism, and concentrations of 0 - 6.6 mg/L have been reported. Oral doses of approximately 2.5 g (1 teaspoon of GHB powder) dissolved in water, produced urine GHB concentrations of 29 mg/L in a 100 kg man.

Studies also indicate peak urine GHB concentrations of 100 mg/L following a 100 mg/kg oral dose, and no detectable drug in the urine by 12 hours. Less than 5% of an oral dose is eliminated unchanged in urine. To distinguish between endogenous and exogenous GHB, a reporting cutoff of 10 µg/mL is suggested.

How do I collect the urine and send in a specimen?
Collection and shipping guidelines are included in the RTL Reference Guide. A copy is provided with your new account supplies. Please read these instructions carefully. RTL also offers telephonic training and client service support.

How long does it take for results?
Negative results for GHB are reported within 48 hours. Positive results are reported within 72 hours of receipt of specimen at the lab.

How will RTL report the GHB results?
RTL offers reporting for GHB testing via internet, U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

11 000 3273 REV3

1. Excludes specimens received Saturday

REDWOOD TOXICOLOGY LABORATORY™
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3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

steroid testing

LABORATORY SERVICES

Are they on steroids? We'll find out.

Detect a full list of prescription androgenic anabolic steroids, prohormones, designer anabolic steroids, essential masking, anti-estrogen agents and diuretics.

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY STEROID TESTING

Due to popular demand, Redwood Toxicology Laboratory, Inc. (RTL) developed a comprehensive and affordable steroid panel that is comparable to WADA[1] testing. In addition, RTL also offers a diuretics panel. Our tests are ideal for sports organizations, colleges and high schools, certified athletic trainers, coaches, corrections and law enforcement, and occupational health agencies[2]. RTL offers the same high quality test results for steroids and diuretics as we do for urine and oral fluid drug testing.

RTL utilizes the most sophisticated, sensitive and specific equipment and technology available, (GC/MS - gas chromatography/mass spectrometry), to confirm and quantitate steroids and diuretics. This methodology provides highly accurate results. As with all of RTL's testing options, full customer support and training is provided. Turn to RTL for confidence in testing—we'll find out.

1. World Anti-Doping Agency
2. Compliance with RTL non-pretesting policy is required
3. Excludes specimens received Saturday

BENEFITS INCLUDE:

- *Tests a wide range of steroids and diuretics*
- *Toll-free customer support services with access to board certified toxicologists*
- *Expert witness services and litigation packages available*
- *All laboratory tests performed on state of the art GC/MS equipment*
- *Fast turn-around time from receipt of specimen (48 hours[3] negative, 72 hours positive)*
- *Results available via internet, fax and/or U.S. mail*
- *Affordable pricing (ask about combining your drug testing panels)*

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/3265

REDWOOD TOXICOLOGY LABORATORY

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FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com

What are anabolic steroids?

Androgenic-anabolic steroids (AAS) are a class of steroid hormones with dual pharmacological actions: androgenic (promote development of male sexual characteristics) and anabolic (increase nitrogen retention, protein synthesis, muscle growth in the body).

AAS have limited medical use, but are abused as performance enhancing drugs in sports and more recently in some professional areas, where strong muscular appearance is important. In the general population, especially among adolescents and young adults, AAS are abused as a cosmetic tool helping to create attractive muscular bodies and to improve the physique.

What are Prohormones and Designer Steroids?

The number of available prescription anabolic steroids has not changed since the late 1960's. However, since 1997 many new AAS have been released into circulation as nutritional supplements. They are commonly known as prohormones and designer steroids.

The term Prohormone has been used during the last decade to designate a substance (dietary supplement), which readily converts in the body into an illegal anabolic steroid. The most common prohormones are precursors of such anabolic steroids as testosterone, nandrolone (19-nortestosterone) and boldenone (1-dehydrotestosterone). These prohormones are now specifically banned and are included as an amendment to the Controlled Substances Act of January 2005.

What steroids on the RTL Steroid Test are popular?

Statistically, nandrolone, testosterone and stanozolol are found in routine testing more often than the others. However, consumer preferences vary depending on supply. Boldenone became very popular, when its precursor was released into the supplement market and was heavily advertised in the media. It was followed by the efficient anabolic steroid, 1-testosterone and its precursors. Then methyl-1-testosterone appeared as an even stronger drug. Each new generation of designer steroids seems to be more efficient pharmacologically than the previous ones. The most recent designer steroids, desoxymethyltestosterone, methasterone, prostanozol and 6-methylandrostendione, are now often seen in routine testing.

What are diuretics?

Diuretics elevate the rate of bodily urine excretion (diuresis). All diuretics increase the excretion of water from the body, although each class of diuretics does so in a distinct way employing different mechanisms of action. Use of diuretics is prohibited in sports. Increased urine flow would reduce concentrations of banned performance enhancing substances in urine such as anabolic steroids, thus complicating their detection in doping control (masking). In sports where weight categories are involved diuretics are abused as weight reducing agents. Diuretic abuse in sports is unethical and dangerous for athlete health (dehydration). Diuretic testing is a part of routine doping control in sports.

COMPREHENSIVE STEROID PANEL — Test panel list updated periodically to include new prohormones and designer steroids.

Comparable to WADA* Tests
*World Anti-Doping Agency
Prohibited anabolic agents

1-Androstendiol	Desoxymethyltestosterone	Methandrostenolone	Oxandrolone
1-Androstendione	5α-Dihydrotestosterone/ Drostandiol	Methasterone	Oxymesterone
4-Androstendiol	Drostanolone	Methenolone	Oxymetholone
4-Androstendione	Epitestosterone (masking agent)	6-Methylandrostendione	Probenecid (masking agent)
5-Androstendiol	Ethisterone	Methyl-1-testosterone	Prostanozol
5-Androstendione	Ethylestrenol	Methylnortestosterone	Quinbolone
Bolandiol (Norandrostendiol)	Fluoxymesterone	Methyltestosterone	Stanozolol
Bolasterone	Formebolone	Mibolerone	Stenbolone
Boldenone	Formestane (anti-estrogen)	Nandrolone	Testolactone (anti-estrogen)
Boldione	Furazabol	19-Norandrostadiendione	1-Testosterone
Calusterone	Halodrol	19-Norandrostendione	Testosterone
Clenbuterol (anabolic agent)	4-Hydroxy-testosterone	Norbolethone	Trenbolone
Clostebol	Mestanolone	Norclostebol	
Danazol	Mesterolone	Norethandrolone	
Dehydrochlormethyltestosterone	Methandriol	Oxabolone	

DIURETIC PANEL— Test panel list updated periodically to include new diuretics.

Acetazolamide	Amiloride	Bumethanide	Bendroflumethiazide	Canrenone	Chlorthalidone
Chlorothiazide	Clopamide	Cyclothiazide	Dichlorphenamide	Ethacrynic acid	Furosemide
Hydrochlorothiazide	Hydroflumethiazide	Spironolactone	Triamterene		

11 000 3265 REV4

REDWOOD TOXICOLOGY LABORATORY™

800-255-2159

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REDWOOD TOXICOLOGY LABORATORY | The confidence of scientific confirmation.

Steroid Testing / *frequently asked questions*

Why Redwood Toxicology Laboratory?
Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state of the art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 customers.

RTL now offers comprehensive state of the art anabolic steroid testing in urine. Advantages of using RTL include:

- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse,
- Highly qualified scientific staff,
- Tests performed on state of the art instrumentation,
- Excellent client services, and;
- Extensive quality assurance and quality control procedures that help to ensure accurate results.

What are anabolic steroids?
Androgenic-anabolic steroids (AAS) are a class of steroid hormones with dual pharmacological actions: androgenic (promote development of male sexual characteristics) and anabolic (increase nitrogen retention, protein synthesis, muscle growth in the body).

Testosterone, the principal endogenous AAS, is produced in the testes by males and in the adrenal glands by both males and females.

Synthetic AAS are the chemical alterations of testosterone. They are designed to slow down metabolism in the body, enhance or reduce either anabolic or androgenic properties relative to testosterone, improve bioavailability and prolong the action of the drug.

AAS have limited medical use, but are abused as performance enhancing drugs in sports and more recently in some professional areas, where strong muscular appearance is important. In the general population, especially among adolescents and young adults, AAS are abused as a cosmetic tool helping to create attractive muscular bodies and to improve the physique.

AAS have been classified as Schedule III Controlled Substances in the United States since 1991. Side effects include suppression of endogenous hormone production, gynecomastia (female type breast growth in males), acne, liver toxicity, mood swings, aggression, infertility and masculinisation in females: deepening of the voice, male type hair growth.

What are Prohormones and Designer Steroids?
The number of available prescription anabolic steroids has not changed since the late 1960's. However, since 1997 many new AAS have been released into circulation as nutritional supplements. They are commonly known as prohormones and designer steroids.

The term Prohormone has been used during the last decade to designate a substance (dietary supplement), which readily converts in the body into an illegal anabolic steroid. The most common prohormones are precursors of such anabolic steroids as testosterone, nandrolone (19-nortestosterone) and boldenone (1-dehydrotestosterone). These prohormones are now specifically banned and are included as an amendment to the Controlled Substances Act of January 2005.

More recent generations of anabolic dietary supplements feature synthetic designer anabolic steroids. Most of them were developed and studied more than 40 years ago, but have never been approved or marketed as legitimate drugs. As such, they have not been specifically listed as Controlled Substances. Legislation is catching up with these designer steroids as well.

How will my agency benefit by choosing RTL's Steroid Test?
Key benefits of using RTL's anabolic Steroid Test include:

- Most comprehensive panel available, detects full list of prescription androgenic anabolic steroids, prohormones, designer anabolic steroids, essential masking and anti-estrogen agents
- RTL Steroid Test comparable to World Anti-Doping Agency (WADA) testing
- Toxicologists with a high level of expertise in athletic drug testing, including extensive experience in the Olympic laboratory
- Best turn-around time in the industry
- Ideal for high schools, colleges, professional testing and sports federations.
- Tests are performed by GC/MS on state of the art equipment for accuracy and reliability
- Results available by internet, fax and U.S. mail
- Collection and shipping supplies provided at no additional cost
- Toll-free customer support and training services
- Expert witness and affidavit services available

What else is included in the RTL Steroid Test?
RTL's Steroid Test also includes a popular non-steroid anabolic agent, Clenbuterol; two masking agents, Prebenecid and Epitestosterone; and two anti-estrogens, Formestane and Testolactone. These drugs are also banned in sports.

Probenecid is a uricosuric drug. It restricts steroid excretion into urine, making detection difficult. Epiotestosterone may be used as a masking agent to balance excessive testosterone levels after testosterone ingestion, in order to keep the T/E levels below the cut-off limit of 6.

Anti-estrogens are often used to counteract so-called aromatization, conversion of excessive amounts of abused testosterone into female hormones, estrogens. Estrogens cause unpleasant effect in males such as female type breast growth.

What steroids on the RTL Steroid Test are popular?
Statistically, nandrolone, testosterone and stanozolol are found in routine testing more often than the others. However, consumer preferences vary depending on supply. Boldenone became very popular, when its precursor was released into the supplement market and was heavily advertised in the media. It was followed by the efficient anabolic steroid, 1-testosterone and its precursors. Then methyl-1-testosterone appeared as an even stronger drug. Each new generation of designer steroids seems to be more efficient pharmacologically than the previous ones. The most recent designer steroids, desoxymethyl-testosterone, methasterone, prostanozol and 6-methylandrostendione, are now often seen in routine testing.

Why are some steroids on the RTL Steroid Test grouped together?
Some steroids, when ingested, convert into each other forming an identical set of urinary metabolites. It is impossible to determine which drug in the group was administered.

Why are steroids screened by GC/MS?
Most steroids break down in the body into multiple metabolites that are excreted in urine at low concentrations. These substances are similar to each other and to the endogenous steroids, normally present in urine in higher concentrations. RTL performs GC/MS screening for the Steroid Test because it provides an efficient separation and specific detection of individual compounds.

The GC/MS confirmation procedure is specific to each individual steroid. For multiple positive screens, multiple individual confirmations are set up. Specimens that screen positive are also confirmed by GC/MS using a separate aliquot of urine.

How accurate and reliable is the RTL Steroid Test?
RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available. This methodology provides highly accurate results. The RTL Steroid Test shows what steroids or metabolites are present in the urine at the time the sample was collected. In most cases, confirmation is based on positive identification of more than one metabolite (metabolic pattern), providing added confidence. Accurate quantification is performed for nandrolone and testosterone with cut-off levels of 2 ng/mL (nandrolone metabolite) and testosterone to epitestosteroine ratio above 6 (T/E > 6).

What is the T/E ratio?
Testosterone and its precursors may be endogenous (produced in the body naturally) or exogenous (ingested as drugs or supplements). The T/E ratio is used to distinguish between the two. This ratio is a urine concentration ratio of two steroids, testosterone (T) and its natural isomer, epitestosterone (E). The normal average ratio is approximately 1, with individual variation on both sides, either higher or lower.

Ingestion of exogenous testosterone or its precursors suppresses internal steroid production in the body. Both endogenous T and E would be suppressed. However, total testosterone concentration in urine will rise above normal due to ingested drug. Low E and high T cause the T/E ratio to rise above 6 (cut-off), indicating testosterone abuse.

How long can steroids be detected in urine?
Detection time may vary from a few days (short-term pill) to as long as 12-18 months (oil-based injection), depending on the pharmacological form used, route of administration, length of usage and quantity. Individual differences may also contribute to the duration of the drug in the body. Test results cannot show when the drug was used, i.e. how long before the urine was collected.

What are diuretics?
Diuretics elevate the rate of bodily urine excretion (diuresis). All diuretics increase the excretion of water from the body, although each class of diuretics does so in a distinct way employing different mechanisms of action. Use of diuretics is prohibited in sports. Increased urine flow would reduce concentrations of banned performance enhancing substances in urine such as anabolic steroids, thus complicating their detection in doping control (masking). In sports where weight categories are involved diuretics are abused as weight reducing agents. Diuretic abuse in sports is unethical and dangerous for athlete health (dehydration). Diuretic testing is a part of routine doping control in sports.

How stable are steroid metabolites in urine?
Refrigerated or frozen urine shows very little or no steroid metabolite degradation during prolonged (several years) storage.

How much does RTL's Steroid Test cost?
For information about steroid pricing, contact the RTL sales staff toll-free at (800) 255-2159.

How will RTL report my steroid results?
RTL offers steroid reporting by internet (www.webtoxicology.com), U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

How do I sign up for steroid testing?
Contact RTL to set up your account. Let us know that you are interested in steroid testing and indicate any other drugs of abuse you would like to test. Call us toll-free at (800) 255-2159.

REDWOOD TOXICOLOGY LABORATORY

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Phone: 707-577-7959 / 800-255-2159
Fax: 707-577-0365
www.redwoodtoxicology.com

ACCOUNT NUMBER	ACCESSION NUMBER
000001	070531-20119

IDENTIFICATION
SAMPLE Positive Steroid
Req#: 123456

ORDERED BY
SAMPLE AGENCY

ST1 *

NOTES
(800) 255-2159

COLLECTED
05/01/2007 by John Doe

RECEIVED	REPORTED
05/31/2007	06/01/2007

Sample Agency
300 Sample Road
Santa Rosa, CA 95403

Tests ordered: [550] Anabolic Steroids and Agents; [069] Creatinine

POSITIVES	TEST NAME	RESULT
	Anabolic Steroids and Agents	
	Nandrolone metabolite	Positive
	T/E Ratio > 6	Positive
	Creatinine	176.8 mg/dL

NOTE: Nandrolone metabolite 105 ng/mL; T/E = 9.4

Anabolic steroid GC/MS procedure detects urinary metabolites and/or parent substance of the following drugs:

1- Androstendiol / 1-Androstendione / 1-Testosterone*
Bolasterone
Boldenone / Boldione / Quinbolone*
Calusterone
Clostebol
Danazol / Ethisterone
Dehydrochlormethyltestosterone
Drostanolone
Epitestosterone (>200 ng/mL) (masking agent)
Estra-4, 9-dien-3, 17-dione
Fluoxymesterone
Formebolone

** CONTINUED **

070531-20119 06/13/2007 12:54 PM

Laboratory Directors:
MARK J. DeMEO, M.D.
RICHARD R. WILBER, M.D.

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ACCOUNT NUMBER	ACCESSION NUMBER
000001	070531-20119

IDENTIFICATION
SAMPLE Positive Steroid
Req#: 123456

ORDERED BY
SAMPLE AGENCY

ST1 *

NOTES
(800) 255-2159

COLLECTED
05/01/2007 by John Doe

RECEIVED	REPORTED
05/31/2007	06/01/2007

Sample Agency
300 Sample Road
Santa Rosa, CA 95403

** CONTINUED **

Fuzazabol
Halodrol
4-Hydroxytestosterone / Formestane (anti-estrogen)*
6a-Methylandrostendione
Mestanolone
Mesterolone
Methandriol
Methandrostenolone (Methandienone)
Methasterone
Methenolone
Methylnortestosterone
Methyltestosterone
Methyl-1-testosterone
Mibolerone
Nondrolone / 19-Norandostenedione / 19-Norandrostendiol (Bolandiol)*
Norclostebol
Norethandrolone / Ethylesternol
Oxabolone
Oxandrolone
Oxymesterone
Oxymethalone
Probenecid (masking agent)
Prostanozol
Stanozolol
Stenbolone
Testolactone (anti-estrogen)
Testosterone / Androstendione / Androstendiol / DHEA*(T/E Ratio > 6)
Trenbolone

** CONTINUED **

070531-20119 06/13/2007 12:54 PM

Laboratory Directors:
MARK J. DeMEO, M.D.
RICHARD R. WILBER, M.D.

Specimen disposition: Specimens will be disposed of as follows: Negatives: destroyed within 2 days; Positives: destroyed after 6 months; all methadone maintenance urines after 2 months.

SEE REVERSE SIDE FOR CERTIFICATION & TECHNICAL INFORMATION

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ACCOUNT NUMBER	ACCESSION NUMBER
000001	070531-20119

IDENTIFICATION
SAMPLE Positive Steroid
Req#: 123456

ORDERED BY
SAMPLE AGENCY

ST1 *

NOTES
(800) 255-2159

COLLECTED
05/01/2007 by John Doe

RECEIVED	REPORTED
05/31/2007	06/01/2007

Sample Agency
300 Sample Road
Santa Rosa, CA 95403

** CONTINUED **

* Steroids producing similar metabolites in urine are detected and reported as a group.

The results for this specimen have been tested in accordence to all Redwood Toxicology Laboratory standard operating procedures and have been reviewed by laboratory certifying scientists.

Chief Toxicologist: Wayne Ross, M.C.L.S.
Director of Sports Testing: Victor Uralets, Ph.D.

Laboratory Directors:
MARK J. DeMEO, M.D.
RICHARD R. WILBER, M.D.

Specimen disposition: Specimens will be disposed of as follows: Negatives: destroyed within 2 days; Positives: destroyed after 6 months; all methadone maintenance urines after 2 months.

SEE REVERSE SIDE FOR CERTIFICATION & TECHNICAL INFORMATION

comprehensive drug testing

LABORATORY SERVICES

Are they abusing? *Target drugs in urine with an all-inclusive lab test. Comprehensive Drug Testing from RTL is ideal for addiction treatment, suspicion/cause workplace issues, pain-patient drug compliance, and healthcare facilities with direct access to controlled substances.* We'll find out.

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY COMPREHENSIVE PANEL

Most people take prescription medications responsibly; however, an estimated 48 million people have used prescription drugs for non-medical reasons. This represents approximately 20% of the U.S. population[1]. The liability issue is tremendous and may damage the lives of employees or patients, your facility's reputation, and revenue.

Now your agency has the opportunity to choose a new testing option from RTL, America's premier drug testing lab. The solution is Comprehensive Drug Testing, detecting a wide-range of prescriptions, illicit drugs, and alcohol in urine. RTL screens and confirms the drugs in the comprehensive panel using the "gold standard" in testing—gas chromatography/mass spectrometry (GC/MS).

Features

- *Detects over 600 brand name prescription drugs, illicit drugs, and alcohol (specimen validity included)*
- *Includes expanded list of opiates/narcotics*
- *High specificity—GC/MS analysis provides confirmative evidence of use*
- *Highly sensitive—includes quantitative, semi-quantitative, or qualitative test result data*
- *Qualified scientific team and committed support staff*
- *Secure and reliable toxicology reporting*

Benefits

- *Limit workplace liability and employee costs*
- *Ideal for nursing/physician workplace testing*
- *Well-suited for treatment admittance and monitoring*
- *Determines compliance of pain medication patients*
- *Fast turn-around time from receipt of specimen (48 hours[2] negative, 72 hours positive)*

Call Now: **800-255-2159**

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REDWOOD TOXICOLOGY LABORATORY

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FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com.

Which prescription drugs are abused most often?

A few types of prescription drugs are misused or abused most often:

- ***Opiates/Narcotics***—alleviate pain, depress body functions and reactions, and when taken in large doses, cause strong euphoria.
- ***Barbiturates/Benzodiazepines***—slow down brain activity, treat anxiety, muscle tension, pain, insomnia, acute stress reactions, panic attacks, and seizure disorders. In higher doses, some CNS depressants may be used as general anesthetics.
- ***Antidepressants***—used to treat depression, anxiety and eating disorders. They are known as lifestyle drugs or "mood brighteners". Their side effects are the subject of many recent studies.
- ***Stimulants***—increase activity in certain areas of the brain. They are prescribed for attention-deficit hyperactivity disorder (ADHD), the sleep disorder narcolepsy, or obesity.

Each of these pharmacological classes may be divided into sub-groups and includes a variety of drugs, which may or may not be structurally related and differ in their effect and potency.

The Drug Abuse Warning Network (DAWN), which monitors medications and illicit drugs reported in emergency departments across the nation, recently found that two of the most frequently reported prescription medications in drug abuse-related cases are benzodiazepines and opioid pain relievers[3].

How accurate and reliable is the Comprehensive Drug Test?

RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available. Confirmations of all presumptive positive samples are performed from a separate urine aliquot. The Comprehensive Drug Test utilizes an optimal method of extraction and GC/MS analysis for each individual drug.

COMPREHENSIVE DRUG TEST

Prescription brand names covered and cut-off levels by method are available at www.redwoodtoxicology.com.

Alcohol (Ethanol)				
Antidepressants				
Amitriptyline	Bupropion	Citalopram	Desipramine	Doxepin
Escitalopram	Fluoxetine	Imipramine	Maprotiline	Paroxetine
Sertraline	Trazodone/Nefazodone	Venlafaxine		
Anticonvulsants				
Carbamazepine	Oxcarbazepine			
Barbiturates				
Amobarbital	Butabarbital	Butalbital	Pentobarbital	Phenobarbital
Secobarbital				
Benzodiazepines				
Alprazolam	Clonazepam	Flunitrazepam	Flurazepam	Lorazepam
Midazolam	Nordiazepam	Oxazepam	Temazepam	Triazolam
Narcotics/Opiates				
Buprenorphine	Butorphanol	Codeine	Fentanyl	Hydrocodone
Hydromorphone	Ketamine	Meperidine	Methadone	Morphine
Nalbuphine	Oxycodone	Oxymorphone	Pentazocine	Propoxyphene
Tramadol				
Phencyclidine (PCP)				
Sedative/Hypnotic Agents				
Carisoprodol	Meprobamate	Zolpidem		
Stimulants				
Amphetamine	Cocaine	Methamphetamine	Methylenedioxyamphetamine (MDA)	Methylenedioxymethamphetamine (MDMA)
Methylenedioxyethylamphetamine (MDEA)	Methylphenidate			
THC (Marijuana)				

Includes specimen validity (Creatinine). List updated periodically.

1. Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, "Prescription Drugs—Abuse and Addiction".
2. Excludes specimens received Saturday.
3. Trends in prescription drug abuse, "Prescription Drugs—Abuse and Addiction", NIDA Research Report, 2005.

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REDWOOD TOXICOLOGY LABORATORY

Confidence in drug testing.

Comprehensive Drug Testing / *frequently asked questions*

Why Redwood Toxicology Laboratory?
Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state of the art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 customers.

Advantages of using RTL include:

- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse,
- Highly qualified scientific staff,
- Tests performed on state of the art instrumentation,
- Excellent client services, and;
- Extensive quality assurance and quality control procedures that help to ensure accurate results.

How will my agency benefit from choosing the Comprehensive Drug Test?

Key features include:

- Detects over 600 brand name prescription drugs, illicit drugs, and alcohol (specimen validity included)
- Includes expanded list of opiates/narcotics
- High specificity—GC/MS analysis provides confirmative evidence of use
- Highly sensitive—includes quantitative, semi-quantitative, or qualitative test result data

Key benefits include:

- Limit workplace liability and employee costs
- Ideal for nursing/physician workplace testing
- Well-suited for treatment admittance and monitoring
- Determines compliance of pain medication patient

Are prescription drugs abused for non-medical use?
Prescription drug abuse is a growing problem across the country. Most people take prescription medications responsibly; however, an estimated 48 million people (ages 12 and older) have used prescription drugs for non-medical reasons. This represents approximately 20 percent of the U.S. population.[1] The liability issue is tremendous and may damage the lives of employees, patients, your facility's reputation, and revenue.

Which prescription drugs are abused most often?
A few types of prescription drugs are misused or abused most often:

- ***Opiates/Narcotics***—alleviate pain, depress body functions and reactions, and when taken in large doses, cause strong euphoria.
- ***Barbiturates/Benzodiazepines***—slow down brain activity, treat anxiety, muscle tension, pain, insomnia, acute stress reactions, panic attacks, and seizure disorders. In higher doses, some CNS depressants may be used as general anesthetics.
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Each of these pharmacological classes may be divided into sub-groups and includes a variety of drugs, which may or may not be structurally related and differ in their effect and potency.

The Drug Abuse Warning Network (DAWN), which monitors medications and illicit drugs reported in emergency departments across the nation, recently found that two of the most frequently reported prescription medications in drug abuse-related cases are benzodiazepines and opioid pain relievers.[2]

Where is prescription drug abuse most prevalent?
In 2003, approximately 15 million Americans reported using a prescription drug for non-medical reasons at least once during the year. This phenomenon is fairly common for some society groups in the U.S. Among them, medical worker abuse, drug seeking pain-patients, and teen abuse are the most alarming.

Comprehensive drug testing is well suited for a variety of environments including, healthcare settings—where easy access to prescription drugs is prevalent, medication adherence/monitoring settings, and any other facility needing to detect an extensive range of controlled substances.

In a world where prescription drug abuse is increasing, Comprehensive Drug Testing from RTL is the perfect solution—the valuable, dependable, and verifiable choice.

Will a standard drug test detect prescription drugs?
Conventional drug test panels will not detect the broad variety of addictive prescription drugs. They pass undetected in standard testing for such drugs as cocaine, marijuana, heroin and amphetamines. RTL's Comprehensive Drug Test solves this problem.

How accurate and reliable is the Comprehensive Drug Test?
RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available. Confirmations of all presumptive positive samples are performed from a separate urine aliquot. The Comprehensive Drug Test utilizes an optimal method of extraction and GC/MS analysis for each individual drug.

What prescription drugs are tested?
This panel is designed to detect, in urine, a wide range of addictive prescription medications with high potential for abuse.

RTL's Comprehensive Drug Test detects prescription drugs within a variety of categories, including:

Antidepressants	Narcotics/Opiates
Anticonvulsants	Sedatives/Hypnotic Agents
Barbiturates	Stimulants
Benzodiazepines	

See the complete list of prescription drug brand names covered, and cut-off levels by procedure online at: www.redwoodtoxicology.com. List updated periodically.

RTL's Comprehensive Drug Test also tests for alcohol, illicit drugs, therapeutic drugs and specimen validity.

Alcohol	Marijuana
Amphetamine	Methadone
Methamphetamine	PCP
Barbiturates	Propoxyphene
Cocaine	Specimen validity *(Creatinine)*

What other tests can I purchase?
RTL's offers the following additional drug and alcohol tests:

- Numerous laboratory drug test panels (urine/saliva)
- Numerous on-site drug test devices (urine/saliva)
- EtG/EtS Alcohol Testing
- Steroid Testing
- GHB Testing
- Pregnancy Testing

Can I combine on-site screening devices with a Comprehensive Drug Test?
Yes, you can combine Reditest® on-site screening devices with a Comprehensive Drug Test Panel. On-site devices are fast, convenient, and cost-effective. The Reditest® product family covers an extensive list of illicit and therapeutic drugs, and are a reliable first step in detection.

Can I combine EtG/EtS Alcohol Testing with a Comprehensive Drug Test?
Yes, you can combine ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing to detect recent alcohol ingestion. EtG may be detectable in urine for up to 80 hours after the consumption of alcohol.

How much does RTL's Comprehensive Drug Test cost?
For information about Comprehensive Drug Test pricing, contact the RTL sales staff toll-free at (800) 255-2159.

How will RTL report my test results?
RTL offers Comprehensive Drug Test result reporting by internet (www.webtoxicology.com) or U.S. mail.

REFERENCES

1) Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, "Prescription Drugs—Abuse and Addiction", NIDA Research Report, 2005.

2) Trends in prescription drug abuse, "Prescription Drugs—Abuse and Addiction", NIDA Research Report, 2005.

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etg/ets alcohol testing

LABORATORY SERVICES

Are they drinking? Alcohol abuse leads to safety problems affecting the public at large and it gives rise to increased costs, lower productivity and potential loss of life. The EtG/EtS Alcohol Test is ideal for treatment and workplace situations. **We'll find out.**

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY ETG/ETS TESTING

EtG is a direct metabolite of alcohol (ethanol). Its presence in urine may be used to detect recent ethanol ingestion, even after ethanol is no longer measurable. The presence of EtG in urine is an indicator that ethanol was ingested and can be detected in urine for up to 80 hours after ingestion. EtG is only evident when ethanol is ingested and is not produced as a result of fermentation.

In addition to EtG, recent scientific studies have identified ethyl sulfate (EtS) as a second specific metabolite or biomarker of ethanol. For this reason, RTL tests and reports EtS, in conjunction with EtG, to confirm recent ethanol ingestion or exposure. The detection of EtG and EtS offers greater sensitivity and accuracy for determination of recent ethanol ingestion, than by detection of either biomarker alone.

The RTL drug testing lab utilizes the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry), to screen confirm and quantitate EtG/EtS. This methodology provides highly accurate alcohol biomarker test results.

BENEFITS INCLUDE:

- *Detects recent usage more accurately and for a longer period of time than standard alcohol testing*
- *Combined test for EtG and EtS provides greater sensitivity and accuracy*
- *Ideal for zero tolerance and abstinence situations*
- *Strong indicator of ethanol ingestion within the previous 3 to 4 days*
- *Allows monitoring in alcohol treatment programs*
- *Acts as early warning system to detect trends towards relapse*
- *Tests performed by LC/MS/MS on state of the art equipment*
- *EtG/EtS tests may be run on urine specimens in conjunction with other RTL drug testing panels*
- *Fast turn-around time from receipt of specimen (48 hours[2] negative, 72 hours positive)*
- *Results available via internet, fax and/or U.S. mail*

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/3274

REDWOOD TOXICOLOGY LABORATORY™

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FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com

What is Ethyl Glucuronide?
Ethyl glucuronide (EtG) is a direct metabolite of alcohol (ethanol). Its presence in urine may be used to detect recent ethanol ingestion, even after ethanol is no longer measurable. The presence of EtG in urine is an indicator that ethanol was ingested.

What is Ethyl Sulfate?
In addition to EtG, recent scientific studies have identified ethyl sulfate (EtS) as a second specific metabolite or biomarker of ethanol. For this reason, RTL tests and reports EtS, in conjunction with EtG, to confirm recent ethanol ingestion or exposure. The detection of EtG and EtS offers greater sensitivity and accuracy for determination of recent ethanol ingestion, than by detection of either biomarker alone.

How long can EtG/EtS be detected in urine?
Traditional laboratory methods detect the actual alcohol in the body, which reflects current use within the past few hours (depending on how much is ingested). The presence of EtG/EtS in urine indicates that ethanol was ingested within the previous 3 to 4 days, or approximately 80 hours after ethanol has been ingested. Therefore, EtG/EtS is a more accurate indicator of the recent ingestion of ethanol than measuring for the presence of ethanol itself.

How accurate and reliable is the EtG/EtS test?
EtG/EtS are direct metabolites of alcohol (ethanol), and their detection in urine is highly specific, similar to testing for other drugs. Add to this, RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available, LC/MS/MS, to screen, confirm, and quantitate EtG/EtS. This methodology provides highly accurate results. As is the case with any laboratory test, it is also very important to obtain clinical correlation.

Can residual EtG/EtS be detected in the urine of long-term alcoholics who abstain?
Studies indicate that alcoholics in abstinence have no detectable levels of EtG/EtS in their urine after approximately 80 hours of detoxification.

What about urine alcohol produced by fermentation?
EtG/EtS is only detected in urine when ethanol is ingested. This is important since it is possible to have ethanol in urine without drinking. Ethanol in urine without drinking is due to the production of ethanol in vitro. Ethanol in vitro is spontaneously produced in the bladder or the specimen container itself, due to fermentation of urine samples containing sugars (diabetes) and yeast or bacteria. Since the ethanol produced is not metabolized by the liver, EtG/EtS will not be produced and will therefore not be detected in a urine containing ethanol as a result of fermentation.

Why do EtG cut-off values vary at different labs?
Various cut-off levels (100, 250, 500, or 1000 ng/mL) are suggested for use in EtG testing. Any EtG level over 100 ng/mL and EtS level over 25 ng/mL indicates exposure to ethanol. In order to provide alcohol abstinence programs with the most clinically relevant answer to whether or not recent ethanol ingestion has occurred, using a 100 ng/mL cut-off for EtG and a 25 ng/mL cut-off for EtS detection is the best and most definitive test available to answer this question. RTL uses a 100 ng/mL EtG cut-off level and a 25 ng/mL EtS cut-off level.

What does a positive EtG test above 100 ng/mL and an EtS above 25 ng/mL mean?
A positive EtG test above 100 ng/mL and and EtS above 25 ng/mL indicates recent ethanol ingestion. The only way you can have EtG/EtS in the urine is if ethanol is in your body. In addition, using a 100/25 ng/mL cut-off nearly doubles the time of detection of recent ethanol detection versus the use of a 250 ng/mL EtG cut-off. In summary, the 100/25 ng/mL EtG/EtS cut-off is superior for monitoring purposes, and provides the most sensitive and definitive indicator of recent ethanol ingestion.

EtG Cut-off	Abuse Episodes Detected
1000 ng/mL	~80 – 90%
500 ng/mL	~90%
250 ng/mL	~ 98%
100 ng/mL	~ 99%

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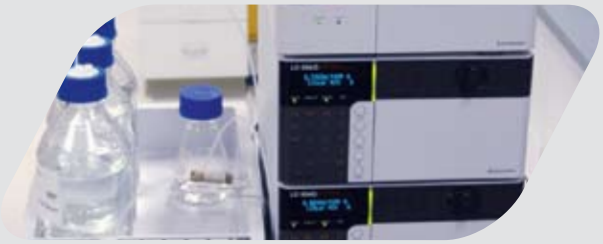
Will the use of incidental alcohol, such as mouthwash and Over-the-Counter (OTC) cough syrups trigger a positive result?
Tests show that "incidental exposure" to the chronic use of food products (vanilla extract), hygiene products, mouthwash, or OTC medications (cough syrups), which contain ethanol, can produce EtG concentrations in excess of 100 ng/mL. However, if measurable ethanol is detected (>.04 gm %) in the urine, and EtG is detected in excess of 100 ng/mL and EtS is also detected in exess of 25 ng/mL, then this is very strong evidence that beverage alcohol was ingested.

Most alcohol abstinence programs require an agreement to avoid all products containing alcohol, including; mouthwash, Nyquil®, OTC medications, etc. Consumption of these products could produce a positive test for alcohol and/or EtG/EtS and would thus violate the agreement.



1. Richard Saitz, M.D., M.P.H., "Unhealthy Alcohol Use", The New England Journal of Medicine, Feb., 2005.
2. Excludes specimens received Saturday

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REDWOOD TOXICOLOGY LABORATORY™

The confidence of scientific confirmation.

Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS) Alcohol Metabolite Testing

FREQUENTLY ASKED QUESTIONS

Why Redwood Toxicology Laboratory?
Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state of the art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 clients.

RTL offers numerous advantages to your agency, including the following:

- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse,
- Highly qualified scientific staff,
- State of the art instrumentation for the detection of alcohol and drugs of abuse,
- Excellent client services, and;
- Extensive quality assurance and quality control procedures that help to ensure accurate results.

What is Ethyl Glucuronide?
Ethyl glucuronide (EtG) is a direct metabolite of alcohol (ethanol). Its presence in urine may be used to detect recent ethanol ingestion, even after ethanol is no longer measurable. The presence of EtG in urine is an indicator that ethanol was ingested.

What is Ethyl Sulfate?
In addition to EtG, recent scientific studies have identified ethyl sulfate (EtS) as a second specific metabolite or biomarker of ethanol. For this reason, RTL tests and reports EtS, in conjunction with EtG, to confirm recent ethanol ingestion or exposure. The detection of EtG and EtS offers greater sensitivity and accuracy for determination of recent ethanol ingestion, than by detection of either biomarker alone.

How will my agency benefit by choosing RTL's EtG/EtS test?
Key benefits of using RTL's EtG/EtS test include:

- Detects recent usage more accurately and for a longer period of time than standard testing
- Ideal for zero tolerance and abstinence situations
- Strong indicator of ethanol ingestion within the previous 3 to 4 days
- EtG/EtS is only evident when ethanol is ingested and is not produced as a result of fermentation
- Allows monitoring in alcohol treatment programs
- Acts as an early warning system to detect trends towards relapse
- Tests are performed by LC/MS/MS on state of the art equipment for accuracy and reliability
- Fast turn-around time from receipt of specimen (48 hours* negative, 72 hours positive)
- EtG/EtS may be run on urine specimens in conjunction with other RTL drug testing panels
- Results available via internet, fax and U.S. mail
- Toll-free customer support and training services
- Expert witness and affidavit services available

How long can EtG/EtS be detected in urine?
Traditional laboratory methods detect the actual ethanol in the body, which reflects current use within the past few hours (depending on how much is ingested). The presence of EtG/EtS in urine indicates that ethanol was ingested within the previous 3 to 4 days, or approximately 80 hours after ethanol has been ingested. Therefore, EtG/EtS is a more accurate indicator of the recent ingestion of ethanol than measuring for the presence of ethanol itself.

How accurate and reliable is the EtG/EtS test?
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How much does RTL's EtG/EtS test cost?
For information about EtG/EtS pricing, contact the RTL sales staff toll-free at (800) 255-2159. Tested on state of the art equipment, this affordable test allows for accurate and reliable results.

How do I sign up for EtG/EtS testing?
There are two easy ways to request EtG/EtS testing.

1. Contact RTL. If you are not already a client, contact RTL to set up your account. Let us know that you are interested in EtG/EtS and indicate any other drugs you would like to test. Call us toll-free at (800) 255-2159.

* Excludes specimens received Saturday

2. Choose "EtG" on your specimen labels. If you are an RTL client, simply choose "647 ETG" on your specimen collection / chain of custody labels. This code is pre-printed for all clients.

Can residual EtG/EtS be detected in the urine of long-term alcoholics who abstain?
Studies indicate that alcoholics in abstinence have no detectable levels of EtG/EtS in their urine after approximately 80 hours of detoxification.

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How stable is EtG/EtS in urine?
Studies show that EtG/EtS is stable in urine for more than 4 days at room temperature. Recent experiments indicate that heating urine to 100°C actually increased the stability of EtG/EtS. Therefore, heat does not cause the breakdown of EtG/EtS, it actually increases stability. In addition, no artificial formation of EtG/EtS was found to occur following the prolonged storage of urine at room temperature fortified with 1% ethanol. Presence of some bacteria in urine may affect the stability of EtG, but EtS is found to be stable even in the presence of bacteria.

In general, what methods are used to detect EtG? What method does RTL use?
Methods to detect EtG/EtS include immunoassay (EIA or ELISA), gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). Immunoassay methods are of limited specificity and sensitivity with a limit of detection of approximately 1000 ng/mL. GC/MS and LC/MS methods are much more specific than immunoassay, and offer detection limits of approximately 500 ng/mL.

LC/MS/MS methods utilize the most technologically advanced instrumentation currently available in forensic and clinical toxicology and provide the highest sensitivity. Redwood utilizes an LC/MS/MS instrument for the confirmation of EtG, which has a limit of detection below 100 ng/mL for each compound.

Why do EtG cut-off values vary at different labs?
Various cut-off levels (100, 250, 500, or 1000 ng/mL) are suggested for use in EtG testing. Any EtG level over 100 ng/mL and EtS level over 25 ng/mL indicates exposure to ethanol. In order to provide alcohol abstinence programs with the most clinically relevant answer to whether or not recent ethanol ingestion has occurred, using a 100 ng/mL cut-off for EtG and a 25 ng/mL cut-off for EtS detection is the best and most definitive test available to answer this question. RTL uses a 100 ng/mL EtG cut-off level and a 25 ng/mL EtS cut-off level.

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Most alcohol abstinence programs require an agreement to avoid all products containing alcohol, including; mouthwash, Nyquil®, OTC medications, etc. Consumption of these products could produce a positive test for ethanol and/or EtG/EtS and would thus violate the agreement.

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How will RTL report my EtG/EtS results?
RTL offers reporting for EtG/EtS via internet (www.webtoxicology.com), U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

How can I get more information on EtG/EtS testing?
For more information about EtG/EtS testing, contact the RTL sales staff toll-free at (800) 255-2159.

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synthetic cannabinoid drug testing

LABORATORY SERVICES

Are they abusing "fake marijuana"? Herbal smoking blends have gained increasing attention as an alternative to marijuana. Utilizing the most sophisticated and sensitive technology available, the test is ideal for a number of criminal situations including drug courts, probation, parole and more. **We'll find out.**

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY SYNTHETIC CANNABINOID

RTL now offers lab-based testing for the detection of JWH-018 and JWH-073 metabolites in urine. JWH-018 and JWH-073 are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana and are among the numerous compounds found in "herbal" incense or smoke blends.

JWH-compounds are now being sprayed on herbal material and sold as "fake weed" or "synthetic marijuana." Users looking for a "legal high" often turn to popular herbal smoking products marketed under brand names such as K2, K3, Spice, Genie, Smoke, Pot-pourri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Serenity and many others.

Features & Benefits

- *Identifies the parent synthetic cannabinoids (JWH-018 and JWH-073) and their metabolites in human urine*
- *Precise urine metabolite detection, significantly more reliable than only testing for parent-drug*
- *Presence of metabolites confirms ingestion; window of detection up to 72 hours (depending on dosage)*
- *Performed on QTrap LC/MS/MS equipment; providing definitive synthetic cannabinoid biomarker test results*
- *Results available via internet, fax and/or U.S. mail*
- *Toll-free customer support services with access to board certified toxicologists*

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com

REDWOOD TOXICOLOGY LABORATORY

FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com.

What are synthetic cannabinoids?

Synthetic cannabinoids are chemical compounds that mimic the effect of THC, the principle active ingredient of cannabis. Like THC, they bind to cannabinoid receptors in the brain and were initially developed as therapeutic agents for the treatment of pain. However, these psychoactive research chemicals are frequently being sprayed on herbal mixtures and sold as "fake weed" or "synthetic marijuana." JWH-018 and JWH-073 are the two most common synthetic cannabinoid chemicals found in a variety of herbal smoking blends.

How are synthetic cannabinoids being used?

Legal in most states, JWH-018 and JWH-073 are the two most popular synthetic cannabinoids used today. Reportedly offering a high 4 times stronger than marijuana, JWH-018 and JWH-073 are commonly associated with herbal smoke and incense products sold under names like K2, Spice, Serenity and others.

Synthetic cannabinoid chemicals are often laced in the herbal smoking products that are readily available via the Internet and in many "headshops" around the country. Users looking for a "legal high" often turn to these herbal smoking or incense products because they do not show up on a standard urine drug test. Users smoke the product by wrapping joints, smoking it in pipes, or inhaling fumes via vaporizers. Users also report that herbal blends or pure chemical concoctions can be ingested with an infusion or solvent process; purportedly allowing them to manage the potency and dose of the active ingredient(s).

What are the effects of using JWH-018 and JWH-073 synthetic cannabinoids?

JWH-018 and JWH-073 are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana and are among the numerous compounds found in herbal incense and smoke blends.

JWH-018 and JWH-073 do not contain cannabis but produce effects reported up to 4 times the strength of THC/marijuana. Users indicate the high comes on slow at first, then with surprising potency. There have been many reports about the adverse effects including agitation, rapid heart rate, confusion, dizziness and nausea. In fact, the American Association of Poison Control Centers issued a warning about the dangers of synthetic marijuana products in March 2010.

Long-term effects from these research chemicals are unknown.

What herbal incense brand names are being used?

These products are marketed under brand names such as K2, K3, Spice, Genie, Smoke, Pot-pourri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Serenity and many others.

Little is known about the recipe of each herbal preparation or how much of the active ingredient is present. The Food and Drug Administration (FDA) does not regulate the products, but maintains they are not approved for human consumption. Without proper ingredient labeling or measured potency, users increase the risk of overdosing. To complicate labeling and dose concerns, some reports indicate many popular brands are now counterfeit or fake brands.

What is the legal status of these chemicals?

While legal under federal law, products containing JWH-018 and JWH-073 are banned in several states and by the U.S. armed forces. Legal restrictions on these compounds are likely to be imposed nationwide. Additionally, they are banned by a number of European countries, including Britain, France, Germany, Poland and Russia, as well as South Korea.

The Drug Enforcement Administration (DEA) labeled them a "drug and chemical of concern" in 2009.

Why use Redwood Toxicology Laboratory to test for synthetic cannabinoids?

Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state-of-the-art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 customers. These customers rely on the RTL promise that "We'll find out."

Advantages of using RTL include:

- First lab in the world to offer synthetic cannabinoid metabolite testing in urine
- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse
- Highly qualified and credentialed scientific staff
- Tests performed on state-of-the-art instrumentation
- Excellent client services and support
- Quality assurance and quality control procedures ensure accurate results

Why are JWH-018 and JWH-073 tested by RTL?

RTL laboratory analysis confirmed JWH-018 and JWH-073 as the active ingredients in 27 herbal smoking mixtures, and established test methods to identify the presence of their metabolites.

How long can JWH-018 and JWH-073 be detected in urine?

The presence of metabolites in urine confirms ingestion of JWH-018 and JWH-073. JWH-018 and JWH-073 metabolites can be detected in urine up to 72 hours (depending on usage/dosage).

How is JWH-018 and JWH-073 metabolized in urine?

Both JWH-018 and JWH-073 metabolize extensively in humans via oxidation and glucuronide conjugation. Depending on dosage, the hydroxylated JWH-018 and JWH-073 and the carboxylated JWH-018 metabolites can be detected up to 72 hours in urine. Parent drug excreted in human urine has not been reported.

Will a standard drug test detect synthetic cannabinoids?

Conventional drug test panels will not detect the broad range of synthetic cannabinoids. They pass undetected in standard urine testing for such drugs as cocaine, marijuana, heroin and amphetamines. RTL's Synthetic Cannabinoid Test can be ordered with your standard panel to ensure JWH-018 and JWH-073 are detected.

REDWOOD TOXICOLOGY LABORATORY™

800-255-2159

Laboratory: 800-255-2159 // Screening Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

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NEW!
Saliva testing for K2, Spice and more.

synthetic cannabinoid test

ORAL FLUID LABORATORY TESTING

Detect Synthetic Marijuana in Saliva!

Synthetic Cannabinoid Oral Fluid Testing — *a convenient, gender-neutral solution, ideal for recent use detection. You need to know. We'll find out.*

RTL-Oral Collector with saliva volume indicator— for sufficient volume collection every time.

WHAT ARE SYNTHETIC CANNABINOIDS?

Synthetic cannabinoids are psychoactive chemicals that are often sprayed on herbal smoking material and referred to as synthetic marijuana. It is sold in the U.S. under brand names such as **K2**, K3, **Spice**, Genie, Smoke, Pot-pourri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Serenity and many others. Users looking for a "legal high" often turn to these herbal smoking or incense products because they do not show up on a standard drug test.

WHAT ARE THE EFFECTS OF JWH-018, JWH-073, JWH-250 AND OTHERS?

JWH-018, JWH-073, JWH-250 and other similar chemicals are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana. However, these chemicals can be up to 4 times stronger than standard THC/Marijuana. There have been many reports about the adverse effects of these chemicals including agitation, rapid heart rate, confusion and more. The American Association of Poison Control Centers issued a warning about the dangers of synthetic marijuana products. As a result, the U.S. Drug Enforcement Agency (DEA) has declared their intent to do an emergency scheduling of these substances.

Interested in adding synthetic cannabinoids to your drug test?

Upgrade your panel to include K2/Spice or run it as a separate test. See details on page 2.

Features and benefits

- *First lab to offer synthetic cannabinoid oral fluid parent drug test and urine metabolite test*
- *Identifies the parent drugs JWH-018, JWH-073, & JWH-250 in oral fluid; detection window up to 24-48 hours*
- *Detect recent abuse more accurately than urine; oral fluid testing is ideal for monitoring current and recent ingestion*
- *Simple collection process limits exposure to donor sample and protects against adulteration*
- *Performed on LC/MS/MS equipment providing definitive synthetic cannabinoid biomarker test results*
- *Results available via internet, fax and/or U.S. mail*

REDWOOD TOXICOLOGY LABORATORY™

Call for details: **800-255-2159**

or visit: www.redwoodtoxicology.com

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ADD SYNTHETIC CANNABINOID ORAL FLUID TESTING—*Select from multiple test panels or add to your existing panel*

NEW! Oral Fluid 7 Panel – *9203*	NEW! Oral Fluid 8 Panel – *9217*	NEW! Oral Fluid 9 Panel – *9220*
Amphetamines (AMP)	Amphetamines (AMP)	Amphetamines (AMP)
Cocaine (COC)	Benzodiazepines (BZO)	Barbiturates (BAR)
Marijuana (THC)	Cocaine (COC)	Benzodiazepines (BZO)
Methamphetamine (M-AMP) [1]	Marijuana (THC)	Cocaine (COC)
Opiates (OPI)	Methamphetamine (M-AMP) [1]	Marijuana (THC)
Phencyclidine (PCP)	Opiates (OPI)	Methadone (MTD)
NEW! Synthetic Cannabinoids (CANN)	Phencyclidine (PCP)	Methamphetamine (M-AMP) [1]
	NEW! Synthetic Cannabinoids (CANN)	Opiates (OPI)
		NEW! Synthetic Cannabinoids (CANN)

Don't see the drug panel you need? *Just ask, we offer a wide range of panel configurations.*

[1] *Methamphetamine includes MDMA/Ecstasy*

Add Synthetic Cannabinoid Testing to an existing panel

To run a Synthetic Cannabinoid Test in addition to your default oral fluid panel, just write **"F25"** next to the panel ordered on the chain of custody. See detailed labeling instructions below or call your sales representative to order one of these RTL-Oral panels with Synthetic Cannabinoids included!

REQUESTING A SYNTHETIC CANNABINOID ORAL FLUID TEST

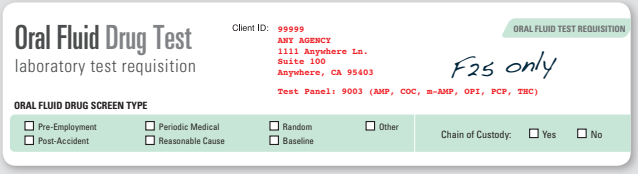
Ordering a K2/Spice test is easy to add to any specimen you wish to have tested. Whether you're combining K2/Spice testing to your existing RTL-Oral test panel or only want to test K2/Spice, follow these three easy steps:

1. **Collect the specimen.** *For quick and easy specimen collection, follow the instructions on the RTL-Oral collection device or on the RTL website: http://www.redwoodtoxicology.com/resources/collection/oral_collection.html*

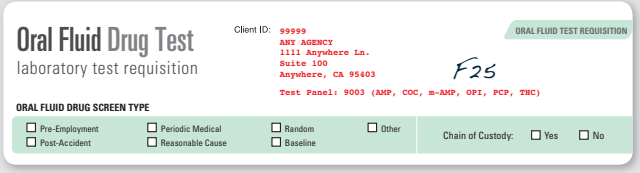
2. **Fill out the chain of custody form.** *Your primary oral fluid panel is pre-printed on the chain of custody (laboratory test requisition) form. You may request your free specimen as a stand-alone test or in addition to your primary panel. For examples on how to fill out your form, please see the examples to the right.*

   For a more convenient solution, RTL can also add the K2/Spice test code (F25) directly to your RTL-Oral chain of custody forms.

3. **Send the RTL-Oral collection device to RTL.** *Package the RTL-Oral collection device and send to RTL in your prepaid shipping container. When the specimen is received, it is tested and results are reported by internet within 48 to 72 hours.*


Oral Fluid Drug Test
laboratory test requisition
Client ID: 99999
ANY AGENCY
1111 Anywhere Ln.
Suite 100
Anywhere, CA 95403
ORAL FLUID TEST REQUISITION
F25 only
Test Panel: 9003 (AMP, COC, m-AMP, OPI, PCP, THC)
ORAL FLUID DRUG SCREEN TYPE
Pre-Employment
Post-Accident
Periodic Medical
Reasonable Cause
Random
Baseline
Other
Chain of Custody: Yes No

Stand-alone K2/Spice test: Write **"F25 ONLY"** on the upper right hand portion of the chain of custody form next to or below your primary panel. The lab will only run the K2/Spice RTL-Oral lab test. RTL will not run your primary panel.


Oral Fluid Drug Test
laboratory test requisition
Client ID: 99999
ANY AGENCY
1111 Anywhere Ln.
Suite 100
Anywhere, CA 95403
ORAL FLUID TEST REQUISITION
F25
Test Panel: 9003 (AMP, COC, m-AMP, OPI, PCP, THC)
ORAL FLUID DRUG SCREEN TYPE
Pre-Employment
Post-Accident
Periodic Medical
Reasonable Cause
Random
Baseline
Other
Chain of Custody: Yes No

Standard Panel plus K2/Spice test: Write **"F25"** on the upper right hand portion of the chain of custody form next to or below your primary panel. The lab will run your primary panel and the K2/Spice lab-oral test.

Additional information is available on our website:

Oral Fluid Specimen Collection Protocol:
http://www.redwoodtoxicology.com/resources/collection/oral_collection.html

Oral Fluid Specimen Labeling Protocol:
http://www.redwoodtoxicology.com/resources/labeling_shipping/labeling_protocol_oral.html

If further training is required, please contact your sales rep at **(800) 255-2159** to schedule a webinar training session.

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800-255-2159

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REDWOOD TOXICOLOGY LABORATORY

Confidence in drug testing.

Synthetic Cannabinoid Testing (urine & oral fluid)

frequently asked questions

What are synthetic cannabinoids?
Synthetic cannabinoids are chemical compounds that mimic the effect of THC, the principle active ingredient of cannabis. Like THC, they bind to cannabinoid receptors in the brain and were initially developed as therapeutic agents for the treatment of pain. However, these psychoactive research chemicals are frequently being sprayed on herbal mixtures and sold as "fake weed" or "synthetic marijuana." JWH-018 and JWH-073 are the two most common synthetic cannabinoid chemicals found in a variety of herbal smoking blends. Others like JWH-250, JWH-081 and CP47, 497 have also started appearing in some products and preparations.

How are synthetic cannabinoids being used?
Legal in most states, JWH-018 and JWH-073 are the two most popular synthetic cannabinoids used today. Reportedly offering a high 4 times stronger than marijuana, JWH-018 and JWH-073 are commonly associated with herbal smoke and incense products sold under names like K2, Spice, Serenity and others.

Synthetic cannabinoid chemicals are often laced in the herbal smoking products that are readily available via the Internet and in many "head-shops" around the country. Users looking for a "legal high" often turn to these herbal smoking or incense products because they do not show up on a standard urine drug test.

Users smoke the product by wrapping joints, smoking it in pipes, or inhaling fumes via vaporizers. Users also report that herbal blends or pure chemical concoctions can be ingested with an infusion or solvent process; purportedly allowing them to manage the potency and dose of the active ingredient(s).

What are the effects of using synthetic cannabinoids like JWH-018, JWH-073, JWH-250 and others?
JWH-018, JWH-073, JWH-250 and other similar chemicals are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana and are among the numerous compounds found in herbal incense and smoke blends.

These synthetic cannabinoids do not contain cannabis but produce effects reported up to 4 times the strength of THC/marijuana. Users indicate the high comes on slow at first, then with surprising potency. There have been many reports about the adverse effects including agitation, rapid heart rate, confusion, dizziness and nausea. In fact, the American Association of Poison Control Centers issued a warning about the dangers of synthetic marijuana products in March 2010.

Long-term effects from these research chemicals are unknown.

What herbal incense brand names are being used?
Users looking for a "legal high" often turn to popular herbal smoking products marketed under brand names such as K2, K3, Spice, Genie, Smoke, Pot-pourri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Serenity and many others. RTL maintains a composition and concentration list for different products, brands and preparations. View the list on our website at: www.redwoodtoxicology.com (list updated periodically).

The Food and Drug Administration (FDA) does not regulate the products, but maintains they are not approved for human consumption. Without proper ingredient labeling or measured potency, users increase the risk of overdosing. To complicate labeling and dose concerns, some reports indicate many popular brands are now counterfeit or fake brands.

What is the legal status of these chemicals?
While legal under federal law, products containing JWH-018 and JWH-073 are banned in several states and by the U.S. armed forces. At present, JWH-250 is illegal in only one state. Legal restrictions on these compounds are likely to be imposed nationwide. Additionally, they are banned by a number of European countries, including Britain, France, Germany, Poland and Russia, as well as South Korea.

The Drug Enforcement Administration (DEA) labeled them a "drug and chemical of concern" in 2009.

Why use Redwood Toxicology Laboratory to test for synthetic cannabinoids?
Redwood Toxicology Laboratory (RTL) is one of the largest, full-service, independent drug and alcohol testing laboratories in the United States. RTL utilizes state-of-the-art screening and confirmation methodologies for urine and oral fluid drug testing and is trusted by over 7,000 customers. These customers rely on the RTL promise that "We'll find out."

Advantages of using RTL include:

- First lab in the world to offer synthetic cannabinoid urine metabolite test; to our knowledge, first to provide saliva testing too
- Extensive experience in performing forensic toxicology analysis for alcohol and drugs of abuse
- Highly qualified and credentialed scientific staff
- Tests performed on state-of-the-art instrumentation
- Excellent client services and support
- Quality assurance and quality control procedures ensure accurate results

How will my agency benefit from choosing the RTL Synthetic Cannabinoid Test?

Key benefits include:

- First lab to offer synthetic cannabinoid oral fluid parent drug test and urine metabolite test
- Ideal for a number of criminal situations including drug courts, probation and parole
- Well-suited for addiction admittance, treatment and monitoring
- Limits teen drug abuse, workplace liability and employee costs

Urine test features include:

- Urine test identifies synthetic cannabinoids (JWH-018 and JWH-073) and their metabolites
- Precise urine metabolite detection, significantly more reliable than only testing for parent-drug in human urine
- Presence of metabolites confirms ingestion; window of detection up to 72 hours (depending on usage/dosage)

Oral fluid test features include:

- Accurately identifies the parent drugs JWH-018, JWH-073, JWH-250 in human oral fluid/saliva
- Includes RTL-Oral collection device with saliva volume indicator—for sufficient volume collection every time; simple process, limits exposure to sample and protects against adulteration
- Presence of parent drug in saliva confirms ingestion; detection window up to 24-48 hours

Why are JWH-018 and JWH-073 tested by RTL?

RTL laboratory analysis confirmed JWH-018 and JWH-073 as the primary active ingredients in 37 herbal smoking mixtures, and established test methods to identify the presence of their metabolites in urine.

How long can JWH-018 and JWH-073 be detected in urine?

The presence of metabolites in urine confirms ingestion of JWH-018 and JWH-073. JWH-018 and JWH-073 metabolites can be detected in urine up to 72 hours (depending on usage/dosage).

How long can JWH-018, JWH-073 and JWH-250 be detected in oral fluid?

Drugs in oral fluid can be detected from minutes up to 24-48 hours after ingestion.

How is JWH-018 and JWH-073 metabolized in urine?

Both JWH-018 and JWH-073 metabolize extensively in humans via oxidation and glucuronide conjugation. Depending on dosage, the hydroxylated JWH-018 and JWH-073 and the carboxylated JWH-018 metabolites can be detected up to 72 hours in urine. Parent drug excreted in human urine has not been reported.

What are the cut-off levels?

There are no cut-off levels for RTL's Urine Synthetic Cannabinoid Test. Toxicology result reporting for JWH-018 and JWH-073 will indicate either "Detected" or "Not Detected." The cut-off level for the oral fluid test is 0.5 ng/mL for JWH-018, JWH-073 and JWH-250.

Will a standard drug test detect synthetic cannabinoids?

Conventional drug test panels will not detect the broad range of synthetic cannabinoids. They pass undetected in standard urine or oral fluid testing for such drugs as cocaine, marijuana, heroin and amphetamines. RTL's Urine or Oral Fluid Synthetic Cannabinoid Test can be ordered with your standard panel to ensure detection.

How accurate and reliable is the RTL Urine Synthetic Cannabinoid Test?

RTL's test will utilize the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018 and JWH-073 urine metabolites.

To reduce false-negative results, the detection method relies on monitoring multiple metabolites for each of the compounds. Other labs that only look for the parent drug in urine will report many false negative results. RTL's test methodology provides the most definitive synthetic cannabinoid biomarker test results.

How accurate and reliable is the RTL Oral Fluid Synthetic Cannabinoid Test?

RTL's test utilizes the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018, JWH-073 and JWH-250 in oral fluid.

How do I request the RTL Urine and Oral Fluid Synthetic Cannabinoid Test?

Indicate the following information in the appropriate area of the specimen label:

Urine: indicate the test to be ordered by placing a check mark next to Test Code "473". Alternatively, you can write one of the following: "K2", "Spice", or "Syn Cannab" on the line marked "other".

Oral fluid: write one of the following: "K2", "Spice" or "Syn Cannab" next to the panel ordered or on the GC/MS line.

Labels can be updated for appropriate tests.

Can I combine RTL Synthetic Cannabinoid Testing with other lab tests or on-site screening devices?

Yes. This test may be run in conjunction with your primary urine or oral fluid laboratory test panel. Likewise, a variety of solutions are available that combine rapid on-site devices with lab analysis.

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11 000 3370 REV2

NEW!
Test for MDPV, 'Ivory Wave' & others

designer stimulant drug test

URINE LABORATORY TESTING

Detect Designer Stimulant Drugs in Human Urine!

Designer Stimulant Testing — *detect the presence of synthetic stimulant substances found in "bath salts", "plant food" or disguised as MDMA.*

TWO TEST PANEL OPTIONS AVAILABLE!

The National Drug Intelligence Center and U.S. Poison Control Centers issued alerts about synthetic stimulants, noting the ease of access concerns and the number of nationwide emergency room visits related to these drugs.

WHAT ARE SYNTHETIC STIMULANTS?

Synthetic stimulants are produced in clandestine labs and sold online or available at smoke shops. Promoted as "bath salts," "research chemicals," or "plant food," product labeling attempts to circumvent regulation by suggesting they are not for human consumption. Additionally, some forms of designer stimulants may be sold as "legal" MDMA (Legal X), or sold and veiled as MDMA tablets.

WHAT ARE THE EFFECTS OF SYNTHETIC STIMULANTS?

Young adults in the U.S. and other countries have reportedly died from using these products. While synthetic stimulants appear to affect users in ways similar to amphetamines and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. Long-term effects are unknown, although experts have stated that cardiovascular effects can last for days after ingestion.

Features and benefits

- *Detect many illicitly synthesized forms of stimulants sold online and in head shops nationwide*
- *Accurately identifies active ingredient of many "legal high" products labeled as "bath salt" and "plant food", or sold as "Legal X"*
- *Choose from two test panels: Expanded Designer Stimulant Panel or the MDPV & Mephedrone Panel*
- *Presence of parent drug in urine confirms ingestion; detection window up to 24-48 hours (depending on dosage)*
- *Performed on GC/MS equipment; providing definitive synthetic stimulant biomarker test results*
- *Results available via internet, fax and/or U.S. mail*

Upgrade your panel to include these drugs or run it as a separate test. See details on page 2.

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Call for details: **800-255-2159**

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DESIGNER STIMULANT URINE PANELS *For a complete list of cut-off levels and test methods, visit: www.redwoodtoxicology.com*

NEW! Panel P81: Designer Stimulants (MDPV & Mephedrone) — *Detects 2 common synthetic stimulants*

MDPV
(Methylenedioxypyrovalerone, Cloud 9, Ivory Wave, White Lightning)

Mephedrone
(4-methylmethcathinone [4-MMC], 4-methylephedrone, "Meph", "MCat")

NEW! Panel P80: Expanded Designer Stimulants — *Detects 14 synthetic stimulants*

BZP
(Benzylpiperazine)

Butylone
(β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB)

Cathinone
(Khat or Benzoylethanamine)

Ethylone
(3,4-methylenedioxy-N-ethylcathinone, MDEC, bk-MDEA)

MBDB
(Methylbenzodioxolylbutanamine, Methyl-J, "Eden")

mCPP
(meta-Chlorophenylpiperazine)

MDA
(3,4-Methylenedioxyamphetamine, tenamfetamine)

MDEA
(3,4-Methylenedioxy-N-ethylamphetamine, MDEA, MDE, "Eve")

MDPV
(Methylenedioxypyrovalerone, Cloud 9, Ivory Wave, White Lightning)

MDMA
(3,4-Methylenedioxymethamphetamine, ecstasy, "E", "X")

Mephedrone
(4-methylmethcathinone [4-MMC], 4-methylephedrone, "Meph", "MCat")

Methcathinone
(α-methylamino-propiophenone, may be confused with mephedrone)

Methylone
(3,4-methylenedioxy-N-methylcathinone, bk-MDMA, MDMC, "M1")

TFMPP
(3-Trifluoromethylphenylpiperazine, "Legal X")

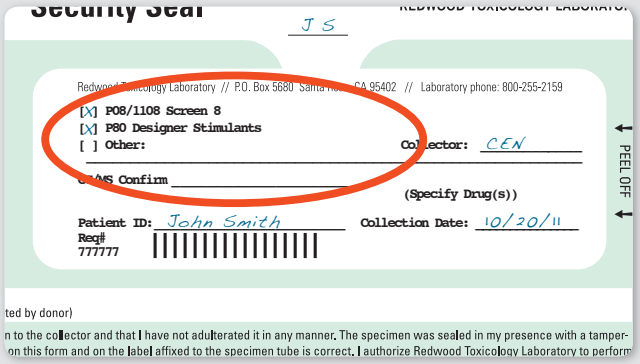
REQUESTING A DESIGNER STIMULANT URINE TEST

To add **Designer Stimulant Testing**

Call 800-255-2159

or contact us online

Ordering a Designer Stimulant Drug Test is easy for any specimen you wish to have tested. Whether you're combining designer stimulant testing with your existing urine test panel or only want to test designer stimulants, our sales representatives are ready to help you set up your agency's test panel. Contact a RTL sales representative to ensure the Designer Stimulant test code (P80 or P81) is added to your labels.



Label with Test Code: To test for designer stimulants, check the box for **"P80"** or **"P81"** under your primary test panel on the specimen label. The lab will run whichever tests you check on the label. In the example above, RTL will run the P08 Screen 8 and the Designer Stimulant test panel.

Label without Test Code: If your current labels do not include **"P80"** or **"P81"**, please call your RTL sales representative to have the test added to your agency's test panel options.

Additional information is available on our website:

Urine Specimen Collection Protocol:
http://www.redwoodtoxicology.com/resources/collection/urine_collection.html

Urine Specimen Labeling Protocol:
http://www.redwoodtoxicology.com/resources/labeling_shipping/labeling_protocol_urine.html

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11 000 3396 REV1

drugs of abuse testing–*urine*

LABORATORY SERVICES

Are they abusing? We'll find out.

Urine testing from Redwood Toxicology Laboratory accurately detects drugs of abuse in urine with the assurance of legally defensible test results.

Confidence in testing.

REDWOOD TOXICOLOGY LABORATORY DoA URINE TESTING

Redwood Toxicology Laboratory, Inc. (RTL) utilizes the most sophisticated, sensitive and specific equipment and technology available to screen, confirm and quantitate drugs of abuse in urine. Our methodologies provide highly accurate, legally defensible results. As with all of RTL's testing options, full customer support is provided.

RTL's objective is to help its clients detect and prevent drug and alcohol abuse. Urine testing through RTL is reliable, affordable and convenient. Turn to RTL for confidence in testing—we'll find out.

BENEFITS INCLUDE:

- *Toll-free customer support services with access to board certified toxicologists*
- *Expert witness services and litigation packages available*
- *Results available via internet, fax and/or U.S. mail*
- *Affordable pricing (ask about combining your drug testing panels)*
- *Fast turn-around time from receipt of specimen (24 hours[1] negative, 48-72 hours positive)*
- *Third party government insurance billing consultation*

RTL'S MOST POPULAR TESTS

New Available! Buprenorphine & Oxycodone

FIVE PANEL SCREEN	EIGHT PANEL SCREEN		TEN PANEL SCREEN	
+ Amphetamines	+ Amphetamines	+ PCP	+ Amphetamines	+ PCP
+ Cocaine	+ Barbiturates	+ THC (Semi-Quant)	+ Barbiturates	+ Propoxyphene
+ Opiates	+ Benzodiazepines	+ Alcohol	+ Benzodiazepines	+ THC (Semi-Quant)
+ PCP or Benzodiazepines	+ Cocaine		+ Cocaine	+ Alcohol
+ THC (Semi-Quant)	+ Opiates		+ Methadone	+ Opiates
Test Panel: *P28 w/ BZO or H39 w/ PCP*	**Test Panel:** *R53*		**Test Panel:** *R57*	

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/3279

REDWOOD TOXICOLOGY LABORATORY

an inverness medical company

FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com

How do I collect the urine and send in a specimen?

Collection and shipping guidelines are included in the RTL Reference Guide. A copy is provided with your new account supplies. Please read these instructions carefully. RTL also offers telephonic training and client service support.

How long does it take for results?

Results are typically reported in 24 hours[1] for negatives, 48-72 hours for positives. All presumptive positive results go through a confirmation process to ensure accurate results.

What methodology does RTL use to perform initial screening?

RTL screens urine specimens by enzyme immunoassay (EIA). An immunoassay is a test that uses antibodies to detect the presence of drugs and other substances in urine. The initial screening process does not measure the specific amount of drug present in urine samples. It provides either a positive or negative result, indicating the presence or absence of detectable drug.

Cut-off levels updated periodically

Screening Cut-off Levels by EIA

Drug	EIA
Amphetamine	1000 ng/mL
Methamphetamine	1000 ng/mL
Barbiturates	200 ng/mL
Benzodiazepines	200 ng/mL
Buprenorphine	5 ng/mL
Cocaine Metabolite (Benzoylecgonine)	300 ng/mL
Ethanol	0.04gm/dL
Methadone	150 ng/mL
Methadone Metabolite	150 ng/mL
Opiates (Morphine and Codeine)	300 ng/mL
Oxycodone	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene	300 ng/mL
THC (Cannabinoids)	20/50 ng/mL[2]

What testing methodology does RTL use for confirmations?

Confirmations are available by thin layer chromatography (TLC), radioimmunoassay (RIA), gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). GC/MS is used to confirm presumptive positive drug screen specimens obtained from RTL's instant on-site screening devices.

Confirmation Cut-off Levels by Procedure *Cut-off levels updated periodically*

Drug	TLC	RIA	GC/MS
Amphetamines			
- Amphetamine	<500 ng/mL		100 ng/mL
- Methamphetamine	<500 ng/mL		100 ng/mL
- MDMA	<500 ng/mL		100 ng/mL
- MDA	<500 ng/mL		100 ng/mL
Barbiturates	<500 ng/mL		200 ng/mL
Benzodiazepines		200 ng/mL	50 ng/mL
Buprenorphine			0.5 ng/mL
Cocaine Metabolite (Benzoylecgonine)		150 ng/mL	50 ng/mL
EtG (LC/MS/MS)[3]			100 ng/mL
EtS (LC/MS/MS)[3]			100 ng/mL
Fentanyl			5 ng/mL
GHB			10 mcg/mL
6-monoacetyl-morphine			5 ng/mL
Marijuana Metabolite (THC-COOH)		25 ng/mL	5 ng/mL
Methadone	<500 ng/mL		150 ng/mL
Opiates			
- Total Morphine	<500 ng/mL		100 ng/mL
- Codeine	<500 ng/mL		100 ng/mL
- Hydrocodone	1000 ng/mL		100 ng/mL
- Hydromorphone			100 ng/mL
- Oxycodone	1000 ng/mL		100 ng/mL
Phencyclidine (PCP)			10 ng/mL
Propoxyphene	<500 ng/mL		200 ng/mL
Alcohol (GC-FID)[4]			.02 gm/dL

Why are screening & confirmation cut-off levels different?

Screening and confirmation testing are performed using different methodologies that require separate cut-off levels. The immunoassay tests used to perform initial drug screens are designed to detect a wide range of chemically similar compounds that react with antibodies which are at the core of the chemistry making up the tests. In contrast, GC/MS confirmatory testing detects specific metabolites that provide identification and quantification of a specific drug.

1. Excludes specimens received Saturday
2. Agency has the ability to choose cut-off levels indicated.
3. Test performed by Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS)
4. Test performed by Gas Chromatography Flame Ionization Detection (GC/FID)

11 000 3279 REV4

REDWOOD TOXICOLOGY LABORATORY™

800-255-2159

Laboratory: 800-255-2159 // Screening Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

Urine Creatinine / *INTERPRETATION AND THC/CREATININE RATIOS*

INFORMATION SHEET

CREATININE INTERPRETATION

Introduction

In an effort to further enhance the reliability of analyzing urine specimens for drugs of abuse, Redwood Toxicology Laboratory (RTL) routinely determines the creatinine concentration in all specimens submitted. Creatinine is a by-product of muscle metabolism that is excreted in the urine. Its measurement is routinely used clinically to evaluate kidney function. Additionally, urinary creatinine determination is an important parameter for evaluating the validity of a urine specimen for drugs of abuse detection. Because of the potential consequences of a positive drug test, an individual may be motivated to beat the drug test by various techniques. One of the most common practices used to avoid a positive drug test is the intentional consumption of excess fluid in a relatively short period of time in an effort to flush their system. This is commonly referred to as water-loading or dilution and can result in the drug being below the positive cut-off concentration. Thus, even though an individual may have recently used drugs, intentional dilution can lower the drug concentration, resulting in a false negative drug test.

Another important aspect of creatinine interpretation is its use to monitor abstinence from marijuana. The concentration of the THC metabolite, carboxy-THC, can fluctuate from day-to-day depending upon a persons fluid intake. The calculation of the carboxy-THC to creatinine ratio is of considerable value when trying to determine if an individual has abstained from marijuana use.

Dilution

A search of the Internet will quickly reveal many websites, that market products "guaranteed" to beat the drug test. A majority of these sites advertise teas, carbohydrate drinks, and/or other liquid concoctions whose primary action is based on excessive fluid intake. These products have names such as Detoxify Carbo Clean, Ultimate Blend, Naturally Klean Herbal Tea, Goldenseal, Certo, and The Eliminator to name a few.

The following is an example of a product's Internet advertisement:

> *Easy & Convenient. When you want a drink with quick cleansing power, the #1 seller in the Industry is the ideal choice. READY-CLEAN is an easy-to-use cleansing beverage. Simply drink, and you're clean after one hour with a clinically proven cleansing power for up to five full hours. There is no mixing. No lengthy procedures. It is that easy. Thousands of consumers have trusted the Powerful effects of READY-CLEAN and its #1 status is proof of its superior cleansing abilities.*
>
> *IF TIME PERMITS: For the two days prior to the days of your deadline avoid toxins and consume a minimum of (6) 16 ounce glasses of water per day.*
>
> 1. *It is permissible to consume up to 20 oz. of fluids every two hours until taking READY-CLEAN and 16 oz. of fluid every two hours thereafter.*
> 2. *Begin taking READY-CLEAN at least 60 minutes prior to your deadline.*
> 3. *Drink entire contents of bottle.*
> 4. *Wait 15 minutes. Refill the READY-CLEAN bottle with water, shake and drink.*
> 5. *Urinate frequently to remove toxins. Eat light meals the day of your deadline.*

Figure 1: Internet product advertisement promoting a cleansing formula—guaranteed to beat the drug test.

The measurement of creatinine can aid in establishing if any of these products were used. Creatinine production and excretion is directly related to muscle mass and is sex and age dependent. Normal random urine creatinine concentrations range from 40-300 mg/dL in males and 37-250 mg/dL in females. Values as low as 17 mg/dL have been observed in rare instances. Certain physiological conditions such as diabetes may result in consistently dilute urine specimens. Scientific water loading studies in which participants used specified amounts of cocaine and marijuana determined that subjects consistently produced dilute urine specimens upon drinking large volumes of water (2-4 quarts) and corresponding urinary drug concentrations declined below cut-off concentrations. Dilute urines—generally observed at 2 hours and persisted for up to 5 hours after liquid consumption.

Numerous scientific studies have been conducted in an effort to establish criteria to determine forensically dilute specimens based on creatinine concentrations. Several of these studies have recommended that creatinine concentrations below 45 mg/dL be used as a basis to determine if a urine specimen has been physiologically or non-physiologically dilute and if a corresponding negative drug result is valid. Federal regulations set forth by SAMHSA, have two critical points for creatinine concentration to assess the validity of a urine specimen for drug testing. One critical point is set at less than 20 mg/dL while the second is set at less than or equal to 2 mg/dL. These creatinine concentrations, in conjunction with a corresponding specific gravity level, are used to report a urine specimen as either dilute or substituted because it is not consistent with clinical characteristics associated with normal human urine.

Recommendations

RTL's creatinine criteria reflect the critical points set forth by SAMHSA to report dilute or abnormally diluted urine specimens. RTL believes that the scientific evidence supports these values and provides a strong basis to defend the interpretation in medical-legal settings.

In conclusion, low urine creatinine values may indicate that an individual attempted to beat the drug test by drinking excessive fluid in an effort to flush the drugs from his system. When low creatinine concentrations are observed, it should be a concern for the agency performing the urine collection.

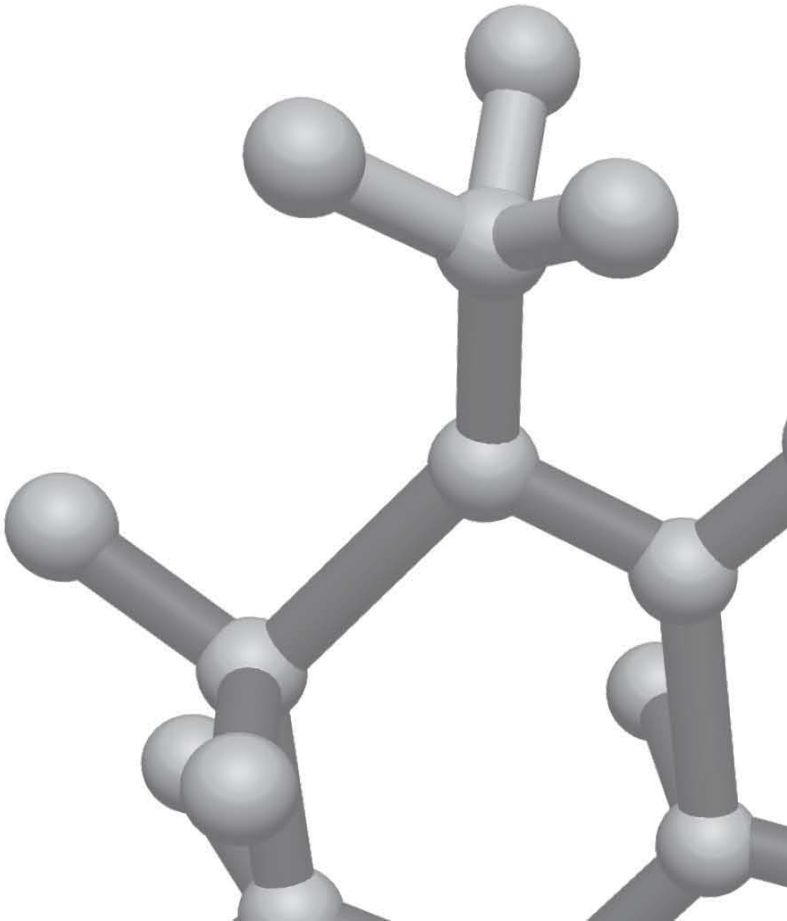
	Cocaine (Benzoylecgonine)	None Detected
	Benzodiazepines	None Detected
	Alcohol (Ethanol)	None Detected
POS--------->	THC (Marijuana) Confirmed by RIA.	300
	Creatinine	50 mg/dL

Figure 2: Sample Toxicology Report indicating normal levels of creatinine.

	Cocaine (Benzoylecgonine)	None Detected
	Benzodiazepines	None Detected
	Alcohol (Ethanol)	None Detected
POS--------->	THC (Marijuana) Confirmed by RIA.	300
	Creatinine Specimen is abnormally dilute.	1.7 mg/dL

Figure 3: Sample Toxicology Report indicating abnormal levels of creatinine.

If an individual produces urine with low creatinine concentrations, RTL recommends that the frequency of urine collections be increased and if possible, the donor be instructed to donate his urine either in the morning or within two hours of being notified that they are to provide a urine specimen. Additionally, they should limit their water intake to two eight-ounce glasses within two hours of the collection. These factors would minimize the likelihood of dilute urines and beating the drug tests by flushing the drug from their system.



THC/CREATININE RATIOS

Introduction

THC is one of the numerous cannabinoid chemicals present in marijuana as well as the primary psychoactive ingredient. Cannabinoid metabolites appear in urine within two to four hours after smoking marijuana and may persist up to 30 days (at the 50 ng/mL cut-off concentration) depending upon a person's previous pattern of abuse. In general, infrequent use of marijuana may only be detected for 1-3 days after use. Regular use, several times per week, may be detected for 7-10 days, while chronic use of marijuana may be detectable for up to 30 days. Routine passive inhalation to marijuana will not cause a positive urine drug test for THC at a 50 ng/mL screening cut-off concentration.

The measurement of creatinine concentrations is an important variable to monitor when attempting to determine if an individual has abstained from marijuana between successive urine specimens. The concentration of the THC metabolite, carboxy-THC, can fluctuate from day-to-day depending upon a person's fluid intake. Increased fluid intake will lower both the carboxy-THC and creatinine concentration in a urine specimen while dehydration will have the opposite effect.

Calculation of the carboxy-THC to creatinine ratio neutralizes any change in the carboxy-THC concentration due to variation in a person's hydration state. This calculation makes it possible to compare urine specimens to establish if renewed use of marijuana has occurred.

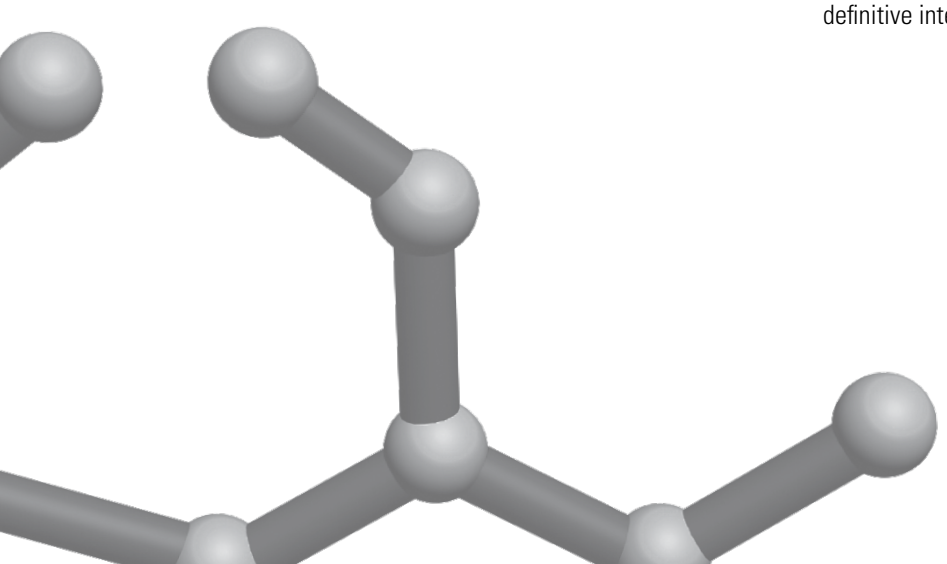
Semi-quantitative RIA Results

The radioimmunoassay (RIA) values reported by Redwood Toxicology Laboratory for THC (marijuana) are only to be interpreted as an estimation of the concentration of total cannabinoids (marijuana metabolites) present in a urine specimen. Urinary cannabinoid values are difficult to interpret due to variables such as frequency of use, duration of use, amount used, and an individual's liquid consumption. Therefore, positive RIA results for THC (cannabinoids) indicate use of marijuana but numerous additional considerations, such as THC/Creatinine ratio are required to establish renewed or continued use.

Based on our experience at RTL, the following offers some general guidelines for interpreting laboratory RIA results:

RIA Value	Use Pattern
> 500	Possible recent/high use
250-500	Possible continued elimination in chronic use or recent use in infrequent user
<250	Possible terminal elimination in chronic use or recent use in infrequent user

The use of the RIA values provides preliminary clinical information for single use of marijuana. Because the analysis of a single urine specimen cannot typically distinguish between very recent use and chronic use, the exact time of use cannot be determined with any certainty. A more reliable determination of renewed use of marijuana requires the comparison of the THC/Creatinine ratios between multiple urine specimens. This ratio can be calculated by dividing the "THC" value by the Creatinine value then multiplying by 100. In general, an increase of more than 50% in the THC/Creatinine ratios between two urine specimens provides clinical evidence of possible renewed use. If the THC/Creatinine results are to be used for punitive or administrative purposes, GC/MS confirmation analysis must be performed to provide a definitive interpretation of renewed marijuana use.



The following graph is actual data from a client with a chronic history of smoking marijuana who was being routinely monitored for drug use:

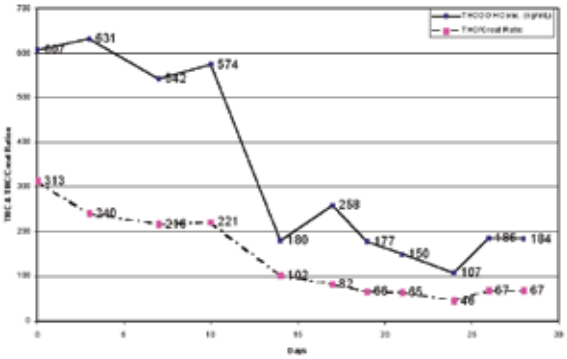


Figure 4: Chronic marijuana smoker, routinely monitored.

The top curve represents the THC (cannabinoid) values based upon the RIA analysis while the bottom curve is a plot of the respective "THC/creatinine" ratios. Although the graph shows an increase in the THC value from 180 to 258 between days 14 and 17, respectively, the corresponding ratios actually decreased from 102 to 82. Thus, although the THC values might have caused concern of renewed marijuana use, the THC/creatinine ratios actually decreased. This decrease in the ratio is more indicative of continued elimination of marijuana.

A plot of the THC and THC/creatinine ratios from another subject yields a different interpretation:

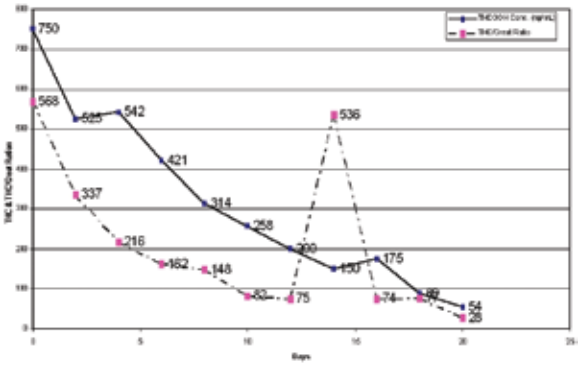


Figure 5: THC and THC/creatinine ratios with strong clinical evidence of renewed use.

The data reveals decreasing "THC" values of 200 and 150 for days 12 and 14, respectively. In contrast, the corresponding THC/Creatinine ratios show a sharp increase from 75 to 536, respectively. Although the THC values do not suggest renewed use between the two urine specimens, the ratios provide strong clinical evidence of renewed use. For conclusive evidence, only these two urine specimens need to be confirmed by GC/MS analyses. If the increase in the ratios is further substantiated with GC/MS analyses, then it can be concluded, with a high degree of scientific certainty, that the individual had used marijuana between the two urine collections.

Finally, although an initial EIA positive test in combination with a RIA semi-quantitative positive result provides preliminary interpretation information, clinical consideration and professional judgment should be considered for more reliable interpretation. Redwood Toxicology Laboratory (RTL) strongly recommends consultation with a toxicologist, and a gas chromatography/mass spectrometry (GC/MS) confirmation prior to any administrative or legal action.

REDWOOD TOXICOLOGY LABORATORY

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Phone: 800-255-2159 | 707-577-7959
Fax: 707-577-8102
www.redwoodtoxicology.com

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REDWOOD TOXICOLOGY LABORATORY™

Confidence in testing

Corporate Overview / *REDWOOD TOXICOLOGY LABORATORY*

Redwood Toxicology Laboratory, Inc. (RTL), located in Santa Rosa, California, is a federally certified laboratory specializing in low-cost, rapid turnaround drug testing. RTL is the largest single-location drug testing laboratory in the United States. Urine and oral fluid specimens are analyzed for drugs of abuse by state of the art screening and confirmation methodologies. RTL screens urine specimens by enzyme immunoassay (EIA) and oral fluid specimens by enzyme-linked immunosorbent assay (ELISA). Positive screens are confirmed by radioimmunoassay (RIA), thin layer chromatography (TLC), gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS) and/or liquid chromatography/tandem mass spectrometry (LC/MS/MS).

ABOUT US

Employing over 200 people, RTL services thousands of clients, including correctional, probation and parole, police and sheriff, medical facilities and employment agencies. A number of our over 7,000 clients have utilized the laboratory's services in excess of fourteen (14) years. RTL has the experience to supply your agency with the highest quality drug testing services.

- Extensive experience in performing forensic toxicology analyses,
- Highly qualified scientific staff,
- State of the art scientific instrumentation for the detection of drugs of abuse,
- Excellent client services with the ability to adapt to differing needs, and,
- Extensive quality assurance and quality control procedures help to ensure accurate results as well as maintaining the superior service provided to our clients.

CERTIFICATION

The following technical proposal outlines various aspects of the laboratory, including certification, proficiency testing, results reporting, and methodologies.

RTL is licensed and accredited by the following federal and state agencies:

- Department of Health and Human Services CLIA '88, #05D0707588
- California Department of Health Services Clinical Laboratory License, #05D0707588
- DEA License # RR0340113-Analytical Laboratory
- Florida Clinical Laboratory License, #L800010955
- Pennsylvania Clinical Laboratory Permit, #025348
- Maryland Medical Laboratory, Permit #880

3650 Westwind Blvd. // Santa Rosa, CA 95403 // www.redwoodtoxicology.com
Laboratory Services: 800-255-2159 // Screening Devices: 877-444-0049 // Local: 707-577-7959 // Fax: 707-577-8102

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REDWOOD TOXICOLOGY LABORATORY™

Confidence in testing

TURNAROUND TIME

Results are reported within twenty four (24) hours for negative specimens and forty eight to seventy two (48-72) hours for positive specimens. This excludes specimens received on Saturdays.

PROFICIENCY TESTING

RTL subscribes to the American Association of Bioanalysts, College of American Pathologist's, RTI Oral Fluid Program, GTFCH German EtG/EtS, and the Pennsylvania State Department of Health's proficiency testing services. Each agency sends samples three or four times a year that are graded and all testing outcomes have been successful.

RESULT REPORTING

RTL is able to provide internet reporting in compliance with HIPAA standards. Internet access is password protected and various passwords can be provided depending on your agency's needs. For a demonstration of RTL's internet reporting, please visit http://www.webtoxicology.com. Enter Agency Code: 9999, User ID: guest and Password: guest.

Reporting options include:

- Results available securely over the internet at http://www.webtoxicology.com
- Results communicated by facsimile (for agencies that do not require HIPAA compliance)
- Daily summary of multiple specimen results on one page
- Hard copies of reports sent by mail

SUPPLIES & SERVICES

Below is a comprehensive list of the ancillary supplies and services Redwood Toxicology Laboratory, Inc. provides at no additional cost to your agency.

Collection supplies include:

- Specimen collection containers
- Specimen baggies with absorbent material
- Chain of Custody forms and labels of various configurations
- Security seals
- Temperature strips (upon request)
- Pre-paid U.S. mail or FedEx/UPS shipping (Five specimens required for FedEx/UPS service)

Additional services include:

- Phone consultation: Timely response to questions ranging from specimen collection to confirmation.
- Website/Drugs of Abuse Literature: Information from street names to retention/detection times.
- Training: Telephonic training on collection procedures and results interpretation.
- Expert Witness Testimony: Available by affidavit, telephonically or in-court.
- Air Shipment Tracking and Scheduling: Track FedEx or UPS specimen shipments to the laboratory or call to arrange pick-up for specimens (five or more specimens).
- IT/Computer Support: Available for internet reporting support and to answer all IT questions.
- Supply Fulfillment: Call toll free for all your collection supply needs.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS	CLIA ID NUMBER
REDWOOD TOXICOLOGY LABORATORY,INC 3650 WESTWIND BLVD SANTA ROSA, CA 95403	05D0707588
	EFFECTIVE DATE 10/14/2010
LABORATORY DIRECTOR	EXPIRATION DATE
MARK DE MEO	10/13/2012

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

190 certs2_103010

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
TOXICOLOGY (340)	10/14/1994		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

State of California Department of Public Health
Clinical Laboratory License

In accordance with the provisions of Chapter 3, Division 2, of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

REDWOOD TOXICOLOGY LABORATORY, INC.
3650 WESTWIND BOULEVARD
SANTA ROSA, CA 95403

OWNER(S):

REDWOOD TOXICOLOGY LABORATORY, INC.
RTL HOLDINGS, INC.
IVERNESS MEDICAL INNOVATIONS, INC.
ROBERT MOUNT
ALBERT BERGER
JOHN BRIGDEN

DIRECTOR(S):

MARK J DE MEO MD
RICHARD R WILBER MD

CLIA Number:	05D0707588
Lab ID Number:	CLF 3738
Effective Date:	FEBRUARY 26, 2010
Valid Until:	FEBRUARY 25, 2011

Karen L. Nickel

Karen L. Nickel, Chief
Laboratory Field Services

AMERICAN ASSOCIATION OF BIOANALYSTS

PROFICIENCY TESTING SERVICE

2010

CERTIFICATE OF PARTICIPATION

This certifies that

Redwood Toxicology Laboratory Inc

is a participant in a continuous program
of quality control for laboratory testing.

THE AMERICAN ASSOCIATION OF BIOANALYSTS

AAB

Director

CLINICAL LABORATORY PERMIT

pennsylvania
DEPARTMENT OF HEALTH

Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 025348A

Name and Director of Laboratory:

REDWOOD TOXICOLOGY LABORATORY
MARK J DEMEO, MD
3650 WESTWIND BOULEVARD
SANTA ROSA, CA 95403

AUTHORIZED CATEGORIES:

CLINICAL CHEMISTRY
NON-SYPHILIS SEROLOGY
PREGNANCY TESTING
TOXICOLOGY - DRUGS URINE CONFIRMATORY
TOXICOLOGY - DRUGS URINE SCREENING

Owner:
RTL HOLDINGS INC

Issued: August 15, 2010

This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.

DATE EXPIRES: August 15, 2011

Michael Huff
Deputy Secretary for Health Planning and Assessment

Everette James
Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY

MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY
SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

MEDICAL LABORATORY PERMIT

NUMBER: 880 EFFECTIVE PERIOD: 07/01/2010 - 06/30/2012

Pursuant to the provisions of TITLE 17, subtitle 2, Health-General Article § 17-201 et seq., Annotated Code of Maryland, this permit is issued to:

REDWOOD TOXICOLOGY LABORATORY, INC.
3650 Westwind Blvd.
SANTA ROSA, CA 95403

Director: MARK DE MEO
Owner: R T L HOLDINGS INC

For the performance of Medical Laboratory Tests in the following disciplines:

Forensic Toxicology - Job Related Testi
Urine Drug Confirmation by GC/MS; GC/MS/MS; OR MS/MS

Immunology:
Urine Pregnancy Test

Chemistry:
Special Chemistry, other, Toxicology - Drug of Abuse Level

CONTROL: **41169**

Nancy B. Grasso
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the impostition of civil fines.

CERTIFICATE #: 85217

LICENSE #: 800010955

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION

DIVISION OF HEALTH QUALITY ASSURANCE

CLINICAL LABORATORY

This is to confirm that REDWOOD TOXICOLOGY LABORATORY, INC. has complied with Chapter 483, Part I, Florida Statutes, and with Chapter 59A-7, Florida Administrative Code, and is authorized to operate the following laboratory in the specialties or subspecialties of:

Toxicology

REDWOOD TOXICOLOGY LABORATORY
3650 WESTWIND BLVD
SANTA ROSA, CA 95403

EFFECTIVE DATE: February 10, 2010

EXPIRATION DATE: February 09, 2012

Elizabeth Dudek

Deputy Secretary, Division of Health Quality Assurance

cap

The College of American Pathologists recognizes

Redwood Toxicology Laboratory

71824-00-01

For participation in the Surveys and Anatomic Pathology Education Program

Stephen N. Bauer MD FCAP

Stephen N. Bauer, MD, FCAP
CAP President

2010

Surveys, EXCEL and Anatomic Pathology Education Programs

Cross Reactants / *potential reactants and cross-reactants chart*

Cross-reactivity of structurally similar substances is a problem associated with immunoassay methodologies, resulting in false positive or negative results. Screening technologies are predominantly immunoassay techniques which may proved high sensitivity but are of limited specificity. Manufacturers will test for common potential interfering substances and list these on package inserts, however it is not possible to test every compound. Also some compounds ingested in therapeutic dosage may not cross-react, however when abused in "mega" doses may significantly influence urine immunoassay results.

Listed below are potential reactants and cross-reactants with **most** immunoassay methodologies:

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Acetaminophen (see also Paracetamol)	Aceta, Acephen, Apacet, Dapacen, Feverall, Tylenol, Excedrin (combination), Panadol, Tempra	Non-reactive
Acetaminophen with Codeine (see also Paracetamol with codeine)	Tylenol 3, Tylenol with codeine	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Acetophenetidin	Phenacetin	Non-reactive
Acetylsalicyclic acid	Aspirin, Anadin, Anasin, Bufferin, Caprin, Disprin, Ecotrin, Empirin, Excedrin (combination)	Non-reactive
Allobarbital	No known trade names	Positive for Barbiturates (BAR)
Alphenol	No known trade names	Positive for Barbiturates (BAR)
Alprazolam	Xanax	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Aluminum Chloride Hexahydrate	Drichlor, Anhydrol Forte	Non-reactive
Aluminum Hydroxide	Alu-Cap, Alisone, Gastrocote, Kolanticon, Maalox, Maalox TC, Mucogel, Pyrogastrone, Topal	Non-reactive
Alverine Citrate	Spasmonal, Spasmonal Fibre	Non-reactive
Aminopyrine		Non-reactive
Amitriptyline	Elavil, Lentizol, Tryptizol, Triptafen, Triptafen-M	Positive for Tricyclic Antidepressants (TCA)
Ammonia/Ipeacuanha	Ipecac	Non-reactive
Amobarbital	Amytal, Tuinal	Positive for Barbiturates (BAR)
Amoxicillin or Amoxycillin	Amoxil, Amoram, Augmentin, Heliclear	Non-reactive

Therapeutic dosages may not be detected in urine.

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Amphetamine / Methamphetamine	AMP: Adderall, Dexedrine, Benzedrine M/AMP: Desoxyn, Didrex Eldepryl	Positive for Amphetamines/ Methamphetamines Potential cross reactants: Epherdrine, Pseudoephedrine, Phenylpropanolamine, Phentermine, Phenmetrazine, Ranitidine
Ampicillin	Penbritin, Polycillin, Principen	Non-reactive
Antazoline Sulphate	Otrivine-Anistin	Non-reactive
Aprobarbital		Positive for Barbiturates (BAR)
Aspirin	Bayer Aspirin, Excedrin, ASA, Angettes, Asasantin, Caprin	Non-reactive
Atenolol	Beta-adlat, Co-tenidone, Kalten, Tenben, Tenif, Tenoret50, Tenorectic, Tenormin	Non-reactive
Atorvastatin	Lipitor	Non-reactive
Azlocillin	Securopen	Non-reactive
Barbital		Positive for Barbiturates (BAR)
Beclometasone	AeroBec, AeroBec Forte, Asmabec, Beclazone, Becloforte, Becodisks, Beconase, Becotide, Fillair, Nasobec, Qvar, Ventide, Zonivent	Non-reactive
Bendrofluazide	Aprinox, Cogaretic, Indertic, Inderex, Neo-Naclax, Neo-Naclax-K, Prestim, Tenben	Non-reactive
Benzalknonium	Bradosol	Non-reactive
Benzydamine HCl	Difflam	Non-reactive
Benzodiazepines	See individual Benzodiazepines listed	Potential cross reactants: Oxaprozin (Daypro), Sertraline
Benzylpenicillin	Crystapen	Non-reactive
Bromazepam	Lexotan	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Bromopheniramine	Dimetapp, Dimotapp, Dimotane	Non-reactive
Buprenorphine	Subutex, Temgesic	Non-reactive
Buproprion	Wellbutrin, Zyban	Non-reactive
Butabarbital	Butisol, Soneryl	Positive for Barbiturates (BAR)
Butalbital	Fioricet, Fiorinal	Positive for Barbiturates (BAR)
Canestan	Canestan ear/skin/vaginitis/HC	Non-reactive
Carbamazepine	Tegretol, Teril, Timonil	Non-reactive
Cephalexin	Ceporex, Keflex	Non-reactive
Chloral Hydrate	Welldorm	Non-reactive
Chlordiazepoxide	Librium	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Chlorhexidine Gluconate	Bactrigras, Cordsodyl, Chlorohex, CX Powder, Dermol, Hibicet, Hibiscrub, Hibisol, Hibitane, Instillagel, Naseptin, Nystaform, Serotulle, Steripod, Tisept, Unisept, Uriflex, Uro-Trainer	Non-reactive
Chlorpheniramine Maleate	Galpseud, Haymine, Piriton	Non-reactive
Chlorpromazine	Largactil	Non-reactive
Cimetidine	Dyspamet, Tagamet, Zita	Non-reactive
Clobazam	Frisium	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Clonazepam	Clonopin, Klonopin, Rivotril	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Clorazepate	Tranxene	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Citalopram	Cipramil	Non-reactive
Co-Amoxiclav	Augmentin, Augmentin Duo	Non-reactive
Codeine Phosphate	Codafen Continus, Codeine Linctus, Pediatric BP, Galcodine, Kapake, Migraleve, Solpadol, Tylex	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Co-Fluampicil	Magnapen	Non-reactive
Co-Phenotrope (atropine/diphenoxylate)	Lomotil, Trepergen	Non-reactive
Delorazepam	Briantum	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Dexamethasone	Decadron, Dexa-Rhinaspray Duo, Maxidex, Maxidrol, Minims, Otomize, Sofradex	Non-reactive
Dextroamphetamine	Adderall, Adderall XR, Dexedrine	Positive for Amphetamine (AMP)
Dextropropoxyphene	Darvon, Darvocet, Co-proximal	Positive for Propoxyphene (PPX)
Diazepam	Diazemuls, Stesolid,Valclair, Valium	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Diclofenac Sodium	Dicloflex, Diclomax, Motifene, Volraman, Volsaid, Voltarol	Non-reactive
Dicyclomine	Kolanticon, Merbentyl	Non-reactive
Dihydrocodeine	DHC Continus, Paramol, Remedeine, Remedeine Forte	Potential Positive for Opiates (OPI, MOR/MOP)
Dimethicone	Asilone, Fancorsil	Non-reactive
Diphenhydramine	Benadryl, Medinex, Nytol, Panadol Night	Non-reactive

Therapeutic dosages may not be detected in urine.

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Dipenoxylate with Atropine	Lomotil	Non-reactive
Dothiepin	Prothiaden	Non-reactive
Doxycycline	Vibramycin, Vibramycin-D	Non-reactive
Doxepin	Sinequan, Xepin	Positive for Tricyclic Antidepressants (TCA)
Efavirenz	Sustiva	Potential Positive for Cannabinoids (THC)*
Erythromycin	Arpimycin, Benzymycin, Erycane, Erymax, Erythrocin, Erythroped, Ilosone, Isotrexin, Lactobinate, Stiemycin, Tiloryth, Zineryl	Non-reactive
Estazolam	ProSom	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Ethambutol	Myambutol	Non-reactive
Ethylmorphine		Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Flucloxacillin	Co-fluampicil, Floxapen, Magnapen	Non-reactive
Flunitrazepam	Rohypnol	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Fluoxetine	Prozac, Sarafem	Non-reactive
Flupentixol Decanoate	Depixol, Fluanxol	Non-reactive
Fusidic Acid (Sodium Fusidate)	Fucithalmic, Fucibet, Fucidin	Non-reactive
Gentamicin Sulphate	Cidomycin, Genticin, Gentisone	Non-reactive
Hydrocodone	Lorcet, Loratab, Vicodin	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Hydrocortisone	Actinac, Alphaderm, Alphosyl-HC, Anugesic-HC, Anusol-HC, Calmurid-HC, Canesten-HC, Colioam, Daktacort, Dioderm, Econacort, Efortelan, Efcortesel, Eurax-HC, Gregoderm, Hydrocortistab, Hydrocortone, Mildisonlipo-cream, Neo-cortef, Nystaform, Perinal, Proc-tofoam, Quinocort, Terra-cortil, Timodine, Uniroid-HC, Vioform-HC, Xyloproct	Non-reactive
Hydrocortisone-17-butyrate	Locoid, Locoid C	Non-reactive
Hydromorphone	Dilaudid, Hydrostat	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Hydroxychloroquine	Plaquenil	Non-reactive
Hydroxyzine Hydrochloride	Atarax, Ucerax	Non-reactive
Hyoscine butylbromide	Busocopan, Scopoderm	Non-reactive
Ibuprofen	Brufen, Codafen, Fenbid, Ibugel, Ibuspray, Motrin, Proflex	Non-reactive
Indomethacin	Flexin continus, Indocid, Indomod	Non-reactive

Therapeutic dosages may not be detected in urine.

* Urinary metabolite(s) only; parent compound is non-reactive

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Interferon Alfa	Roferon-A, Intron A, Viraferon, Wellferon	Non-reactive
Isoniazide	INH	Non-reactive
Isosorbide Dinitrate	Angitak, Cedocard, Isocard, Isoket, Isordil, Sorbichew, Sorbitrate, Sorbid SA	Non-reactive
Koalin and Morphine Mixture	Diocalm, Entersan, Opazimes	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Ketoprofen	Orudis, Oruvail, Powergel	Non-reactive
Lactulose	Lactugal, Duphalec	Non-reactive
Lamotrigine	Lamitcal	Potential Positive for PCP
Lansoprazole	Heliclear, Zoton	Non-reactive
Lisinopril HCl	Carace, Zestril, Zestoretic	Non-reactive
Lofepramine	Gamanil, Lomont	Positive for Tricyclic Antidepressants (TCA)
Lofexidine	Britoflex	Non-reactive
Loperamide HCl	Imodium, Loperagen, Norimide	Non-reactive
Loratadine	Claritin	Non-reactive
Lorazepam	Ativan	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Lormetazepam	Noctamide	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Magnesium Alginate	Gaviscon	Non-reactive
Mannitol	Gaviscon	Non-reactive
Medazepam	Anxitol, Lerisum, Medacepan, Nobritol, Nobrium	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Mefenamic Acid	Ponstan, Ponstel	Non-reactive
Meperidine	Demerol, Pethidine	Non-reactive
Metoclopramide	Reglan	Non-reactive
Methadone Hydrochloride	Dolophine, Methadose, Physetone	Positive for Methadone (MTD) Potential cross reactants: Doxylamine
d-Methamphetamine HCL	Desoxyn, Methedrine, Methamprex	Positive for Methamphetamine (M-AMP) Potential cross reactants: Epherdrine, Pseudoephedrine, Phenylpropanolamine, Phentermine, Phenmetrazine, Ranitidine
l-Methamphetamine HCL	Vick's Inhaler	Positive for Methamphetamine (M-AMP) Potential cross reactants: Epherdrine, Pseudoephedrine, Phenylpropanolamine, Phentermine, Phenmetrazine, Ranitidine

Therapeutic dosages may not be detected in urine.

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Methylenedioxyamphetamine (MDA)	Eve (slang), Love Drug (slang)	Positive for Amphetamine (AMP) Potential cross reactants: Epherdrine, Pseudoephedrine, Phenylpropanolamine, Phentermine, Phenmetrazine, Ranitidine
Methylenedioxymethamphetamine (MDMA)	Ecstasy (slang), XTC (slang), Adam (slang), E (slang)	Positive for Methamphetamine (M-AMP) and Ecstasy (MDMA) Potential cross reactants: Epherdrine, Pseudoephedrine, Phenylpropanolamine, Phentermine, Phenmetrazine, Ranitidine
Metronidazole	Anabact, Elyzol, Flagyl, Metrogel, Metrolyl, Metrotop, Neuratop, Noritate, Rozex, Zidoval, Zymoet	Non-reactive
Morphine	Astramorph, Cyclimorph, Duramorph, Morcap, Morphine Sulfate, MS Contin, Oramorph, Roxanol, Severedol	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Nadolol	Corgard, Corgaretic, Corgartic	Non-reactive
Naloxone	Narcan	Non-reactive
Naltrexone	Antaxone, Nalorex, Trexan	Non-reactive
Naproxen	Aleve, Condrotec, Napratec, Naprosen, Naprosyn, Nycopren, Synflex	Non-reactive
Nicotine	Nicoderm, Nicorette, Nicotinell, Nicotrol, Niquitin	Non-reactive
Nifedipine	Adalat, Nifecard, Nifar, Niften, Procardia	Non-reactive
Nitrazepam	Mogadon, Somnite	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Norethindrone	BiNovum, Brevinor, Climagest, Climesse, Elleste Duet, Etracombi, Evorel, Kliofem, Kliovance, Loestrin, Micronor, Norlutin, Noriday, Norimin, Norinyl, Noristat, Nuvelle, Ovysmen, TriNovum, Trisquens, Utovian	Non-reactive
Noscapine	Narcotine	Non-reactive
d/l-Octopamine	No known trade names	Non-reactive
Olanzapine	Zyprexa	Non-reactive
Orphenadrine	Norflex, Norgesic, Disipil	Non-reactive
Oxazepam	Serax, Ox-pam	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Oxycodone	Oxycontin, Percodan, Roxicet	Positive for Oxycodone
Oxymetazoline	Afrin, Neo-synephrine	Non-reactive
Oxytetracycline	Terra-Cortil, Terramycin, Trimovate	Non-reactive
Paracetamol (Acetaminophen)	Fortagesic, Paradote	Non-reactive

Therapeutic dosages may not be detected in urine.

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Paracetamol (Acetaminophen)/Codeine Preparations	Tylenol 3, Co-codamol, Codafen, Co-dydramol, Kapake, Remedine, Solpadol, Tylex	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Paroxetine	Paxil, Seroxat	Non-reactive
Penicillin	Combicillin, Mefoxin	Non-reactive
Pentobarbital	Nembutal	Positive for Barbiturates (BAR)
Pericyazine	Amplan, Aolept, Apamin, Iryakin, Nemactil, Neulactil, Propetyl, Psycholept	Non-reactive
Phencyclidine	PCP	Potential cross reactants: Thioridazine, Chlorpromazine, Doxylamine, Lamotrigine
Phenobarbitone (see also Phenobarbital)	Luminal	Positive for Barbiturates (BAR)
Phenytoin	Dilantin, Epanutin, Epitard	Non-reactive
Phenobarbital	Donnatal	Positive for Barbiturates (BAR)
Pholcodine	Galenphol, Strong BP, Pavacol-D, Thebacon	Positive for Opiates (OPI, MOR/MOP) Potential cross reactants: Dihydrocodeine
Piperacillin	Pipracil, Tazobactam	Non-reactive
Prazepam	Centrax, Demetrin	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Prednisolone	Delta-cortef, Econopred, Inflamase, Pediapred, Prelone	Non-reactive
Procaine	Novocain	Non-reactive
Progesterol		Non-reactive
Promethazine	Allerfen, Anergan, Antinaus, Aprobit, Avomine, Baymethzine, Diprozin, Fenergan, Methazine, Phenergen	Non-reactive
Propranolol	Beta-Progane, Inderal, Inderetic, Inderex	Non-reactive
Pseudoephedrine	Afrinol, Sudafed, Tylenol Cold (combination)	Potential Positive for Amphetamine (AMP) and Methamphetamine (M-AMP)*
Ranitidine	Pylorid, Zantac	Potential Positive for Methamphetamine (M-AMP)*
Salbutamol	Aerocrom, Aerolin, Airomir, Asmasal, Combivent, Duovent, Ventide, Ventodisks, Venotlin, Volmax	Non-reactive
Secobarbital	Seconal	Positive for Barbiturates (BAR)
Sennosides	Senokot	Non-reactive
Sertraline	Zoloft	Potential Positive for Benzodiazepines (BZO)
Sodium Valproate	Depakene, Depakote, Epilim	Non-reactive
Temazepam	Restoril	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline

Therapeutic dosages may not be detected in urine.

* Urinary metabolite(s) only; parent compound is non-reactive

COMPOUND (Generic Name)	COMPOUND (Trade Name)	RESULTS/CROSS REACTANTS
Testosterone	Andropatch, Restandol, Sustanon, Virormone, slang name "anabolic steroids"	Non-reactive
Thioridazine Hydrochloride	Mellaril	Non-reactive
Thyroxine Sodium	Eltroxin	Non-reactive
Tramadol	Ultram, Tramake, Zamadol, Zydol	Non-reactive
Trazodone (Also known as Molipaxin)	Desyrel, Molipaxin, Trialodine	Non-reactive
Triazolam	Halcion	Positive for Benzodiazepines (BZO) Potential cross reactants: Oxaprozin (Daypro), Sertraline
Venlafaxine	Effexor, Effexor XL	Non-reactive
Warfarin Sodium	Coumadin, Marevan	Non-reactive

Therapeutic dosages may not be detected in urine.

List not all inclusive:
It is possible that other substances and/or factors not listed may interfere with the test and cause false results e.g. technical or procedural.

All positive results from onsite drug testing are presumptive and should be confirmed by an alternative method such as gas chromatography/mass spectrometry (GC/MS)

11 000 0136 REV6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.
INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Re: k061718
Trade/Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN
Dated: October 20, 2006
Received: October 23, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integarted Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ... X ... AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061718

NOV 13 2006

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K061718.

Submitter:

INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 16, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

Innovacon® Spectrum II Test Card
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Common Name:

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

Regulation Name:

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems.

Product Code:

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

Classification Number:

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100, 21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150, 21 CFR § 862.3910, 21 CFR § 862.3700

Device Classification:

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

Intended Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Description:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices:

The Innovacon® Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a "modified" product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

Previously Cleared ACON Drug of Abuse Test	510(k) Number	Product Code
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DIS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 4 2003

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: k031759
Trade/Device Name: ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ; DIO; DJC; DKZ; DJG; LCM; JXM; DJR; DIS; LFG
Dated: July 7, 2003
Received: July 11, 2003

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE:

510(k) Number: K031759

Device Name: ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)

Indications for Use: The ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with three types of Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine at the cutoff concentrations of:

50 ng/mL for Marijuana,
300 ng/mL for Cocaine,
1,000 ng/mL for Methamphetamine,
1,000 ng/mL for Amphetamine,
2,000 or 300 ng/mL for Opiates (OPI2000 or MOP300),
25 ng/mL for Phencyclidine,
300 ng/mL for Benzodiazepine,
300 ng/mL for Methadone,
300 ng/mL for Barbiturate,
1,000 ng/mL for Tricyclic Antidepressants, and
500 ng/mL for Methylenedioxymethamphetamine

These assay systems can only provide a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, especially when preliminary positive results are indicated.

They are only intended for healthcare professionals including professionals at point of care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of *In Vitro* Device Evaluation and Safety

Prescription Use ✓ Or over-the-counter Use_____

(Per 21 CFR 801.109)

Division Sign-Off For Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

K031759

AUG - 4 2003

SUMMARY OF 510(k)

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is **K031759**.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

July 28, 2003

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON Spectrum Multi-Drug Multi-Line Screen Test Card

ACON Spectrum Multi-Drug Multi-Line Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup)

Common Name:

Immunochromatographic test for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

Device Classification:

Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine test systems have been classified as Class II devices with moderate complexity.

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

Intended Use:

The ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with three types of Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup, and ACON 009 Cup or E-Z Split Key Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine.

These assay systems can only provide a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, especially when preliminary positive results are indicated.

They are only intended for healthcare professionals including professionals at point of care sites.

Description:

The ACON Spectrum Multi-Drug Multi-Line Screen Test Card and ACON Spectrum Multi-Drug Multi-Line Screen Test Card with Integrated Cups (ACON 006 Cup or RediCup, ACON 008 Cup or *i*Cup and ACON 009 Cup or E-Z Split Key Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine in human urine at the cutoff concentrations of:

50 ng/mL for Marijuana,
300 ng/mL for Cocaine,
1,000 ng/mL for Methamphetamine,
1,000 ng/mL for Amphetamine,
2,000 or 300 ng/mL for Opiates (OPI2000 or MOP300),
25 ng/mL for Phencyclidine,
300 ng/mL for Benzodiazepine,
300 ng/mL for Methadone,
300 ng/mL for Barbiturate,
1,000 ng/mL for Tricyclic Antidepressants,
and 500 ng/mL for Methylenedioxymethamphetamine.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, Barbiturate, Tricyclic Antidepressants and Methylenedioxymethamphetamine at the concentrations below the designated cut-off levels will generate a colored-line in the designated test region for the drug. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices

The ACON® Spectrum Multi-drug Multi-line Drug Screen Test Card (12-in-4) is a "combined" product format of the two previously cleared 6-in-2 ACON One Step Multi-drug Multi-line Drug Test Card. The test Cards in these 6-in-2 formats have up to six DOA tests on one or two Test Strips. These two legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

ACON DOA Test		K Number	Product Code
1. ACON One Step Multi-drug Multi-line Test Card & Test Device with drug calibrator and cutoff concentration used for each analyte listed		**K020313**	
COCAINE ((Benzoylecgonine)	300 ng/mL		DIO
AMPHETAMINE (Amphetamine)	1,000 ng/mL		DKZ
OPIATES (Morphine)	2,000 ng/mL		DJG
METHAMPHETAMINE (Methamphetamine)	1,000 ng/mL		LAF
MARIJUANA (Δ-11-nor-9-THC-9-COOH)	50 ng/mL		LDJ
Phencyclidine (PCP)	25 ng/mL		LCM
2. ACON One Step Multi-drug Multi-line Test Card & Test Device (II) with drug calibrator and cutoff concentration used for each analyte listed		**K023946**	
TRICYCLIC ANTIDEPRESSANTS (Nortriptyline)	1,000 ng/mL		DJC
MDMA (Methylenedioxymethamphetamine)	500 ng/mL		LFG
BENZODIAZEPINE (Oxazepam)	300 ng/mL		JXM
METHADONE (Methadone)	300 ng/mL		DJR
BARBITURATES (Secobarbital)	300 ng/mL		DIS
MORPHINE (Morphine)	300 ng/mL		DJG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

MAY 15 2002

Re: k020771
Trade/Device Names: ACON® One Step Drug Screen Test Card
ACON® One Step Drug Screen Test Card with Integrated Cup
Regulation Numbers: 21 CFR 862.3610; 21 CFR 862.3650; 21 CFR 862.3100; 21 CFR 862.3150; 21 CFR 862.3170; 21 CFR 862.3870; 21 CFR 862.3250; 21 CFR 862.3640; 21 CFR 862.3620
Regulation Names: Methamphetamine test system; Opiate test system; Amphetamine test system; Barbiturate test system; Benzodiazepine test system; Cannabinoid test system; Cocaine and cocaine metabolite test system; Morphine test system; Methadone test system
Regulatory Class: Class II
Product Codes: DJG; LCM; DKZ; DIS; JXM; LDJ; DIO; DPK; DJR
Dated: March 6, 2002
Received: March 8, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

MAY 15 2002

K020771

7. 510(k) SUMMARY

This 510 (k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K020771.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

March 4, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® One Step Drug Screen Test Card
ACON® One Step Drug Screen Test Card with Integrated Cup

Common Name:

Immunochromatographic test for the qualitative detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and barbiturate in human urine.

Device Classification:

The ACON One Step Drug Screen Test Card ACON and ACON One Step Drug Screen Test Card with Integrated Cup is similar to other FDA-cleared devices for the qualitative and simultaneous detection of drugs in urine specimens. These drug test devices are used only to provide a preliminary analytical result (21 CFR 862.3650). The test systems have been classified as Class II devices with moderate complexity. Product codes LDJ, DIO, LAF, DKZ, DJG, LCM, JXM, DJR, and DIS have been assigned for the test system.

Classification Name:

Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and barbiturate test systems

Intended Use:

The ACON One Step Drug Screen Test Card and ACON One Step Drug Screen Test Card with Integrated Cup are rapid chromatographic immunoassay devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine. The test is calibrated using analytes with their respective cutoff concentrations listed in the following table.

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Morphine (MOP 300 or OPI 300)	Morphine	300 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL

The configurations of the ACON One Step Multi-Drug Screen Test Card and ACON One Step Multi-Drug Screen Test Card with Integrated Cup come with any combination of the above listed drug analytes. They are intended for the healthcare professionals including professionals at point-of-care sites.

Description:

The ACON One Step Drug Screen Test card are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous screening of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine.

The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in urine. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing the drug concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been applied and membrane wicking has occurred.

10. INDICATIONS FOR USE

510(k) Number: K020771

Device Name: ACON One Step Drug Screen Test Card
ACON One Step Drug Screen Test Card with Integrated Cup

Indications for Use:

The ACON One Step Drug Screen Test Card and ACON One Step Drug Screen Test Card with Integrated Cup are rapid chromatographic immunoassay devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine. The test is calibrated against analytes with their respective cutoff concentrations listed in the following table.

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Morphine (MOP 300 or OPI 300)	Morphine	300 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL

The configurations of the ACON One Step Multi-Drug Screen Test Card and ACON One Step Multi-Drug Screen Test Card with Integrated Cup come with any combination of the above listed drug analytes. They are intended for the healthcare professionals including professionals at point-of-care sites.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020771

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or over-the-counter Use _____

(Per 21 CFR 801.109)

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k060761

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Qualitative

E. Applicant:

Akers Biosciences Inc.

F. Proprietary and Established Names:

BreathScan Alcohol Detectors (0.02, 0.04, 0.05 and 0.08% BAC)

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.3050, Breath-alcohol test system

2. Classification:

   Class I, reserved

3. Product code:

   DJZ

4. Panel:

   Toxicology, 91

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The BreathScan Alcohol Detector is an in vitro medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available at several detection cut-offs including 0.02, 0.04, 0.05 and 0.08 percent breath alcohol. The device is used only as a screening device and is only indication of the possible presence of alcohol in the blood of the test subject.

3. Special conditions for use statement(s):

   For Over-the-counter use.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The BreathScan Alcohol Detector is a qualitative visually read single-use device. The device contains yellow crystals inside a 2-part glass vessel, which is housed inside a plastic tube. One end of the plastic tube is open for sample collection and immediate testing of human breath for alcohol. The device is available at four different detection levels (0.02, 0.04, 0.05 and 0.08% BAC).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Connectables Alcohol Tester, Connectables, LLC

2. Predicate 510(k) number(s):

   k052448

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Detect the presence of alcohol in the human breath.	Detect the presence of alcohol in the human breath.
Target Populations	Over the Counter	Over the Counter
Calibration/Accuracy Checks	None required	None required
Anatomical Site	Mouth	Mouth
Test Sample	Human breath	Human breath

Differences		
Item	Device	Predicate
Result	Qualitative	Semi-Quantitative
Interpretation	Visual Color Change	Red, Yellow, and Green LEDs
Instrument system	None	Semiconductor-Oxide Sensor
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08%	Upper limit undefined – any concentration greater than 0.04% will produce red light

K. Standard/Guidance Document Referenced (if applicable):

Department of Transportation/ National Highway Traffic Safety Administration [NHTSA Docket No. 94-004; Notice 2] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids

L. Test Principle:

The BreathScan Alcohol Detector contains chemicals that change color in the presence of alcohol in human breath. The detector is squeezed to break the glass vessel which contains the chemically coated yellow crystals. The user blows into the open end of the plastic tube allowing the breath to come in contact with the yellow crystals. A color change from yellow to blue-green will occur if the alcohol in the breath is at or above the detection limit of the device.

M. Performance Characteristics (if/when applicable):

The BreathScan Alcohol Detector was not eligible for testing by the National Highway Traffic Safety Administration (NHTSA) (Department of Transportation (DOT)). The sponsor performed DOT-like testing using the guidelines found in the August 1994 NHTSA/DOT Model Specifications for Alcohol Screening Devices.

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor performed precision and accuracy testing for each of the four BreathScan Alcohol Detectors (.02, .04, .05 and .08 BAC) using a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate and air composition.

Testing was performed by 43 individuals under five different lighting sources using sixty randomized pre-reacted detectors. The concentrations used were 20 detectors at 0% BAC, 20 at 60% below the cut-off concentration and 20 at 60% above the cut-off concentration. The table below describes the number of devices that resulted in the expected outcome (positive or negative) of the number of devices evaluated.

	Concentration	.02	.04	.05	.08
Fluorescent	0%	200/200	**239/240**	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Daylight	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Incandescent	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	**239/240**	220/220	200/200
Sodium Vapor	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	**239/240**	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Mercury Vapor	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	**238/240**	220/220	200/200
% Agreement		100/100	99.9/99.6	100/100	100/100

b. *Linearity/assay reportable range:*

Not applicable. The assay is a qualitative assay.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The device is traceable to a commercially available certified alcohol reference solution. These solutions are used to verify the cut-off concentration of the devices during manufacture.

d. *Detection limit:*

The NHTSA guidelines do not specifically address the detection limit of breath alcohol devices but require testing at a %BAC of zero (blank reading) to assess the possibility of false positives. The sponsor included a zero concentration samples in their precision study above. Non-alcoholic human breath was used as the sample. All of the devices tested except for the .04 detector under Fluorescent lighting, did not produced a false positive when measuring zero concentration samples. The .04 detector showed one false positive result when read under a Fluorescent light.

e. *Analytical specificity:*

The sponsor performed the following studies for each cut-off concentration (0.02, 0.04, 0.05 and 0.08% BAC) to evaluate the potential interference on the test results from cigarette smoke, temperature and vibration.

Cigarette smoke – An alcohol-free volunteer was asked to smoke approximately one half of a cigarette. The volunteer then performed a breath alcohol reading. The volunteer then smoked another inhalation and repeated test to produce a total of five trials for each cut-off concentration. The BreathScan Alcohol Detector produced no false positives results under these conditions.

Temperature – The sponsor assessed the effect of temperature at 10 and at 40 °C. A total of forty different devices were stored at each temperature for each cut-off concentration. Using simulated breath (BASS) twenty samples that were 60% below the device cut-off and twenty samples were 60% above the cut-off were tested. The results are presented in the table below:

Cut-off	Breath Scan Results			
	10 °C		40 °C	
	60% below Cut-off	60% above Cut-off	60% below Cut-off	60% above Cut-off
.02	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.04	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.05	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.08	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive

Vibration - A total of forty different devices were mounted on a shaketable or rocker for each cut-off concentration for 5 minutes. Using simulated breath (BASS) twenty samples that were 60% below the device cut-off and twenty samples were 60% above the cut-off were tested. The results are presented in the table below:

Cut-off	BreathScan Results	
	60% below Cut-off	60% above Cut-off
.02	20/20 Negative	20/20 Positive

.04	20/20 Negative	20/20 Positive
.05	20/20 Negative	20/20 Positive
.08	20/20 Negative	20/20 Positive

f. Assay cut-off:

Each device will produce a blue-green color at or above the following cut-off concentration, .02, .04, .05 and .08 %BAC.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing the BreathScan Alcohol Detector .04% BAC to a quantitative comparator device device. The purpose of the study was to determine if consumers could correctly perform and interpret the test according to the package insert. There were 24 paired volunteers (drinker, non-drinker). The reported age range of the volunteers was from below 30 to 60 years of age. There were 18 males and 30 females who participated in the trail. The non-drinker administered the test to the drinker and then read the results. The drinker then provided another breath sample, which was analyzed using the quantitative device operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.00% to 0.144% by the predicate device.

Ninety-three breath alcohol tests were performed and the results are in the table below:

BreathScan .04% Tester Result	Quantitative Results			
	Less than 60% below the Cut-off (<0.016%)	Near Cut-Off Negative (0.016 to 0.040%)	Near Cut-off Positive (>0.040 to 0.064%)	High Positive (>0.064%)
Positive	0	0	15	10
Negative	37	25	5	1

After the study, participants completed a questionnaire about the ease of use of the device:

Question	Strongly Disagree	Disagree	Don't Know	Agree	Strongly Agree
The BreathScan Instructions are easy to understand	0	0	0	9	15
The BreathScan Instructions are not	0	0	0	10	14

difficult to follow					
It is easy to see and understand the BreathScan test results	0	0	3	1	11

b. Matrix comparison:

Not applicable. This device is for one sample matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

For this type of device, alcohol should not be detectable in the breath of persons who have not ingested alcohol by this device.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Curriculum Vitae

Richard R. Wilber, M.D.

ADDRESS: Department of Pathology
1165 Montgomery Drive
Message Station 2W10
Santa Rosa, California 95405
E-mail: richard_wilber@msn.com

RESIDENCE: 1031 McDonald Place
Santa Rosa, California 95404

BIRTHDATE: June 23, 1949

BIRTHPLACE: Chicago, Illinois

UNDERGRADUATE EDUCATION: University of California, Santa Barbara
B.A., Biology, 1971

MEDICAL SCHOOL EDUCATION: University of California, San Francisco
School of Medicine, M.D., 1975

POSTGRADUATE MEDICAL EDUCATION: Department of Radiology, 1975-1976
Intern in Pathology, 1976-1977
Resident in Anatomic Pathology, 1977-1979
Resident in Laboratory Medicine, 1979-1981

PROFESSIONAL CERTIFICATION/ LICENSURE: Diplomat, National Board of Medical Examiners, 1977
California Medical License No.: G34845 (Issued 07/1977)
Drug Enforcement Agency Registration No.: AW7694688
Diplomat, American Board of Pathology,
Anatomic and Clinical Pathology, 1981

ACADEMIC AND PROFESSIONAL APPOINTMENTS:

Pathologist, Santa Rosa Memorial Hospital and Santa Rosa General Hospital, Santa Rosa, CA 1981-1984

Pathologist, Diagnostic Pathology Medical Group, Inc Sacramento, CA 1984-2000

Pathologist, Sutter Medical Center, Sacramento Sacramento, CA 1984-2000

Director, Electron Microscopy Laboratory, Sutter Memorial Hospital Sacramento, CA 1984-1995

Associate Medical Director, Sutter Memorial Hospital Clinical Laboratory Sacramento, CA 1984-1986

Medical Director, Sutter Memorial Hospital Clinical Laboratory Sacramento, CA 1986-2000

Chief, Department of Laboratory Medicine Sutter Medical Center Sacramento, CA 1988-1991

President, Diagnostic Pathology Medical Group, Inc. Sacramento, CA 1989, 1990, 1997, 1999

Secretary-Treasurer, Medical Staff, Sutter Medical Center Sacramento, CA 1996-1997

Vice Chief, Medical Staff, Sutter Medical Center Sacramento, CA 1998-1999

Chief of Medical Staff, Sutter Medical Center Sacramento, CA 2000

Medical Director, Santa Rosa Memorial Hospital Clinical Laboratory 11/2000 to Present

CURRICULUM VITAE
Mark James DeMeo, M.D.

February 6, 2001

ADDRESS:

Home	5720 Bennett Valley Road Santa Rosa, California 95404
Business	1165 Montgomery Drive Santa Rosa, CA 95402

DATE OF BIRTH: January 9, 1941

PLACE OF BIRTH: Santa Rosa, California

EDUCATION:

Undergraduate	Santa Rosa Junior College Santa Rosa, California Graduated 1960
	University of California Davis, California Graduated 1961
Medical School	Creighton University Omaha, Nebraska Graduated 1965
Internship	Creighton University St. Joseph's Hospital Omaha, Nebraska 1965 – 1966
Residency	Anatomical and Clinical Pathology Creighton University St. Joseph's Hospital Omaha, Nebraska 1966 – 1967
	University of California San Francisco, California 1967 – 1969

BOARD CERTIFICATION:

American Board of Pathology-
Anatomic and Clinical Pathology, 1981

AWARDS AND HONORARY SOCIETIES:

Squires Honorary Men's Organization, UCSB, 1968
Phi Beta Kappa, UCSF, 1971
Graduation with Highest Honors, UCSB, 1971
Regents Scholar, UCSF, 1971-1975
Alpha Omega Alpha, UCSF, 1974
Member, Medical School Admissions Committee,
UCSF, 1974-1977

PROFESSIONAL ORGANIZATIONS:

College of American Pathologists (Fellow)
Medical Community Relations Committee, 1985-1991
Spokesperson Program, 1986-Present
Public Communications Committee, 1991-1994
American Society of Clinical Pathologists

MEDICAL STAFF COMMITTEES:

Admissions Committee,
School of Medicine, UCSF, 1974-1977
Quality Assurance Committee (Chair)
Santa Rosa General Hospital, Santa Rosa, CA 1983-1984
Infection Control Committee (Chair)
Sutter Medical Center, Sacramento, CA 1990-1996
Transfusion Committee
Sutter Medical Center, Sacramento, CA 1985-1989
Sutter Research Foundation Review Committee
Sutter Medical Center, Sacramento, CA 1987-2000
Cardiac Transplant Task Force
Sutter Medical Center, Sacramento, CA 1987-1989
Medical Executive Committee
Sutter Medical Center, Sacramento, CA 1988-1991, 1992-2000
Credentials Committee (Chair)
Sutter Medical Center, Sacramento, CA 1993-1996

PUBLICATIONS:

Wilber, R.R., King, E.B., and Howes, E.: "Cerebrospinal Fluid Cytology in Five Patients with Cerebral Cysticercosis," ACTA Cytologica 24 (5): 421-426, 1980

Stephens, J.D., Golbus, M.S., Miller, T.R., Wilber, R.R., and Epstein, C.J.: "Multiple Congenital Anomalies in a Fetus Exposed to 5-Fluorouracil During the First Trimester," Amer. J. Obs Gyn., 137 (6): 747-749, 1980

SPECIALTY CERTIFICATION:

Anatomic Pathology	1970
Clinical Pathology	1970
Dermatopathology	1981
Hematology and Coagulation	1983
Immunohematology (Blood Banking)	1984

HOSPITAL APPOINTMENTS:

Santa Rosa Memorial Hospital, Santa Rosa, California
Director of Anatomic and Clinical Laboratories
1970 to 2000

Santa Rosa Memorial Hospital, Santa Rosa, California
Staff Pathologist
1975 to Present

Santa Rosa Memorial Hospital, Santa Rosa, California
Director of Physician Medical Education
1975 to Present

Santa Rosa Memorial Hospital, Santa Rosa, California
Director of Quality Assurance
1981 to 1988

Santa Rosa Memorial Hospital, Santa Rosa, California
Chairman of Transfusion and Surgical Care Review Committee
1991 to 2000

PERSONAL APPOINTMENTS:

Medical Director, Blood Bank of the Redwoods, Santa Rosa, California
Serving Mendocino, Lake and Sonoma Counties
1981 to 1986

College of American Pathologists
Inspector for Laboratories
1980 to Present

Advisory Board for the California Tumor Tissue Registry, Loma Linda University
1994 to Present

PERSONAL APPOINTMENTS, CONTINUED:

Advisory Board, Blood Bank of the Redwoods, Santa Rosa, California
1996 to Present

Medical Doctor, Redwood Toxicology Laboratory
1997 to Present

HONORS:

Alpha Omega Alpha, Honor Medical Society

Graduated number one in Medical School Class of 1965

Sonoma County Medical Society
Outstanding Contribution to Sonoma County Medicine, 1999

LIST OF PROFESSIONAL ORGANIZATIONS:

American Society of Clinical Pathologists (Fellow)
College of American Pathologists (Fellow)
American Society of Dermatopathology (Fellow)
California Academy of Medicine
California Society of Pathologists
Alpha Omega Alpha, Medical Honor Society
California Medical Society
Sonoma County Medical Society

LICENSURE:

State of California, G01288, 1999 to Present

Drug Enforcement Registration No. AD1330339

PUBLICATIONS AND PRESENTATIONS:

Mark J, DeMeo, M.D., et al: Primary Hyperparathyroidism
Western Journal of Medicine 114:52-55, 1971

Numerous Grand Rounds, presentations on hematology, oncology, clinical pathology, coagulation, transfusion therapy, hepatitis, etc.

Wayne B. Ross

CURRICULUM VITAE

EDUCATION:

M.C.L.S. University of California at San Francisco, San Francisco, CA.
MASTER'S IN CLINICAL LABORATORY SCIENCE – Concentrations: Clinical Chemistry and Analytical Toxicology, April 1986.

B.S. California State Polytechnic Univ., San Luis Obispo, CA.
BIOLOGICAL SCIENCE – Medical Laboratory Technology, June 1973

PROFESSIONAL EXPERIENCE:

CHIEF TOXICLOGIST: Redwood Toxicology Laboratory, Santa Rosa, CA. ; 07/94 – Present.
Responsible for planning, organizing, supervising, and coordinating the personnel, methods, and procedures for a high volume urine drug testing laboratory. Duties include maintaining the technical SOP, certifying ongoing compliance to regulations as mandated by the California Dept. of Health (Title 17) and Dept. of Health and Human Services (Health Care Financing Administration) CLIA '88 regulations, evaluate and validate all laboratory methods, and direct GC/MS Dept.. Duties also include reviewing and certifying all analytical results for reporting purposes.

Additional responsibilities include consulting with and interpreting data for many criminal justice agencies such as District Attorney's, County Counsel, Public Defender's, Sheriff and Police Departments, U.S. Attorney's Office, and Parole and Probation Departments. Also provide technical support to drug rehabilitation centers, methadone maintenance clinics, child protective services, etc.

Testified and qualified as an expert witness many hundreds of times in Superior, Municipal, and Juvenile Courts throughout California and several other states, as well as Federal Court -- specifically in regard to interpretation and explanation of forensic and clinical toxicological analytical methods and data.

SUPERVISING CLINICAL TECHNOLOGIST / CHIEF TOXICOLOGIST: Redwood Medical Laboratory Santa Rosa, CA.; 06/76 – 07/94.

Responsibilities included ensuring compliance to all local, state and federal regulations; maintenance of quality control and quality assurance; manage and perform testing in all areas of clinical laboratory including: Therapeutic Drug Monitoring and Toxicology, RIA, Clinical and Special Chemistry, Hematology, Blood Banking and Serology, Microbiology, Parasitology, Coagulation, etc.

In addition performed technical development and management of all aspects of a national drugs of abuse testing program to include: method development, quality assurance and quality control, performance of initial and confirmatory testing, and provide expert witness testimony.

CHIEF TECHNOLOGIST: Physician Office Clinical Laboratory, Santa Rosa, CA.; 06/75 – 06/76

Managed clinical laboratory for hematology / oncology group practice.

GENERAL TECHNOLOGIST / TOXICOLOGIST: Central Pathology Laboratory, Santa Rosa, CA. 08/74 – 06/75

Completed one year traineeship for licensure as a State of California Clinical Laboratory Scientist. Training heavily emphasized clinical and forensic toxicology.

CERTIFICATIONS / LICENSE:

Fellow of the National Academy of Clinical Biochemistry
Diplomate of the American Board of Forensic Examiners
California State License - Clinical Laboratory Scientist - License # MTA22178
American Association of Bioanalysts Board of Registry – Medical Technologist
Department of Health and Human Services, Health Care Financing Administration, CLIA 88 – Qualified as a Clinical Laboratory Technical Consultant, Technical Supervisor, and General Laboratory Supervisor.

PROFESSIONAL ASSOCIATIONS:

American Association of Clinical Chemistry
American Academy of Forensic Sciences
Society of Forensic Toxicologists
American Association of Bioanalysts
California Association of Toxicologists
American College of Forensic Examiners
California Narcotic Officer's Association

CONTINUING EDUCATION / PROFESSIONAL MEETINGS

Society of Forensic Toxicologist's / The International Association of Forensic Toxicologist's Joint Annual Meeting; Washington D.C.; 23 CEU's; (9/04)
American Academy of Forensic Sciences Annual Meeting; Dallas, TX; (2/2004)
Society of Forensic Toxicologist's Annual Meeting; Portland, OR; 23.25 CEU's; (10/03)
California Association of Toxicologist's Workshop & Quarterly Meeting; Santa Rosa, CA; 12 CEU's (8/03)
California Association of Toxicologist's Quarterly Meeting; Oakland, CA; 5.5 CEU's (2/2003)
Society of Forensic Toxicologist's Annual Meeting; Dearborn, MI. (10/2002)
California Association of Toxicologist's Quarterly Meeting; San Jose, CA ; 6.5 CEU's (8/2002)
Society of Forensic Toxicologist's Annual Meeting; New Orleans, LA; 15.5 CEU's (10/2001)
California Association of Toxicologist's Quarterly Meeting; Berkeley, CA; 4.5 CEU's (8/2001) – Co-Host
American Academy of Forensic Sciences Annual Meeting; Seattle, WA; 23.25 CEU's (2/2001)
California Association of Toxicologist's Quarterly Meeting; South San Francisco, CA; 6 CEU's (2/2001)
American Association for Clinical Chemistry (TDM & Toxicology); 18 CEU's (2000)
Society of Forensic Toxicologist's Annual Meeting; Milwaukee, WI (10/2000)
American Academy of Forensic Sciences Annual Meeting; Reno, NV (2/2000)
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1999)
AACC Laboratory Automation Conference; Philadelphia. PA ,14 CEU's (11/99)
American Academy of Forensic Sciences Annual Meeting; Orlando, FL (2/99)
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1998)
California Association of Toxicologist's Quarterly Meeting; San Francisco, CA (2/98)
American Academy of Forensic Sciences Annual Meeting; San Francisco, CA (2/98)
American Association for Clinical Chemistry (TDM & Toxicology); 22 CEU's (1997)
Society of Forensic Toxicologist's Annual Meeting; Salt Lake City, UT (10/97)
California Association of Toxicologist's Quarterly Meeting; San Jose, CA (8/97)
California Association of Toxicologist's Quarterly Meeting; Oakland, CA (2/97)
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1996)
California Association of Toxicologist's Quarterly Meeting; South San Francisco, CA (11/96)
Society of Forensic Toxicologist's Annual Meeting; Denver, CO. (10/96)
California Association of Toxicologist's Quarterly Meeting; North Lake Tahoe, CA (5/96).
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1995)
Society of Forensic Toxicologist's Annual Meeting; Baltimore, MD. (10/95)
California Association of Toxicologist's Quarterly Meeting; Napa, CA (8/95).
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1994)
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1993)

SOCIETY SPONSERED COURSES:

FBI Laboratory Symposium on Forensic Toxicology, Society of Forensic Toxicologists and The International Association of Forensic Toxicologists, FBI and DOJ.
"Ephedrine: Drug or Supplement", American Academy of Forensic Sciences.
"Application of the Principles of Pharmacology and Pharmacokinetics ...", American Academy of Forensic Sciences.
"Tryptamines and Other Psychotropic Substances...", American Academy of Forensic Sciences.
"Practical Applications for LCMS in Routine Toxicology Testing", Society of Forensic Toxicologists.
"Toxicology in the Emergency Room", Society of Forensic Toxicologists.
"Developments in Regulated Drug Testing", Society of Forensic Toxicologists.
"Principles of Sample Preparation", Society of Forensic Toxicologists.
"Club Drugs & Drug-Facilitated Sexual Assault", Society of Forensic Toxicologists.
"DUID – From Research to the Courts", Society of Forensic Toxicologists.
"Urine Testing and Human Performance", Society of Forensic Toxicologists.
"Clinical Toxicology", Society of Forensic Toxicologists.
"Adulterant Testing", Society of Forensic Toxicologists.
"Advances in Toxicological Investigation of Drug-Facilitated Sexual Assault", American Academy of Forensic Sciences.
"AAFS Toxicology Section Drugs and Driving Committee", American Academy of Forensic Sciences.
"Ethical Problems Facing the Expert Witness", American Academy of Forensic Sciences.
"The Agony of Ecstasy", American Academy of Forensic Sciences.
"Benzodiazepines: Pharmacology & Analytical Challenges", Society of Forensic Toxicologists.
"Marijuana Forensic Symposium", Society of Forensic Toxicologists.
"Forensic Toxicology of Opiate Alkaloids and Synthetic Analgesics", American Academy of Forensic Sciences
"Pharmacology and Toxicology of Buprenorphine", American Academy of Forensic Sciences
"Presenting Scientific Evidence in Court: Meeting the Daubert Standard for Reliability", American Academy of Forensic Sciences
"How To Be a Better Expert Witness", American Academy of Forensic
"Marijuana: A Forensic Symposium", American Academy of Forensic Sciences
"The Effects of Alcohol and Drugs on Human Performance and Behavior", American Academy of Forensic Sciences .
"Methamphetamine: Synthesis, Pharmacology, Analysis, and Toxicology", American Academy of Forensic Sciences .
"Laboratory Accreditation: Exploring the Alternatives", American Academy of Forensic Sciences .
"Forensic Expert Witness Court Testimony", American Academy of Forensic Sciences .
"Fundamentals of Alcohol Testing and Interpretation", Society of Forensic Toxicologists
"Automated Sample Preparation for Chromatographic and Mass Spectra Analysis", Society of Forensic Toxicologists
"Forensic Applications of LC/MS", Society of Forensic Toxicologists.
"Capillary Chromatography", Society of Forensic Toxicologists
"New Concepts in Forensic Urine Drug Testing", Society of Forensic Toxicologists.
"Use of LIMS ia a Forensic Laboratory", Society of Forensic Toxicologists.
"Workshop on Stimulant Induced Impairment", California Association of Toxicologists
"Drugs and Driving: Current Pharmacologic Issues", Society of Forensic Toxicologists
"Current Issues in Regulated Urine Drug Testing", Society of Forensic Toxicologists.
"Fundamentals of Forensic Toxicology: A Basic Course", Society of Forensic Toxicologists

PUBLICATIONS:

Ross, W.B., "Specimen Collection for Drugs of Abuse Testing", Treatment Centers Magazine, 1992.
Meeker, J.E., Mount, A.M., and Ross, W.B., "Detection of Drug Abuse by Health Professionals", Occupational Health and Safety, 2002

AWARDS:

Clinical Chemist Recognition Award – 2004: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry.

Victor Uralets, Ph.D.

Victor P. Uralets is currently a Director of Sports Testing at Redwood Toxicology Laboratory in Santa Rosa, California, Forensic drug testing laboratory.

Dr. Uralets received his B.S. degree in Chemistry from Moscow State University, Russia, and a Doctorate Degree (Ph.D.) in Organic Chemistry from The Institute of Organoelement Compounds of the Academy of Sciences of the USSR. He completed a Post Doctoral Fellowship in Analytical Instrumental Analysis at the Eindhoven Technical University in the Netherlands in 1978.

Following graduation from the Moscow University, Dr. Uralets was engaged in a project on synthetic food as a research scientist in the Institute of Organoelement compounds and was particularly focused on detection and identification of volatile food flavor components using various chromatographic techniques.

Since 1980 Dr. Uralets has held positions as a Senior Analyst and Scientific Director of the Olympic Anti-Doping Center in Moscow, which provided a full range of athletic drug testing mandated by the International Olympic Committee (IOC). The Anti-Doping Center in Moscow is one of the first five laboratories originally accredited by the International Olympic Committee. Dr. Uralets participated in the development of analytical testing methods for steroids, stimulants and other pharmacological classes of drugs banned in sports. He was engaged in the international IOC activity, including collaborative work between the Soviet and the US (UCLA) Olympic laboratories during 1986-1992.

Since 1992 Dr. Uralets was a Director of Sports Testing in San Diego, CA, laboratory for Nichols Institute and its successor companies: Corning Clinical Laboratories and Quest Diagnostics Incorporated. He helped to develop the laboratory to the level of International standards and obtain CAP (College of American Pathologists) accreditation for Athletic Drug Testing (ADT). Since February 2003, Dr. Uralets was a Technical Director in the Las Vegas Quest Diagnostics laboratory.

He has published over 60 papers in the peer review scientific journals. He is a member of the California Association of Toxicologists and The International Association of Toxicologists. He is a Certified Toxicological Chemist by The National Registry of Certified Chemists.

CURRICULUM VITAE (Brief)

LAURA ADAMS, D.V.M., C.L.S., MT(ASCP)

EDUCATION

D.V.M. Doctor of Veterinary Medicine, University of California, Davis. June 1995.

B.A. Biological Sciences, University of California, Davis. June 1972.

Kaiser Foundation Hospital, San Francisco, CA. Medical Technologist Internship, completed July 1973.

MEMBERSHIP

California Association of Toxicologists
Phi Zeta Lambda (Veterinary Honor Society)
California Veterinary Medical Association
American Veterinary Medical Association

LICENSURE

State of California, Clinical Laboratory Scientist, MTA 20616, 1973 to present.

State of California, Veterinarian, 12344, 1995 to present.

American Society of Clinical Pathologists, MT-89351, 1973 to present.

RELATED EMPLOYMENT

3/1/01 – Present **Redwood Toxicology Laboratory**
General Laboratory Supervisor / Laboratory Manager. Duties include monitoring quality assurance and quality control, updating procedure manuals, personnel management, monitoring personnel competence.

1996 – 3/1/01 **Redwood Toxicology Laboratory**
Weekend Supervisor, QA/QC, Health and Safety Director, Compliance Officer, Hitachi 717 Supervisor/Testing Personnel. Duties included monitoring quality assurance and quality control, updating procedure manuals, directing the Health and Safety program, performing screening and confirmation procedures, personnel management of the Hitachi department.

1990 – 1994 **Redwood Medical Laboratory**
Bench technologist – worked in all areas of the laboratory.

1975 – 1990 **Warrack Medical Center Hospital**
Laboratory Manager/Chief Technologist. Managed and performed testing in all departments of the clinical laboratory; maintained quality assurance and quality control programs, supervised laboratory employees, developed an outpatient laboratory clientele. Obtained certification by the College of American Pathologists (CAP).

1973 – 1975 **Warrack Medical Center Hospital**
Bench technologist – worked in all areas of the laboratory.

Suzanne M. Bertolucci

819 Stellar Lane
Windsor, California 95492
H: (707) 838-8361

OBJECTIVE: A challenging position in an innovative, goal oriented, flexibly structured sales environment.

BACKGROUND: Sales and marketing, account/customer service relationship management, staff management and mentoring.

QUALIFICATIONS: Excellent sales and interpersonal skills, extraordinary organizational skills, ability to multi-task; over seventeen years management experience in fast-paced, high volume sales and international business environments.

EMPLOYMENT:

Redwood Toxicology Laboratory, Inc./Redwood Biotech, Inc.

1994 – Present **Director of Sales**

- Built sales organization from ground zero, conceptualizing and realizing a strategic nationwide sales plan that currently generates over $30 million in combined sales per year for two separate corporations.
- Manages in-house sales department of ten employees that sustains strong revenue gains and customer-base growth, despite fierce competition.
- Recruits and manages business relationships with sales-related distribution network and application partners.
- Cultivates relationships with customer-base of over 16,000 accounts in the drug testing industry and responds to customer needs.
- Works strategically to understand and respond to competitive market conditions, product developments and industry trends.
- Develops and implements marketing programs, including fax, email and direct mail campaigns, conferences and advertisements.
- Strong working knowledge of competitors' sales and marketing efforts.

BA Cheque Corporation, San Francisco, CA

1982 – 1993 **Division Manager, EMEA-Australasia Division, Global Seller Service**
Responsible for all aspects of account maintenance for over 7,000 selling relationships in Europe, Japan and the Australasia regions, representing over $1 billion in annual sales. Overall duties included; system development, audit and compliance, productivity management, quality assurance, staff management of 10 employees. Major point of contact for customers, field sales representatives, marketing, off shore operations and service centers. Frequently used creative responses to time-critical and complex international business and political developments.

1974 – 1982 **Account Officer, Australasia-Japan Division, Global Seller Service**
Managed a staff of eight employees responsible for inventory management, remittance and accounting resolution, accounts receivable management and administration of credit limits for over 4,000 customers. Communicated closely with field sales and service representatives to ensure high quality customer service. Performed a wide array of special projects and assignments as requested.

SELECTED ACHIEVEMENTS: Trained operations customer service support staff in Sydney, Australia Operations Center. Established procedures, and restructured job junctions while on site.

Mary A. Tardel
122 Talbot Avenue
Santa Rosa, CA 95404
(707) 548-8774 - mobile
mary_tardel@hotmail.com

EXPERIENCE:

Redwood Toxicology Laboratory, Inc., Santa Rosa, California
December 2001 – Present
Bid & Contract Specialist

- Write and create bid response packages to all applicable federal, state and county Requests for Proposals
- Set-up and maintain customer accounts that result from successful bidding
- Maintain contracts and compliance with contract terms including quarterly reports and pricing structure
- Create(d) and maintain a comprehensive peer data matrix, including information on pricing, technology and products
- Write and review content for marketing materials, including; corporate overview, website and product literature
- Ensure consistency and accuracy of all sales correspondence and materials distribution to prospects
- Coordinate sales team training and education on technical product specifications and sales protocol
- Track marketing projects, response rates and success of corresponding sales effort
- Manage a staff of three administrative assistants to efficiently execute sales representative requests
- Coordinate blast faxes, product launches and regional sales and marketing efforts

TrueTime, Inc., Santa Rosa, California
February 2000 – June 2001
Investor Relations Manager

- Developed Investor Relations Department immediately following IPO, including; corporate disclosure policy, internal communications policy, contact database, website, financial publications and corporate presentations
- Worked directly with CEO and CFO to develop Investor Relations strategies and messaging
- Primary contact to the investment community, managed analyst meetings, conference calls and shareholder meetings
- Worked with public relations consultants and marketing department to develop corporate communications strategy
- Responsible for preparing, editing, and distributing all corporate and financial press releases, quarterly reports to shareholders, SEC filings and annual report
- Managed budget and support vendors, including; wire services, conference call providers, designers, printers and mail house
- Supported CEO in development of corporate materials, employee communications, conference calls scripts and positioning Q&A, event planning and correspondence with the Board of Directors
- Tracked press releases, media coverage, analyst reports, stock and peer activity

Kalt Rosen & Co. LLC, San Francisco, California
September 1998 – February 2000
Investor Relations Senior Associate

- Managed multiple accounts simultaneously, including; semiconductor, internet and telecommunications companies
- Wrote and updated corporate fact sheets, press releases, newsletters and website content for multiple clients
- Reviewed management presentations and aided in the development of key messaging
- Arranged client conference calls and assisted in the writing of conference call scripts and positioning Q&A
- Developed content and oversaw the design and development of the Kalt Rosen & Co., LLC website

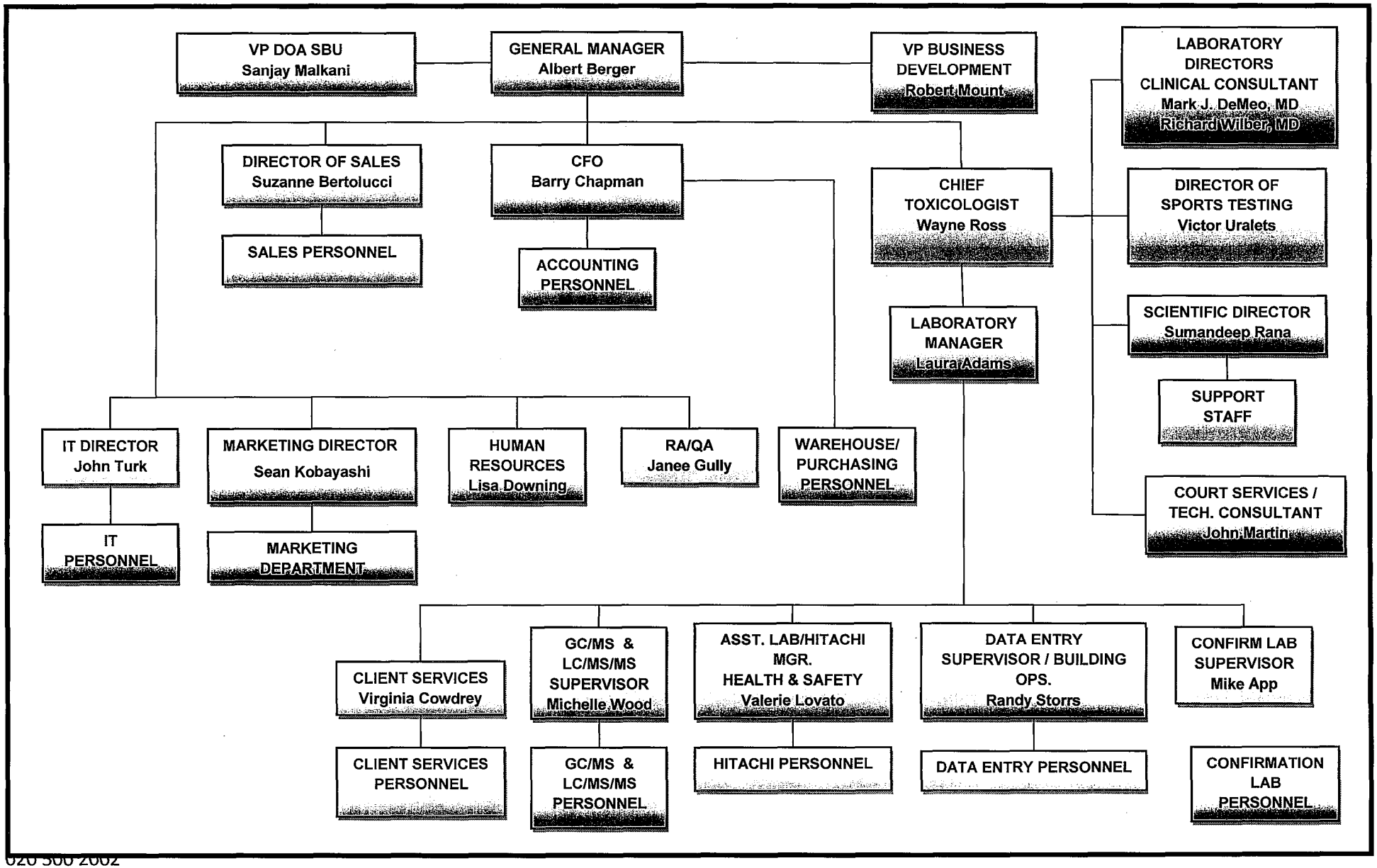
Applied Materials, Santa Clara, California
December 1995 - August 1998
Investor Relations Associate

- Coordinated Investor Relations events including analyst meetings, bus tours and conferences
- Tracked daily stock activity, industry press releases, competitor activity and analyst reports
- Compiled financial schedules and institutional shareholder activity for use by company executives
- Assisted in writing, editing and distributing financial press releases
- Assisted in the production of quarterly earnings conference call scripts quarterly Investor Relations book
- Maintained the Investor Relations external website, research library and communications database

EDUCATION:

Santa Clara University, Bachelor of Arts, Communication, Journalism emphasis, 1997
Activities: Contributor, Santa Clara University Newspaper

REDWOOD TOXICOLOGY LABORATORY	STANDARD OPERATING PROCEDURE	Document #: 020 500 2002	Revision #: 1
Title: **REDWOOD TOXICOLOGY LABORATORY ORGANIZATION CHART**		Approved:	Date



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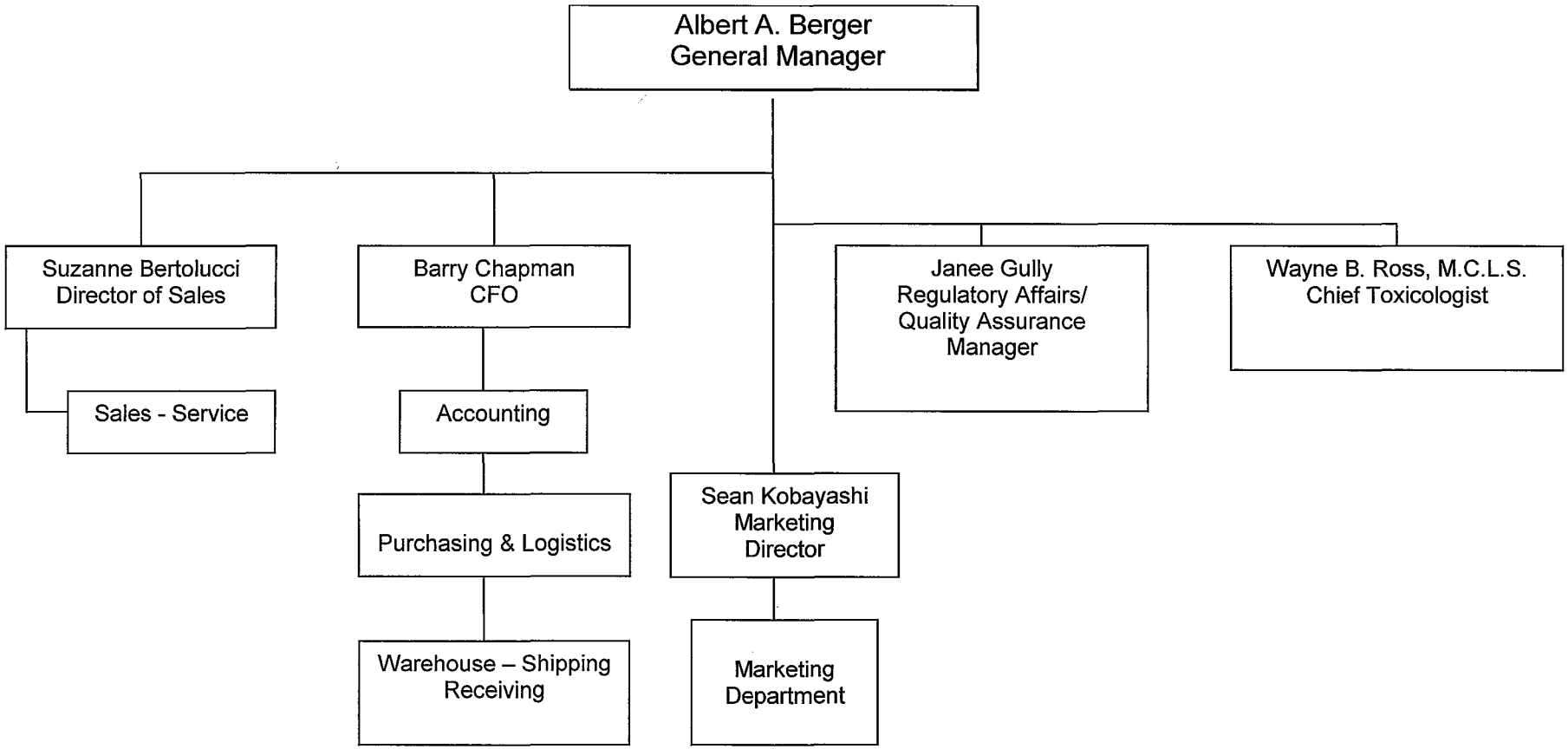

PRICING PAGE

RFP No. OSCA 11-029-00
Product Name: Drug/Alcohol Testing Equipment & Services
Firm Fixed Price per each unit: Pricing provided below next to each line item.

Redwood Toxicology Laboratory, Inc.

LABORATORY-BASED URINE DRUG TESTING AND CONFIRMATION

Urine Lab Tests

Single Drug Test with Lab Panel - Urine	$1.00 firm, fixed price per specimen
Five Drug Lab Panel - Urine	$3.25 firm, fixed price per specimen
Eight Drug Lab Panel - Urine	$3.75 firm, fixed price per specimen
Ten Drug Lab Panel - Urine	$4.25 firm, fixed price per specimen
EtG Test – Urine (*Includes LC/MS/MS Confirmation)*	$13.00 firm, fixed price per specimen
EtG Test – Urine (Screen Only)	$9.00 firm, fixed price per specimen
Synthetic Cannabinoids (Marijuana) - Urine	$20.00 firm, fixed price per specimen
Steroids - Urine	$45.00 firm, fixed price per specimen
Comprehensive Panel (Screen) - Urine	$35.00 firm, fixed price per specimen
Synthetic Stimulants (P80) 14 Drug Screen - Urine	$35.00 firm, fixed price per specimen
Synthetic Stimulants (P81) 2 Drug Screen - Urine	$25.00 firm, fixed price per specimen
Lab-Based Oral Fluid Specimen Collector	$1.90 firm, fixed price per device
Synthetic Cannabinoids (Marijuana) - Oral Fluid	$25.00 firm, fixed price per specimen
Six Drug Oral Fluid Lab Panel (9001) includes GC/MS	$9.00 firm, fixed price per specimen
Six Drug Oral Fluid Lab Panel w/ BZO (9018) includes GC/MS	$9.00 firm, fixed price per specimen
Eight Drug Oral Fluid Lab Panel (9020) screen only	$6.00 firm, fixed price per specimen

Confirmations

Urine GC/MS Confirmation (upon request for urine lab tests)	$9.00 firm, fixed price per drug/analyte
Urine EtG LC/MS/MS Confirmation (upon request for presumptive positives from EtG Screen Only test)	$9.00 firm, fixed price per specimen
Urine GC/MS Confirmation (upon request for presumptive positives from Comprehensive Panel screen)	$9.00 firm, fixed price per drug/analyte
Urine GC/MS Confirmation (upon request for presumptive positives from urine on-site devices)	$9.00 firm, fixed price per drug/analyte
Oral Fluid GC/MS Confirmation (upon request for presumptive positives from oral fluid on-site devices or for lab-test confirmation)	$9.00 firm, fixed price per drug/analyte

INSTANT, ON-SITE DRUG AND ALCOHOL SCREENING DEVICES

Single Drug Panel-Dip

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0001 COCAINE (COC)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0002 METHAMPHETAMINES (MAMP)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0003 OPIATES(300) (OPI)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0004 MARIJUANA (THC)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0018 AMPHETAMINES (AMP)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0019 BARBITURATES (BAR)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0020 METHADONE (MTD)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0021 PHENCYCLIDINE (PCP)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0022 BENZODIAZEPINES (BZO)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0036 MDMA (Ecstasy)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0037 OXYCODONE (OXY)

Reditest One Drug Panel-Dip $0.33 firm, fixed price per each unit
Product No. 01 102 0023 TRI-CYLCIC ANTIDEPRESSANTS (TCA)

Reditest One Drug Panel-Dip $0.80 firm, fixed price per each unit
Product No. 01 102 1955 BUPRENORHPINE (BUP)

Multiple Drug Panel-Dip

Reditest Two Drug Panel-Dip $0.67 firm, fixed price per each unit
Product No. 01 102 0005 COC/OPI(300)

Reditest Two Drug Panel-Dip $0.67 firm, fixed price per each unit
Product No. 01 102 0030 MAMP/ OPI(300)

Reditest Two Drug Panel-Dip $0.67 firm, fixed price per each unit
Product No. 01 102 0006 COC/THC

Reditest Two Drug Panel-Dip $0.67 firm, fixed price per each unit
Product No. 01 102 0007 COC/MAMP

Multiple Drug Panel-Dip, continued…

Reditest Two Drug Panel-Dip $0.67 firm, fixed price per each unit
Product No. 01 102 0008 MAMP/THC

Reditest Three Drug Panel-Dip $0.86 firm, fixed price per each unit
Product No. 01 102 0009 COC/ MAMP/ THC

Reditest Three Drug Panel-Dip $0.86 firm, fixed price per each unit
Product No. 01 102 0010 COC/ OPI(300)/ THC

Reditest Three Drug Panel-Dip $0.86 firm, fixed price per each unit
Product No. 01 102 0011 MAMP/ OPI(300)/ THC

Reditest Three Drug Panel-Dip $0.86 firm, fixed price per each unit
Product No. 01 102 0014 COC/ MAMP/ OPI(300)

Reditest Four Drug Panel-Dip $1.13 firm, fixed price per each unit
Product No. 01 102 0012 COC/ MAMP/ OPI(300)/ THC

Reditest Four Drug Panel-Dip $1.13 firm, fixed price per each unit
Product No. 01 102 0032 AMP/ COC/ OPI(300)/ THC

Reditest Five Drug Panel-Dip $1.39 firm, fixed price per each unit
Product No. 01 102 0013 COC/ MAMP/ OPI(300)/ PCP/ THC

Reditest Five Drug Panel-Dip $1.39 firm, fixed price per each unit
Product No. 01 102 0015 BZO/ COC/ MAMP/ OPI(300)/ THC

Reditest Five Drug Panel-Dip $1.39 firm, fixed price per each unit
Product No. 01 102 0033 AMP/ COC/ OPI(300)/ PCP/ THC

Reditest Five Drug Panel-Dip $1.39 firm, fixed price per each unit
Product No. 01 102 0034 AMP/ COC/ MAMP/ OPI(300)/ THC

Reditest Five Drug Panel-Dip $1.39 firm, fixed price per each unit
Product No. 01 102 0047 AMP/ COC/ PCP/ OPI(2000)/ THC

Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0016 BZO/ COC/ MAMP/ OPI(300)/ PCP/ THC

Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0017 BZO/ COC/ MAMP/ MTD/ OPI(300)/ THC

Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0024 BAR/ BZO/ COC/ MAMP/ OPI(300)/ THC

Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0119 MAMP/ COC/ OPI(300)/ THC/ OXY/ BZO

New! Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0174 AMP (300)/ MAMP(500)/ COC(150)/ OPI(300)/ THC/ MDMA

New! Reditest Six Drug Panel-Dip $1.62 firm, fixed price per each unit
Product No. 01 102 0175 MAMP(500)/ COC(150)/ OPI(300)/ THC/ MDMA/ BZO

Multiple Drug Panel-Dip, continued…

Reditest Seven Drug Panel-Dip $1.85 firm, fixed price per each unit
Product No. 01 102 0035 COC/ THC/ BZO/ OPI(300)/ AMP/ PCP/ TCA

New! Reditest Seven Drug Panel-Dip $1.85 firm, fixed price per each unit
Product No. 01 102 0176 MAMP(500)/ COC(150)/ OPI(300)/ THC/ MDMA/ OXY/ BZO

New! Reditest Seven Drug Panel-Dip $1.85 firm, fixed price per each unit
Product No. 01 102 0177 AMP/ MAMP(500)/ COC(150)/ OPI(300)/ THC/ MDMA/ OXY

New! Reditest Seven Drug Panel-Dip $1.85 firm, fixed price per each unit
Product No. 01 102 0178 AMP/ MAMP(500)/ COC(150)/ OPI(300)/ THC/ MDMA/ PCP

Reditest Eight Drug Panel-Dip $2.14 firm, fixed price per each unit
Product No. 01 102 0169 MAMP/ COC/ THC/ BZO/ MDMA/ OPI(300)/ AMP/ OXY

New! Reditest Eight Drug Panel-Dip $2.14 firm, fixed price per each unit
Product No. 01 102 0179 MAMP/ COC/ THC/ BZO/ PCP/ OPI(300)/ AMP/ OXY

New! Reditest Nine Drug Panel-Dip $2.40 firm, fixed price per each unit
Product No. 01 102 0180 MAMP/ COC/ THC/ BZO/ PCP/ OPI(300)/ AMP/ OXY/ BUP

New! Reditest Nine Drug Panel-Dip $2.40 firm, fixed price per each unit
Product No. 01 102 0181 MAMP(500)/ COC(150)/ THC/ BZO/ PCP/ OPI(300)/ AMP(300)/ OXY/ MDMA

Reditest Ten Drug Panel-Dip $2.66 firm, fixed price per each unit
Product No. 01 102 0138 MAMP/ COC/ THC/ BZO/ MTD/ BAR/ MDMA/ OPI(300)/ PCP/ OXY

Reditest Ten Drug Panel-Dip $2.66 firm, fixed price per each unit
Product No. 01 102 0025 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ OPI(300)/ PCP/ TCA

New! Reditest Ten Drug Panel-Dip $2.66 firm, fixed price per each unit
Product No. 01 102 0182 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ OPI(300)/ OXY/ BUP

New! Reditest Ten Drug Panel-Dip $2.66 firm, fixed price per each unit
Product No. 01 102 0183 MAMP(500)/ COC(150)/ THC/ BZO/ MTD/ BAR/ OPI(300)/ PCP/ MDMA/ OXY

New! Reditest Eleven Drug Panel-Dip $3.25 firm, fixed price per each unit
Product No. 01 102 0184 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ OPI(300)/ PCP/ BUP/ OXY/

New! Reditest Eleven Drug Panel-Dip $3.25 firm, fixed price per each unit
Product No. 01 102 0185 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ OPI(2000)/ PCP/ BUP/ OXY

New! Reditest Eleven Drug Panel-Dip $3.25 firm, fixed price per each unit
Product No. 01 102 0186 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ OPI(300)/ PPX/ BUP/ OXY

New! Reditest Eleven Drug Panel-Dip $3.25 firm, fixed price per each unit
Product No. 01 102 0187 MAMP(500)/ AMP(300)/ COC(150)/ THC/ BZO/ MTD/ BAR/ OPI(300)/ PCP/ MDMA/ OXY

Reditest Twelve Drug Panel-Dip $3.35 firm, fixed price per each unit
Product No. 01 102 0141 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ MDMA/ OPI(300)/ PCP/ OXY/ PPX

New! Reditest Twelve Drug Panel-Dip $3.35 firm, fixed price per each unit
Product No. 01 102 0188 MAMP/ AMP/ COC/ THC/ BZO/ MTD/ BAR/ MDMA/ OPI(300)/ PCP/ OXY/ BUP

RediCup Devices

RediCup Four Drug Device $1.80 firm, fixed price per each unit
Product No. 01 102 0026 COC/ MAMP/ OPI(300)/ THC

RediCup Five Drug Device $1.90 firm, fixed price per each unit
Product No. 01 102 0027 BZO/ COC/ MAMP/ OPI(300)/ THC

RediCup Five Drug Device $1.90 firm, fixed price per each unit
Product No. 01 102 0028 COC/ MAMP/ OPI(300)/ PCP/ THC

RediCup Six Drug Device $2.45 firm, fixed price per each unit
Product No. 01 102 0135 MAMP/ COC/ THC/ AMP/ OPI(2000)/ BZO

RediCup Six Drug Device $2.45 firm, fixed price per each unit
Product No. 01 102 0029 BZO/ COC/ MAMP/ OPI(300)/ PCP/ THC

RediCup Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 0058 AMP/ BAR/ BZO/ COC/ MAMP/ MTD/ OPI(2000)/ PCP/ TCA/ THC

RediCup Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 0059 AMP/ BAR/ BZO/ COC/ MAMP/ MTD/ OPI(300)/ PCP/ TCA/ THC

RediCup Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 0137 MAMP/COC/THC/BZO/MTD/BAR/MDMA/OPI(300)/PCP/OXY

iCup A.D. Devices with Built-in Adulterants
(Oxidants, Specific Gravity ,Ph,)(Nitrite, Glutaraldehyde, Creatinine)

iCup A.D. Four Drug Device $2.16 firm, fixed price per each unit
Product No. 01 102 2032 COC/ MAMP/ OPI(2000)/ THC (OX,SG,pH)

iCup A.D. Four Drug Device $2.16 firm, fixed price per each unit
Product No. 01 102 2033 COC(150)/ MAMP(500)/ AMP/ THC (OX,CR,pH)

iCup A.D. Five Drug Device $2.25 firm, fixed price per each unit
Product No. 01 102 2034 COC/ THC/ MAMP/ OPI(2000)/ AMP (OX,SG,pH)

iCup A.D. Five Drug Device $2.25 firm, fixed price per each unit
Product No. 01 102 2035 COC/ THC/ PCP/ OPI(2000)/ AMP (OX,SG,pH)

iCup A.D. Five Drug Device $2.25 firm, fixed price per each unit
Product No. 01 102 2036 COC/ THC/ MAMP/ OPI(2000)/ PCP (OX,SG,pH)

iCup A.D. Five Drug Device $2.25 firm, fixed price per each unit
Product No. 01 102 2021 COC/ THC/ MAMP/ OPI(300)/ AMP (OX,SG,pH)

iCup A.D. Six Drug Device $2.48 firm, fixed price per each unit
Product No. 01 102 2023 COC/ THC/ MAMP/ OPI(2000)/ AMP/ PCP (OX,SG,pH)

iCup A.D. Six Drug Device $2.48 firm, fixed price per each unit
Product No. 01 102 2022 COC/ THC/ MAMP/ OPI(2000)/ AMP/ BZO (OX,SG,pH)

iCup A.D. Six Drug Device $2.48 firm, fixed price per each unit
Product No. 01 102 2037 COC/ THC/ OPI(2000)/ AMP(300)/ OXY/ MDMA (OX,SG,pH)

iCup Devices with Adulterants, continued…

iCup A.D. Eight Drug Device $2.88 firm, fixed price per each unit
Product No. 01 102 2038 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ PCP (OX,SG,pH)

iCup A.D. Eight Drug Device $2.88 firm, fixed price per each unit
Product No. 01 102 2069 COC/ MAMP/ AMP/ OPI(300)/ THC/ BZO/ OXY/ PCP (OX,CR,pH)

iCup A.D. Nine Drug Device $3.11 firm, fixed price per each unit
Product No. 01 102 2039 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ MTD/ PCP (OX,SG,pH)

iCup A.D. Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 2129 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ TCA/ PCP/ MTD (OX,SG,pH,NI,GL,CR)

iCup A.D. Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 2074 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ MTD/ PPX/ OXY (OX,CR,pH)

iCup A.D. Twelve Drug Device $4.05 firm, fixed price per each unit
Product No. 01 102 2027 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ PPX/ OXY/ PCP/ MTD/ TCA (OX,CR,pH)

iCup Devices

iCup Three Drug Device $2.50 firm, fixed price per each unit
Product No. 01 102 2044 COC/ MAMP/ THC

iCup Three Drug Device $2.50 firm, fixed price per each unit
Product No. 01 102 2064 COC/ OPI(2000)/ THC

iCup Ten Drug Device $3.20 firm, fixed price per each unit
Product No. 01 102 2020 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ MDMA/ PPX/ OXY

iCup Thirteen Drug Device $5.00 firm, fixed price per each unit
Product No. 01 102 2028 COC/ MAMP/ AMP/ OPI(2000)/ THC/ BZO/ BAR/ PPX/ OXY/ PCP/ MTD/ TCA/ BUP

Integrated EZ Cup II Devices

Integrated EZ Cup II Three Drug Devices $2.99 firm, fixed price per each unit
Product No. 01 102 2031 COC/ THC/ MAMP

Integrated EZ Cup II Four Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2001 COC/ THC/ OPI(2000)/ MAMP

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2018 COC/ THC/ OPI(2000)/ AMP/ MAMP

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2141 COC/ THC/ OPI(2000)/ AMP/ MAMP w/ Adulterants (OX,SG,pH)

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 1974 COC/ THC/ OPI(2000)/ AMP/ PCP w/ Adulterants (OX,SG,pH,NI,GL,CR)

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2051 COC/ THC/ OPI(2000)/ AMP/ MAMP w/ Adulterants (OX,SG,pH,NI,GL,CR)

Integrated EZ Cup II Devices, continued…

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2005 COC/ THC/ OPI(2000)/ MAMP/ PCP

Integrated EZ Cup II Five Drug Devices $3.26 firm, fixed price per each unit
Product No. 01 102 2048 COC/ THC/ OPI(2000)/ AMP/ PCP

Integrated EZ Cup II Six Drug Devices $3.59 firm, fixed price per each unit
Product No. 01 102 1972 COC/ THC/ OPI(2000)/ AMP/ MAMP/ PCP

Integrated EZ Cup II Six Drug Devices $3.59 firm, fixed price per each unit
Product No. 01 102 2007 COC/ THC/ OPI(2000)/ MAMP/ MDMA/ OXY

Integrated EZ Cup II Six Drug Devices $3.59 firm, fixed price per each unit
Product No. 01 102 1984 COC/ THC/ OPI(2000)/ AMP/ MAMP/ BZO

Integrated EZ Cup II Eight Drug Devices $4.14 firm, fixed price per each unit
Product No. 01 102 2008 COC/ THC/ OPI(2000)/ AMP/ MAMP/ PCP/ BZO/ BAR

Integrated EZ Cup II Nine Drug Devices $4.25 firm, fixed price per each unit
Product No. 01 102 2140 COC/ THC/ OPI(2000)/ MAMP/ BZO/ BAR/ MTD/ OXY/ PPX w/ Adulterants (OX,SG,pH)

Integrated EZ Cup II Ten Drug Devices $4.50 firm, fixed price per each unit
Product No. 01 102 1985 COC/ THC/ OPI(2000)/ AMP/ MAMP/ PCP/ BZO/ BAR/ MTD/ MDMA

Integrated EZ Cup II Twelve Drug Devices $4.50 firm, fixed price per each unit
Product No. 01 102 2096 COC/ THC/ OPI(300)/ AMP/ MAMP/ BZO/ BAR/ MTD/ MDMA/ OXY/ BUP/ PPX

On-Site Oral Screening Devices

On-Site Oral 6 Drug Screening Device $4.68 firm, fixed price per each unit
Product No. 01 102 0127 COC/MAMP/PCP/THC/OPI/AMP

iScreen OFD Oral 6 Drug Screening Device $4.75 firm, fixed price per each unit
Product No. 01 102 2025 COC/MAMP/PCP/THC/OPI/AMP

Instant Alcohol Test Strips

Instant Alcohol Saliva Test Strips $0.55 firm, fixed price per each unit
Product No. 01 362 0001 Detects 0.02%,0.08% AND 0.30% SAC

Breath Alcohol Test Device

Breath Alcohol Test Device $1.25 firm, fixed price per each unit
Product No. 01 215 0004 0.02% Cut-off level

Additional on-site oral screening - added October 3, 2011
OrAlert 6 panel drug screening
Product No. 01 102 1960 $4.68 firm,fixed price per unit
AMP/COC/M-AMP/OPI(2000)/PCP/THC $117.00 per box of 25
OrAlert 6 panel drug screening
Product No. 01 102 2083 $6.25 firm,fixed price per unit
AMP/COC/M-AMP/OPI(2000)/BZO/THC $156.25 per box of 25

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YY) 09/22/2010

PRODUCER

Serial # 101825

THE WEINER COMPANY, INC.
ONE MCKINLEY SQUARE
BOSTON, MA 02109
(617) 742-2444 PHONE, (617) 742-7744 FAX

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW.

INSURED

REDWOOD TOXICOLOGY LABORATORY, INC. AND
ALERE INC.
3650 WESTWIND BOULEVARD
SANTA ROSA, CA 95403

INSURERS AFFORDING COVERAGE	NAIC#
INSURER A: HARTFORD FIRE INSURANCE CO.	
INSURER B: TWIN CITY FIRE INSURANCE CO.	
INSURER C: NOETIC SPECIALTY INSURANCE COMPANY	
INSURER D:	
INSURER E:	

COVERAGES

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES, AGGREGATE LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	ADD'L INSRD	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YY)	POLICY EXPIRATION DATE (MM/DD/YY)	LIMITS	
A		GENERAL LIABILITY X COMMERCIAL GENERAL LIABILITY CLAIMS MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC	08 UEN AB6559	9/30/2010	9/30/2011	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ INCLUDED $ 10,000 $ 1,000,000 $ 2,000,000 $ EXCLUDED
A		AUTOMOBILE LIABILITY X ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS HIRED AUTOS NON-OWNED AUTOS	08 UEN AB6559 (ALL OTHER STATES) 08 MCPAB 6647 (MA AUTO)	9/30/2010	9/30/2011	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
		GARAGE LIABILITY ANY AUTO				AUTO ONLY - EA ACCIDENT OTHER THAN AUTO ONLY: EA ACC AGG	$ $ $
A		EXCESS/UMBRELLA LIABILITY X OCCUR CLAIMS MADE DEDUCTIBLE RETENTION $	08 RHU TB 7959	9/30/2010	9/30/2011	EACH OCCURRENCE AGGREGATE	$ 4,000,000 $ 4,000,000 $ $ $
B		WORKER'S COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? If yes, describe under SPECIAL PROVISIONS below	08 WB IS 3255	9/30/2010	9/30/2011	X WC STATU-TORY LIMITS OTH-ER EL EACH ACCIDENT EL DISEASE - EA EMPLOYEE EL DISEASE - POLICY LIMIT	 $ 500,000 $ 500,000 $ 500,000
C		OTHER PRODUCTS LIABILITY	N10MA380015	9/30/2010	9/30/2011	$10,000,000 EACH CLAIM $10,000,000 POLICY LIMIT *"CLAIMS MADE" COVERAGE FORM. DEFENSE IS WITHIN THE LIMIT OF INSURANCE.*	

DESCRIPTION OF OPERATIONS/LOCATIONS/VEHICLES/EXCLUSIONS ADDED BY ENDORSEMENT/SPECIAL PROVISIONS

STATE OF MISSOURI DRUG COURTS IS ADDITIONAL INSURED FOR GENERAL LIABILITY ONLY IF REQUIRED IN A WRITTEN CONTRACT OR AGREEMENT WITH THE NAMED INSURED, FOR THE DURATION OF THE CONTRACT, PROVIDED THE INJURY OR DAMAGE OCCURS SUBSEQUENT TO THE EXECUTION OF THE CONTRACT OR AGREEMENT.

CERTIFICATE HOLDER

STATE OF MISSOURI DRUG COURTS
MR. HERB CONNER
2112 INDUSTRIAL DRIVE
P.O. BOX 104480
JEFFERSON CITY, MO 65110

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, THE ISSUING INSURER WILL ENDEAVOR TO MAIL 30 DAYS WRITTEN NOTICE TO THE CERTIFICATE HOLDER NAMED TO THE LEFT, BUT FAILURE TO DO SO SHALL IMPOSE NO OBLIGATION OR LIABILITY OF ANY KIND UPON THE INSURER, ITS AGENTS OR REPRESENTATIVES.

AUTHORIZED REPRESENTATIVE OF THE WEINER COMPANY, INC.

BY: [signature]

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EXHIBIT D

METHOD OF PERFORMANCE

The offeror should use this Exhibit, or any format desired, to present a written plan for performing the requirements specified in this Request for Proposal.

1. Describe what is provided with which to collect the each sample (cups, chain of custody forms, mailing packets).

Redwood Toxicology Laboratory, Inc. strives to take the guesswork out of drug testing. To aid our clients, we provide urine specimen collection and shipping supplies at no additional fee.

Collection supplies include:

- Specimen collection containers (urine and EtG testing)
- Beakers for use with the Panel-Dip on-site devices (urine testing)
- Specimen baggies with absorbent material
- Chain of Custody forms and labels of various configurations
- Security seals and temperature strips
- U.S. mail or FedEx overnight delivery
- Specimen collection guidelines and procedures for on-site devices
- Training DVD for on-site screening devices

Laboratory collection and shipping supplies are sent in three month increments to eliminate the need for excessive phone calls to the laboratory. Automated supply shipments are easily arranged by contacting RTL shipping department at (800) 255-2159, ext. 4324 or 4327. On-site devices are sent when ordered.

2. Describe the instruction or training provided to drug court staff pertaining to properly collecting a sample and completing necessary documentation.

RTL offers many different training options. The most popular options, telephonic, webinar training as well as training from our website, are available at no additional fee to our clients. Jennifer Dippe, Regional Sales Manager will arrange for an RTL Training Specialist to contact each facility to determine the most convenient telephonic training dates and times. The number of attendees, any special needs and specific topics will be discussed at the time of first contract.

On the agreed upon training date, each location will receive a phone call our Training Specialist to discuss specimen collection, chain of custody, shipment to the laboratory and the internet reporting solution. RTL will send all training supplies in advance of the phone call, including sample devices. It is recommended that these supplies be brought to the conference call training session. A question and answer session will follow the training presentation. Certificates of Training Completion are available from our website for all Attendees.

On-site training is available upon request. In addition, RTL provides a comprehensive training DVD to all of its clients who use the instant, on-site devices. This DVD is available at no extra fee. A sample DVD is included in the Attachments section.

A copy of this video (broken down by device type) is also available online at:

http://www.redwoodbiotech.com/products/doa_redicup_training_video.shtml
http://www.redwoodbiotech.com/products/doa_panel-dip_training_video.shtml
http://www.redwoodbiotech.com/products/doa_panel-dip_training_video.shtml

In addition to its training program, RTL offers an extensive suite of customer support services to aid and educate its clients:

- Phone consultation: Timely response to questions about specimen collection, drug interactions, confirmation requests, and results reporting.
- Website/Drugs of abuse literature: Information from street names to retention/detection times. Including cross reactions and chain of custody guidelines.
- Expert witness testimony: Available by affidavit, telephonically or in court.
- Air shipment tracking and scheduling: Track FedEx specimen shipments to the lab or call to arrange pick-up for specimens.
- IT/Computer support: Available for internet reporting support and to answer all IT questions.
- Supply fulfillment: Call toll-free for all your collection supply needs.

3. Describe how the sample is transported to the testing laboratory (U S Postal, Fed Ex, UPS, etc.).

A Federal Express or UPS courier will pick up the specimens for delivery to RTL. Courier pick-ups may be conveniently scheduled by calling RTL's Transportation Specialist, Alice Yip, at (800) 255-2159, ext. 4382. Ms. Yip will work directly with the Drug Courts to ensure that their Courier schedule is as convenient as possible.

4. Describe the methods of testing which are employed (LC/MS/MS, GS/MS, LC/MS, and/or Immunoassay methods).

RTL takes great pride in the accuracy of its results. Only state of the art equipment and methodologies are used to detect drugs of abuse, alcohol, EtG, synthetic cannabinoids, designer stimulants and steroids.

Type of Test	Screening Method	Confirmation Method(s)
Urine Drugs of Abuse Test	EIA	RIA, TLC, GC/MS, LC/MS/MS
Urine Alcohol Test	EA	GC
Urine EtG Test	LC/MS/MS	LC/MS/MS
Urine Synthetic Cannabinoids	LC/MS/MS	LC/MS/MS
Urine Designer Stimulants	GC/MS	GC/MS
Urine Steroid Test	GC/MS	GC/MS
Oral Fluid Drugs of Abuse Test	ELISA	GC/MS
Oral Fluid Synthetic Cannabinoids	LC/MS/MS	LC/MS/MS

Legend
EA = Enzyme Assay
EIA = Enzyme Immunoassay
ELISA = Enzyme-Linked Immunosorbent Assay
RIA – Radioimmunoassay
TLC = Thin Layer Chromatography
GC = Gas Chromatography
GC/MS = Gas Chromatography/Mass Spectrometry
LC/MS/MS = Liquid Chromatography/Tandem Mass Spectrometry

5. Provide the testing cutoff levels which are available (100ng/mL, 250ng/mL, 500ng/mL, 1000 ng/mL). What cutoff level is recommended to safe guard against incidental false positive? _____ng/mL

Methodology - Urine Drugs of Abuse and Alcohol Testing

Urine testing is the industry accepted standard for alcohol and drug testing. In order to determine if a urine sample is negative or positive for drugs of abuse, RTL initially screens all specimens by an enzyme immunoassay (EIA) procedure. Specimens that yield an EIA response below the specified cut-off are reported as negative. Any specimen that shows an EIA response at or above the specified cut-off is considered "presumptive positive" for a particular drug or drug class. All presumptive positive specimens are subsequently confirmed by a second method prior to reporting positive results. Analytical methods of confirmation include thin layer chromatography (TLC), radioimmunoassay (RIA), gas chromatography (GC), or gas chromatography/ mass spectrometry (GC/MS), and/or liquid chromatography tandem mass spectrometry (LC/MS/MS). The subsequent confirmatory procedures are performed on a second independent portion of the original urine specimen.

Following on the next page is a list, by drug class, of RTL's urine screening and confirmation methodologies.

Urine Testing Screening and Confirmation Methodologies

Drug	EIA Screen	TLC Confirmation	RIA Confirmation	GC/MS Confirmation
Amphetamines				
Amphetamine	1000 ng/mL	<500 ng/mL		100 ng/mL
Methamphetamine	1000 ng/mL	<500 ng/mL		100 ng/mL
Barbiturates	200 ng/mL	<500 ng/mL		200 ng/mL
Benzodizepines	200 ng/mL		200 ng/mL	50 ng/mL**
Cocaine-benzoylecgonine	300 ng/mL		150 ng/mL	50 ng/mL
Marijuana Metabolite (9-THC-COOH)	20/50 ng/mL*		25 ng/mL	5 ng/mL
Methadone	150 ng/mL	<500 ng/mL		100 ng/mL
Opiates				
Total Morphine	300 ng/mL	<500 ng/mL		100 ng/mL
Codeine	300 ng/mL	<500 ng/mL		100 ng/mL
Hydrocodone		1000 ng/mL		100 ng/mL
Oxycodone	300 ng/mL	1000 ng/mL	250 ng/mL	100 ng/mL
PCP	25 ng/mL			10 ng/mL
Propoxyphene	300 ng/mL	<500 ng/mL		200 ng/mL
Alcohol (GC-FID)	.04 gm/dL			.02 gm/dL

*Agency has the ability to choose the cut-off levels indicated.
**Test performed by Liquid Chromatography/Mass Spectrometry/Mass Spectrometry

6. Describe the turnaround time for results.

Results for urine specimens that screen negative available within twenty-four (24) hours of receipt of the specimen at the laboratory. Results on specimens that screen positive are available within twenty-four (24) to forty-eight (48) hours. Specimens that require GC/MS or LC/MS/MS confirmation require an additional twenty-four (24) hours to process. Oral fluid specimen results are available within forty-eight (48) to seventy-two (72) hours from receipt of the specimen at the lab.

7. Describe how test results will be reported (telephone, fax, e-mail).

RTL offers many different reporting options for its clients, including:

Internet Reporting: Reports available securely over the internet at http://www.webtoxicology.com. This secure, password protected website is easy to use and is available 24/7. Details on this free on-line service are provided below.

Get Test Results Quickly and Easily

- Receive e-mail notification as soon as new results are available
- View and print test results in batches
- Keep track of printed and unprinted results
- Track onsite testing device results
- Advanced search

www.webtoxicology.com Demo
http://www.webtoxicology.com
User Name: userdemo
Password: train

Test Requisitioning

- Order laboratory tests and print chain of custody forms on your laser printer - no special hardware required
- Chain of custody forms are scanned by the laboratory and made available for viewing on the website
- Track specimens from start to finish – scheduled -> collected -> shipped -> received by laboratory -> reported

Drug Testing Program Management

- Create a testing schedule
- Track no-shows and receive daily no-show lists by e-mail
- Store donor information and organize donors into groups
- Generate a wide variety of customized statistical reports

Custom Solutions

RTL also provides customized data integration solutions to meet your organization's needs.

- **Data formats:** HL7 (Health Level 7), XML (Extensible Markup Language), CSV (Comma Separated Values / Comma Delimited)
- **Delivery methods:** Secure FTP (File Transfer Protocol), Web Services, VPN (Virtual Private Network)

Additional Reporting Options

- Results communicated by facsimile
- Daily summary of multiple specimen results on one page
- Hard copies of reports sent by mail
- Results on the instant, on-site devices are reported on the device itself. Results are available within three to five minutes.

8. Organizational Chart - The offeror should provide an organizational chart showing the staffing and lines of authority for the key personnel to be used. The organizational chart should include (1) The relationship of service personnel to management and support personnel, (2) The names of the personnel and the working titles of each, and (3) Any proposed subcontractors including management, supervisory, and other key personnel.

- **The organizational chart should outline the team proposed for this project and the relationship of those team members to each other and to the management structure of the offeror's organization.**

A copy of RTL's organizational chart is included in the Attachment Section.

Administrative and Contract Support Personnel

The following staff members will be responsible for account management on the Drug Court contract. They are the primary contacts who will coordinate account maintenance, set up account details (chain of custody, shipping supplies, FedEx pick-up schedule development, etc.), take agency orders and facilitate contact with other RTL departments such as IT, customer service and shipping.

Suzanne Bertolucci, the Sales Director for Redwood Toxicology since its inception in 1994, will act as the primary sales contact for the Drug Courts. Ms. Bertolucci may be contacted with questions about account maintenance and service offerings. She reports to the CEO.

(800) 255-2159, ext. 4369– phone
(707) 577-8102 – fax
sbertolucci@redwoodtoxicology.com

Mary Tardel, the Government Sales Manager for RTL since 2001, is the primary contact person for all Government Sales Concerns. She is available at any time for consultation with the Drug Courts. She reports to the Sales Director.

(800) 255-2159, ext. 4359 – phone
(707) 636-2809 – fax
mtardel@redwoodtoxicology.com

Jennifer Dippe, Regional Sales Manager, has been with RTL since 2008. She is the primary customer service contact for the Drug Courts. Ms. Dippe will initiate set-up and update of all Drug Court accounts and contact each agency to discuss any special needs. Jennifer is also the primary customer service contact for the Drug Court's training needs. During the Rollout Period, Ms. Dippe will arrange for each Drug Court account to set-up telephonic training sessions. Training topics will include specimen collection, chain of custody procedures, results interpretation and internet reporting. After rollout, Jennifer will coordinate directly with other RTL Departments to help fulfill the Drug Court's needs to ensure complete compliance with the contract. She reports directly to the Sales Director

(800) 255-2159, ext. 4370 – phone
(707) 577-8102 – fax
jdippe@redwoodtoxicology.com

Sonja McIntosh, is RTL's Sales Operations Manager. Sonja is the primary contact person for all bid and contract matters. All information regarding the RFP response, resulting contract and contract administration should be addressed directly to Ms. McIntosh. She is available at any time for consultation with the Drug Courts. She reports to the Chief Financial Officer.

(800) 255-2159, ext. 4342 - phone
(707) 569-0121 – fax
smcintosh@redwoodtoxicology.com

Virginia Cowdrey, the Client Service Manager for RTL since 2000, is a valuable resource for all client agencies. Ms. Cowdrey is extremely knowledgeable in all Customer Service related topics for RTL, including results interpretation, drugs of abuse, street names, levels of detection and trends in drug usage. She is also the primary contact person for litigation and expert witness requests. She reports directly to the Laboratory Manager.

(800) 255-2159, ext. 4328 - phone
(707) 577-0365 – fax
vcowdrey@redwoodtoxicology.com

9. Along with a detailed organizational chart, the offeror should describe the following:

- **How services of the contract will be managed, controlled, and supervised in order to ensure satisfactory contract performance.**

- **Total Personnel Resources - The offeror should provide information that documents the depth of resources to ensure completion of all requirements on time and on target. If the offeror has other ongoing contracts that also require personnel resources, the offeror should document how sufficient resources will be provided to the STATE OF MISSOURI.**

The resources available to ensure completion of all requirements are answered above in question number eight (8). While we have other ongoing contracts RTL has sufficient qualified staff to fulfill all requirements of this RFP. As the incumbent provider of laboratory services and on-site devices to the State of Missouri Drug Courts, Redwood is intimately familiar with the State's needs. If chosen, we will continue to provide excellent services and products. RTL has over 200 highly trained employees. Given the account managers, Suzanne Bertolucci, Mary Tardel and Jennifer Dippe the State's needs will be met in a timely and professional manner.

10. Outside United States - If any products and/or services offered under this RFP are being manufactured or performed at sites outside the United States, the offeror MUST disclose such fact and provide details in the space below or on an attached page.

Are products and/or services being manufactured or performed at sites outside the United States?	**Yes** ___X__	**No** _

Describe and provide details: Certain product lines that Redwood sells may be manufactured outside of the United States. All of Redwood's laboratory services are performed at our facility in Santa Rosa, California.

EXHIBIT C

PERSONNEL EXPERTISE SUMMARY

(Complete this Exhibit for personnel proposed. Resumes or summaries of key information may be provided)

Personnel	**Background and Expertise of Personnel and Planned Duties**
1. Albert Berger (Name) General Manager (Title) General Manager (Proposed Role/Function)	Primary corporate decision maker. Responsible for running the business and managing all departments including Laboratory, Quality Control, Accounting, Sales and Purchasing.
2. Richard R. Wilber, M.D. (Name) LaboratoryDirector/Clinical Consultant (Title) Medical Director (Proposed Role/Function)	Medical director for Redwood Toxicology Laboratory, Inc. received his medical degree from the University of California, San Francisco School of Medicine and is a board certified pathologist in Anatomic and Clinical Pathology. He has over 20 years experience as a Laboratory Director and has several scientific publications. Dr. Wilber works with senior management to develop testing methodologies, standard operating procedures and makes recommendations on laboratory operations. Curriculum vitae provided in the Attachment Section.
3. Mark DeMeo, M.D. (Name) Laboratory Director (Title) Laboratory Director (Proposed Role/Function)	Medical Director for RTL since 1994, Dr. DeMeo graduated from Creighton University with a degree in medicine and is board certified in the following specialties: Anatomic and Clinical Pathology, Dermatopathology, Hematology and Coagulation, and Immunohematology. He has over 30 years experience and has been an inspector for the College of American Pathologists for over 20 years. Dr. DeMeo works with senior management to develop testing methodologies, standard operating procedures and makes recommendations on laboratory operations. Curriculum vitae provided in the Attachment Section.
4. Wayne Ross, M.C.L.S., C.L.S. (Name) Chief Toxicologist (Title) Chief Toxicologist (Proposed Role/Function)	Chief Toxicologist for RTL since 1994, Mr. Ross was awarded a master's degree in Clinical Chemistry and Analytical toxicology from the University of California at San Francisco. He has over 25 years of experience in toxicology and the clinical laboratory. He is a Diplomate of the American Board of Forensic Examiners, a Fellow of the National Academy of Clinical Biochemistry, and is licensed by the State of California as a Clinical Laboratory Scientist. He has testified as an expert in forensic toxicology in both state and federal courts in excess of two hundred cases. Reviews and signs off on laboratory results. Responsible for laboratory decision making and staff management. Curriculum vitae provided in the Attachment Section.

5. Victor Uralets, Ph.D. (Name) Director of Sports Testing (Title) Sports Testing (Proposed Role/Function)	Dr. Uralets joined RTL in 2007 as its Director of Sports Testing. Dr. Uralets has 26 years of drug test laboratory experience with 11 years focused on Olympic laboratory testing. Dr. Uralets holds a Doctorate Degree in Organic Chemistry from the Institute of Organoelement Compounds of the Russian Academy of Sciences and a BS Degree in Chemistry from the Moscow State University. Curriculum vitae provided in the Attachment Section.
6. Laura Adams, C.L.S., MT (ASCP) (Name) Laboratory Manager (Title) Laboratory Manager, Quality Control (Proposed Role/Function)	Laboratory Manager for RTL since 1995, Dr. Adams received her bachelor's degree from the University of Laboratory Manager California at Davis. She has over 25 years of experience in the clinical laboratory, including toxicology. Dr. Adams is responsible for day to day management of lab staff, operating procedures and Client Services. Curriculum vitae provided in the Attachment Section.
7. Suzanne Bertolucci (Name) Director of Sales (Title) Sales & Customer Relations (Proposed Role/Function)	Sales Director for RTL for over 12 years. Suzanne manages an in-house sales department of 15 employees. She maintains relationships with a customer-base of over 10,000 accounts in the drug testing industry and responds to individual customer needs. Manages national and state level accounts. Curriculum vitae provided in the Attachment Section.
8. Mary Tardel (Name) Government Sales Manager (Title) (Proposed Role/Function)	Government Sales Manager for RTL for over four years. Mary responds to bids and proposals and coordinates contract roll-outs. She ensures consistency and accuracy on all contracted client accounts to ensure that all contract specifications are met in a timely fashion. Curriculum vitae provided in the Attachment Section.

All of the personnel listed above are experienced in the performance of drug testing services for national, state and county-level accounts. Many senior management staff have been with the lab since its inception. All senior managers have at least 25 years of experience in their fields.

The RTL management and operations team has been together over 20 years. Laboratory Directors are pathologists certified by the American Board of Pathology and have over 80 combined years of forensic experience. Certifying scientists are doctorate and master's level toxicologists with extensive forensic toxicology experience. All senior testing personnel have a bachelor's degree at minimum. Curriculums Vitae of personnel providing laboratory and support services are included for review and are include in the Attachment Section. All of the following staff members may be reached during normal business hours at (800) 255-2159.
In addition, there are four medical technologists licensed by the state of California (Clinical Laboratory Scientists), each with over 32 years of laboratory experience. Employment time with RTL ranges from eight years to several months. There are 31 laboratory technicians with experience ranging from several months to 25 years. Some have been employed since the inception of the laboratory in 1994 and others are recent hires. RTL undergoes stringent training practices with all lab technicians.

A Client Services staff of over six personnel is available to the State of Missouri Drug Courts during RTL's normal business hours of 6:30 a.m. to 4:30 p.m., PST, Monday through Friday. Client Services representatives and toxicology experts are available for consultation on issues such as; proper device usage, cut-off levels, specimen collection, test procedures, results interpretations, drug interactions, street names, retention/detection times and expert witness services. Simply call our toll-free hotline at (800) 255-2159.

OSCA 11-029-00 Drug/Alcohol Testing Equipment & Services

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: **Redwood Toxicology Laboratory, Inc.**	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Lafourche Parish Drug Treatment Court
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	Lafourche Parish Drug Treatment Court P.O. Box 649 Thibodaux, LA 70302
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Mr. Fred Duplechin 985-446-1970 administrator@lpdtc.org
Dates of Prior Services:	Customer with Redwood Lab since 2000
Dollar Value of Prior Services:	$138,614.24 (2009 to present)
Description of Prior Services Performed:	Lab Testing for Drugs of Abuse

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

Signature of Reference Contact Person

2/9/11
Date of Signature

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: **Redwood Toxicology Laboratory, Inc.**

Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Rock Island County Court Services
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	2116 25th Avenue Rock Island, IL 61201
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Mr. Trent Vandersnick (309) 558-3723 tvanders@co.rock-island.il.us
Dates of Prior Services:	07/21/2000 – Present
Dollar Value of Prior Services:	$10,557.02 LTM
Description of Prior Services Performed:	Laboratory screens, confirmations, and instant UA tests.

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

Signature of Reference Contact Person

Date of 2-9-11

Signature

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: **Redwood Toxicology Laboratory, Inc.**	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Stone County Drug Courts
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	110 South Maple, Suite F Galena, MO 65656
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Mr. Shawn Billings (302) 892-4521 Shawn.billings@courts.mo.gov
Dates of Prior Services:	2008 to present
Dollar Value of Prior Services:	$24,019.14
Description of Prior Services Performed:	Urinalysis laboratory services and instant on-site devices

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

Signature of Reference Contact Person

2/9/2011

Date of Signature

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: Redwood Toxicology Laboratory, Inc.	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Lubbock County CSCD
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	701 Main Street, Lubbock, TX 79401
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Mr. Tom Madigan 806-775-1211 Tom.madigan@lubbockcscd.com
Dates of Prior Services:	Customer with Redwood Lab since 2005
Dollar Value of Prior Services:	$60,000.00
Description of Prior Services Performed:	Lab Testing for Drugs of Abuse

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

Thomas Madigan
Signature of Reference Contact Person

2/9/11
Date of Signature

EXHIBIT A

OFFEROR INFORMATION

The offeror should provide the following information about the offeror's organization:

a. Vendor Information – The vendor should provide information about the vendor's organization:

Redwood Toxicology Laboratory, Inc. (RTL) was incorporated in the State of California in May of 1994. For over 12 years, RTL has provided millions of drug tests to thousands of agencies across the United States. RTL is federally certified (CLIA) through the Department of Health and Human Services. Albert Berger actively runs the company in the capacity of General Manager. Wayne Ross, Chief Toxicologist, has been with RTL since the company's inception. Most members of RTL's senior management team have worked together for over 15 years. All told, RTL's executive team has over 80 years of combined experience. Employing over 200 people, RTL services thousands of clients, including correctional, probation and parole, police and sheriff, medical facilities and employment agencies. A number of our over 7,000 clients have utilized the laboratory's services in excess of fourteen years. RTL is the incumbent provider of Drug/Alcohol Testing Equipment & Services to the Office of State Courts Administrator. This experience enables RTL to respond to this bid with an excellent understanding of the purpose and objectives of your agencies.

Certification

RTL is licensed and accredited by the following federal and state agencies:

- Department of Health and Human Services CLIA'88 ID# 05DO707588
- California Department of Health Services Clinical Laboratory License No.05DO70758
- DEA License Number RR0340113-Analytical Laboratory
- Florida Clinical Laboratory License #L800010955
- Pennsylvania Clinical Laboratory Permit #025348
- Maryland Medical Laboratory Permit #880

Copies of RTL's licensure are included in the Laboratory Overview and Licensure Tab.

Proficiency Testing

RTL subscribes to the American Association of Bioanalysts and the Pennsylvania State Department of Health's proficiency testing services. Each agency sends samples three times a year that are graded and all testing outcomes, since the inception of the laboratory, have been successful.

RTL is also a corporate member of the Drug and Alcohol Testing Industry Association (DATIA). Five staff members at RTL are Certified Professional Collectors.

b. Describe the nature of the offeror's business, type of services performed, etc.

Redwood Toxicology Laboratory, Inc. (RTL), located in Santa Rosa, California, is a federally certified laboratory specializing in low-cost, rapid turnaround drug testing. We provide instant, on-site drug screening products, as well as, having the capability of detecting drugs of abuse in oral fluids. RTL also provides testing for ethyl glucuronide (EtG) in urine and recently began steroid testing.

Laboratory Services

- *Urine Testing* for Drugs of Abuse and Alcohol
  The industry's preferred lab for your drug testing needs. Quick and accurate results.

- *Ethyl Glucuronide (EtG) Testing* for Alcohol Metabolite
  Detect alcohol up to 80 hours after use. Perfect for zero tolerance situations.

- *Oral Fluid Testing* for Drugs of Abuse
  An easy and gender neutral way to determine recent drugs of abuse usage.

- *Steroid Testing*
  A comprehensive steroid panel. Good for schools, corrections and health agencies.

On-Site Screening Devices

- *RediCup® Substance Abuse Test Device*
  Test up to 10 drugs with no exposure to urine with our patented cup device.

- *Panel-Dip Substance Abuse Test Device*
  An affordable way to test up to 13 different drugs with results within 3 to 5 minutes.

- *On-Site Oral Substance Abuse Test Device*
  Easy to use and gender-neutral oral fluid device tests six drugs in less than 10 minutes.

- *Instant Alcohol Saliva Test Strips*
  Detect the presence of alcohol in saliva at a concentration greater than 0.02%.

- *Integrated Cups – Substance Abuse Test Device*
  Test up to ten drugs and adulterants in a cup device with no exposure to urine.

- *Reditest® Cassette – CLIA Waived*
  A quick way to test six drugs in a CLIA waived (CPT Code 80100QW) cassette device.

- *Reditest® Smoke Cotinine Test Device*
  Detect the presence of cotinine (nicotine metabolite) in urine at 200 ng/mL.

- *Adulteration Strips One Step Validity Test*
  Screen for creatinine, nitrite, glutaraldehyde, pH, specific gravity and oxidants.

RTL offers numerous advantages to the State of Missouri Drug Courts, including:

- Extensive experience in performing forensic toxicology analyses for drugs of abuse;
- Highly qualified scientific staff;
- Urine-based on-site screening devices are FDA 510(k) cleared to market;
- Currently providing services to hundreds of probation and drug court agencies;
- Expert witness services and litigation packages available upon request;
- Excellent track record for outstanding client service and adaptation to client needs; and,
- Extensive quality assurance and quality control procedures to ensure accurate results reporting and the maintenance of excellence in customer service.

Please refer to Section a. above for a detailed list of RTL's products and services.

c. Provide a list of and a short summary of information regarding the offeror's current contracts/clients. List, identify, and provide reasons for each contract/client gained and lost in the past 2 years.

The following device contracts were gained in the past two years:

Washington County, Oregon. RTL was awarded this bid in September 2010 for Rapid On-Site Drug Screening Devices based on competitive pricing.

Hidalgo County, Texas. RTL was awarded this bid in September 2010 for Instant Drug Screening Cups based on competitive pricing and ability to meet delivery requirements.

Region 5 Education Service Center, Texas. RTL was awarded this Cooperative Purchasing Agreement for Drug Testing/Identification Supplies and Services based on competitive pricing and ability to offer members of the Cooperative a drug testing program to meet each agency's needs.

Washington County, Pennsylvania. RTL was awarded this bid in December 2010 for Instant Test Kits and Laboratory Services based on competitive pricing.

State of Vermont, Purchasing & Contract Administration. RTL provides instant, on-site drug screening devices to Vermont state agencies. Clients include correctional facilities, probation and mental health agencies.

State of Utah. The current contract is to provide instant, on-site drug screening devices to State of Utah agencies. Clients include Drug Courts, Probation and Corrections.

The following contracts for laboratory services were gained in the past two years.

Lubbock County, Texas. RTL was awarded this bid for Drug Screening Services in October 2010.

State of Indiana, Department of Corrections. RTL was awarded this bid in November 2010 for Laboratory Services based on competitive pricing, and RTL's ability to provide custom IT solutions to the DOC for their unique IT Enterprise Architecture Requirements.

State of Missouri Drug Courts. RTL was awarded the bid for Drug/Alcohol Testing Equipment & Services in August 2010.

San Bernardino County Probation & Behavioral Health Departments, California. This contract encompasses urinalysis, oral fluid lab testing, as well as on-site drug testing devices. All purchasing for drug testing services and supplies was combined into one county-wide contract. Probation and Behavioral Health both benefit from RTL's services and pricing.

Kane County, Illinois. RTL was awarded this business during a competitive bidding process. Kane County is extremely satisfied with RTL's services. Currently, RTL is providing urine drug testing to Kane County Probation and Drug Court agencies.

Orange County Probation, California. This contract was awarded to provide oral fluid and urine drug testing services to the County. Orange County is a satisfied client and has used RTL for over 4 years through two separate bidding situations.

The following contracts were lost in the past two years.

Medina County Probation, Ohio. RTL lost this bid as result of not being the lowest cost provider of services.

Anne Arundel County, Maryland. RTL lost this client because it was not the low price bidder during the RFP selection process.

Greater Erie Community Action Committee, Pennsylvania. RTL lost this client because it was not the low price bidder during the RFP selection process.

Oklahoma County, Oklahoma. RTL lost this client because it was not the low price bidder during the RFP selection process.

Client references are provided in Exhibit B. Additional references are provided upon request.

d. Describe the structure of the organization including any board of directors, partners, top departmental management, corporate organization, corporate trade affiliations, any parent/subsidiary affiliations with other firms, etc.

Redwood Toxicology Laboratory, Inc. is wholly owned by Alere, Inc. 51 Sawyer Road, Waltham, MA 02453.

The corporate structure is as follows:

Board of Directors:
John Bridgen
David Teitel
Carla Flakne
Robert Mount
Ellen Chiniara
Anne Warner
Jay McNamara
Barry Chapman
Albert Berger

Senior Management:
John Bridgen, President
David Teitel, Vice President Finance
Robert Mount, Vice President
Ellen Chiniara, Secretary
Albert Berger, General Manager
Wayne Ross, Chief Toxicologist
Suzanne Bertolucci, Director of Sales
Barry Chapman, Chief Financial Officer

A copy of RTL's organizational chart is included in the Attachment Section.

a. Provide a list summarizing pending litigation, any civil or criminal judgments, any bankruptcy proceedings, etc., that could affect the offeror's ability to perform. Failure to list such litigation may result in rejection of the proposal or in termination of any subsequent contract.

Redwood Toxicology Laboratory does not have any pending litigation, civil or criminal judgments or bankruptcy proceedings that could affect RTL's ability to perform.

b. Document the offeror's financial solvency in a manner that is acceptable for public review. Audited financial statements for the last year will provide such documentation; however, the statements will become public information. If the offeror is a subsidiary, also provide the documentation for the parent company.

A copy of Alere Inc.'s 2009 Annual Report is included at the end of Exhibit A.

OFFICE OF STATE COURTS ADMINISTRATOR
P.O. Box 104480
2112 Industrial Drive
Jefferson City, MO 65110-4480

RFP NO. OSCA 11-029-00
TITLE: Drug/Alcohol Testing Equipment & Services
ISSUE DATE: January 6, 2011

CONTACT: Russell Rottmann
PHONE NO.: (573) 522-6766
E-MAIL: osca.contracts@courts.mo.gov

RETURN PROPOSAL NO LATER THAN: February 10, 2011 AT 5:00 PM

MAILING INSTRUCTIONS: Print or type **RFP Number** and **Return Due Date** on the lower left hand corner of the envelope or package.

RETURN PROPOSAL TO:

(U.S. Mail)
Office of State Courts Administrator
Contracts Unit
PO Box 104480
Jefferson City Mo 65110 - 4480

or

(Courier Service)
Office of State Courts Administrator
Contracts Unit
2112 Industrial Dr
Jefferson City Mo 65109

CONTRACT PERIOD: JULY 1, 2011 THROUGH JUNE 30, 2012

DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:

MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI

The vendor hereby declares understanding, agreement and certification of compliance to provide the items and/or services, at the prices quoted, in accordance with all requirements and specifications contained herein and the Terms and Conditions Request for Proposal. The vendor further agrees that the language of this RFP shall govern in the event of a conflict with his/her proposal. The vendor further agrees that upon receipt of an authorized purchase order from the Office of State Courts Administrator or when this RFP is countersigned by an authorized official of the Office of State Courts Administrator, a binding contract shall exist between the vendor and the Office of State Courts Administrator.

SIGNATURE REQUIRED

AUTHORIZED SIGNATURE		DATE
PRINTED NAME		TITLE
COMPANY NAME		
MAILING ADDRESS		
CITY, STATE, ZIP		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO.
PHONE NO.	FAX NO.	E-MAIL ADDRESS

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS:		
CONTRACT NO.	CONTRACT PERIOD	
CONTACTS COORDINATOR	DATE	STATE COURTS ADMINISTRATOR

1. INTRODUCTION AND GENERAL INFORMATION

Introduction

This document constitutes a request for sealed proposals from vendors for the establishment of a Qualified Vendor List for drug testing equipment and services for the State of Missouri Treatment Courts. Contracts established as a result of this request for proposal shall be used on an as needed, if needed basis.

The qualified vendor list will allow the local treatment courts to select any contracted vendor that provides services in their county. While prices are established during this process, they are not used during the evaluation process to determine if a vendor is qualified. Once contracts are awarded, the selection of which vendor and services needed are determined by the local treatment courts.

Contracts established as a result of this RFP will be effective July 1, 2011 and will replace existing contracts with OSCA, numbers OSCA 08-005-XX.

The Office of State Courts Administrator, hereafter shall be referred to as "OSCA", anticipates awarding multiple contracts as a result of this RFP. OSCA makes no commitments or guarantees as to the quantity of products or services that may be requested or required once the contracts are awarded.

Background Information

The first drug court in Missouri began in Jackson County in 1993. It was one of the first twelve operational Treatment Courts in the United States. Later, other jurisdictions in Missouri began exploring the idea of Treatment Courts. In April 1998, Office of States Court Administrator staff created the Missouri Resource Manual for the Development and Implementation of Drug Courts. Following the development of the Missouri Association of Drug Court Professionals, drug courts were implemented in many courts in the state.

Statewide drug court coordination occurred with passage of House Bill 471 in 2001, which created the Drug Courts Coordinating Commission (hereafter referred to as DCCC). Specifically, 478.099 RSMo states that the DCCC is to "evaluate resources available for assessment and treatment of persons assigned to drug courts or for operation of drug courts; secure grants, funds and other property and services necessary or desirable to facilitate drug court operation; and allocate such resources among various drug courts operating within the state." The legislation also established a drug court resources fund to be administered by the DCCC. In cooperation with the DCCC staff, OSCA provides technical support to the commission for fiscal and contract administration.

OSCA is establishing contracts for treatment courts throughout Missouri to provide drug testing equipment and/or services addressed by this RFP. The types of treatment courts are Adult Drug Court, Juvenile Drug Court, Family Drug Court, Reintegration Court, Veterans Court and DWI Court**.**

Pre-Proposal Conference

A pre-proposal conference regarding this Request for Proposal will be held on January 24, 2011, at 1:30 p.m., in Conference Room A of the Alameda Building, 121 Alameda Drive, Judicial Education Center, Jefferson City, Missouri 65109. It is anticipated that the conference duration will be approximately two (2) hours. **Vendors may dial into the pre-proposal conference by using the toll free number 866-630-9348, or if in Jefferson City, please use the local number 526-5622. The line will be open beginning at 1:15 p.m.**

All potential vendors are encouraged to attend the pre-proposal conference either in person or telephonically in order to ask questions and provide comments on the RFP. Attendance is not required in order to submit a response; however, vendors are encouraged to participate since information relating to this RFP will be discussed in detail. The RFP will be used as the agenda for the pre-proposal conference.

Vendors are strongly encouraged to advise OSCA within five (5) working days prior to the scheduled pre-proposal conference of any special accommodations needed for persons with disabilities who will be attending the conference so the accommodations can be met.

Vendors are encouraged to submit in writing, their questions regarding the RFP prior to the pre-proposal conference to: Russell Rottmann, at osca.contracts@courts.mo.gov or by facsimile to (573) 522-6937. Response to the questions during the pre-proposal conference is contingent upon when the questions are received.

It shall be the vendor's responsibility to ask questions, request changes or clarification, or otherwise advise OSCA if any language, specifications or requirements of an RFP appear to be ambiguous, contradictory, and/or arbitrary, or appear to inadvertently restrict or limit the requirements stated in the RFP to a single source. Any and all communication from vendors regarding specifications, requirements, competitive proposal process, etc., must be directed to the buyer of record, unless the RFP specifically refers the vendor to another contact. Such communication should be received at least ten calendar days prior to the official proposal response date.

Every attempt shall be made to ensure that the vendor receives an adequate and prompt response. However, in order to maintain a fair and equitable procurement process, all vendors will be advised, via the issuance of an amendment to the RFP, of any relevant or pertinent information related to the procurement. Therefore, vendors are advised that unless specified elsewhere in the RFP, any questions received less than ten calendar days prior to the RFP opening date may not be answered.

Vendors are cautioned that the only official position of OSCA is that which is issued in the RFP or an amendment thereto. No other means of communication, whether oral or written, shall be construed as a formal or official response or statement.

OSCA monitors all procurement activities to detect any possibility of deliberate restraint of competition, collusion among vendors, price-fixing by vendors, or any other anticompetitive conduct by vendors which appears to violate state and federal antitrust laws. Any suspected violation shall be referred to the Missouri Attorney General's Office for appropriate action.

OSCA reserves the right to officially amend or cancel an RFP after issuance.

All specifications and requirements constitute minimum requirements, unless otherwise specifically stated in the RFP,. All proposals must meet or exceed the stated specifications and requirements.

Unless otherwise specifically stated in the RFP, any manufacturer's names, trade names, brand names, information and/or catalog numbers listed in a specification and/or requirement are for informational purposes only and are not intended to limit competition. The vendor may offer any brand which meets or exceeds the specification for any item, but must state the manufacturer's name and model number for any such brands in the proposal. The vendor shall explain, in detail, (1) the reasons why the proposed equivalent meets or exceeds the specifications and/or requirements and (2) why the proposed equivalent should not be considered an exception thereto. Proposals which do not comply with the requirements and specifications are subject to rejection without clarification.

Definitions

Amendment means a written, official modification to an RFP or to a contract.

Vendor means the person or organization that responds to an RFP by submitting a proposal with prices to provide the equipment, services, supplies, and/or services as required in the RFP document.

May means that a certain feature, component, of action is permissible, but not required.

Must means that a certain feature, component, or action is a mandatory condition. Failure to provide or comply will result in a proposal being considered non-responsive.

Will and shall have the same meaning as the word must.

Should means that a certain feature, component, and/or action is desirable but not mandatory

TITLES - Titles of paragraphs used herein are for the purpose of facilitating reference only and shall not be construed to infer a contractual construction of language.

2.0 PERFORMANCE REQUIREMENTS

General Requirements:
The contractor shall provide alcohol and drug testing products and/or related services for OSCA and the various Treatment Courts of the Missouri Judiciary in accordance with the provisions and requirements stated herein.

a. All testing services must be performed in accordance with industry standards or by following the local Treatment Court's internal policy/procedure.

All testing devices must be previously approved by the U.S. Food and Drug Administration (FDA) for commercial distribution as a medical device. The contractor must provide a copy of the active FDA 510K-notification document.

The contractor shall agree and understand that contracts established as a result of this RFP shall not be construed as an exclusive arrangement. If it is in the best interest of OSCA and/or the Treatment Court, alternate products and/or services may be obtained elsewhere.

The contractor shall comply with all confidentiality requirements established by state statute, the Treatment Court or as otherwise stated herein. The contractor shall release the results of testing only to the Treatment Court contact or as otherwise instructed by the Treatment Court Judge or Court Administrator.

The contractor shall provide the required products and/or services on an as needed, if needed, basis as requested by the Treatment Court.

OSCA makes no commitments or guarantees as to the quantity of the testing or laboratory tests that may be required.

The contractor shall understand and agree that any information, record, report, or data derived, compiled, obtained, prepared, or developed by the contractor from services performed pursuant to the contract shall not be released, disseminated, or otherwise disclosed without prior written consent from OSCA.

The contractor and/or the contractor's subcontractor(s) shall deliver products to OSCA or the local treatment court upon receipt of an authorized order. All deliveries must be coordinated with the court placing the order.

If it is deemed by OSCA to be in the best interest of the Treatment Court, OSCA may add additional items to the contract as long it is mutually acceptable to both the contractor and OSCA.

Training & Support
Training Materials: The contractor must provide training materials for end users on the proper use of testing devices to achieve accurate test results. Training may be in various forms such as video, DVD or webinar for each treatment court at no additional cost to the State of Missouri. The training shall include, but not be limited to, basic drug testing training and training on current drug testing issues such as sample tampering, passive inhalation, drug detection periods and drug cross-reactivity's.

Technical Support: The contractor must be able to provide technical support Monday through Friday 7:00 AM to 7:00 PM Central Time Zone, excluding U.S. holidays, at no additional cost to the State of Missouri.

Manufacturer's Legal Support: The contractor must be able to provide manufacturer's legal support should the testing devices identified herein be challenged in court at no additional cost to the State of Missouri.

Accreditation
The contractor must comply with all state laws concerning licensing, accreditation, and regulations and must meet the following accreditation requirements and provide documentation of such credentials.

- The contractor must be Substance Abuse and Mental Health Services Administration (SAMHSA) or Clinical Laboratory Improvement Act (CLIA) certified**.**

- The contractor must be approved by the Commission on Inspection and Accreditation of the College of American Pathologists or Certified by the American Association of Bioanalyst.

- If the contractor is a hospital, the hospital must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The hospital laboratory must be licensed to operate in interstate commerce by the U.S. Department of Health and Human Services under the Clinical Laboratory Improvement Act (CLIA).

- If the contractor is an independent reference laboratory, the contractor must meet CLIA license requirements. In addition, the contractor should be approved by Medicare to provide medial laboratory services.

The contractor shall understand and agree that any information, record, report, or data derived, compiled, obtained, prepared, or developed by the contractor from services performed pursuant to the contract shall not be released, disseminated, or otherwise disclosed without prior written consent of OSCA.

On-Site Drug Testing Kits Non-Instrument Based Immunoassay (both urine and saliva):
The contractor must be able to provide testing devices in both single and multi-drug combinations. At a minimum, these drug tests must be available for the following drugs: Amphetamines, Methamphetamines, Cocaine, Opiates, Phencyclidine (PCP), THC (cannabinoids), Methadone, Barbiturates, Benzodiazepines, Oxycodone, propoxyphene, synthetic cannabinoids and MDMA (Ecstasy). Testing for additional items may be requested during the contract period. If requested, pricing shall be mutually agreed upon between the contractor and OSCA.

Each kit shall contain all elements necessary to complete the test in the field..

Test shall not require electricity, special plumbing, instrumentation, calibration, laboratory environment or refrigeration of reagents. The kits must be able to be stored at room temperature.

All test kits shall have an expiration date clearly marked. Any kits received with an expiration date less than 12 months from date of receipt, will be rejected at the contractor's expense.

The test kits must be self contained, completely portable and packaged for field use.

The testing devices must follow the current Substance Abuse and Mental Health Services Administration's (SAMHSA) cut-off levels for detection of positive drug screens, except for Opiates which must have both 2000 ng/ml and 300 ng/ml cut-off levels and Benzodiazepines and Barbiturates which must have a 300 ng/ml cut-off level available and thus defensible by gas chromatograph/mass spectrometer (GC/MS) confirmatory cut-off levels.

Urinalysis kits
The multi-drug test kits for urinalysis shall include the collection cup with an ID label and temperature strip, a tamper evident seal for maintaining chain of custody, and a bag for the easy, clean disposal of a urine sample once testing is complete.

The testing devices must not require any pretreatment of the urine sample prior to testing and must be able to be test the sample immediately upon collection. The tests must not require the samples to reach room temperature unless it has been refrigerated. The tests must not be affected by abnormal pH levels.

The testing devices shall have a low volume procedure, which may require pipetting of a sample, for cases when a donor sample is less than 5mls of urine.

The testing devices must have an indicator/control line prompting the user when to interpret results and must not require the use of a stopwatch or timing device.

The testing devices must be available for reading results in seven (7) minutes or less.

The test results must be stable for a minimum of thirty (30) minutes.

The test results must be easy to read with test result interpretation of positive or negative clearly defined on the device.

The testing devices must be highly accurate and reliable with performance data comparable to gas chromatograph/mass spectrometer (GC/MS) testing.

The testing devices shall minimize false positive results caused by over-the-counter medications.

The test results must be able to be photocopied or scanned creating either a paper or an electronic permanent file copy for retention.

Testing Service Requirements:
The contractor shall, if requested by the Treatment Court, develop and administer procedures and protocols for random drug and alcohol testing.

The contractor shall maintain proper chain of custody procedures.

The contractor may provide a facility for urine sample collection to ensure that all samples collected are fully observed to assure that no apparatus utilized by the participant to negate the results of a drug test goes undetected.

The contractor shall, if requested by the Treatment Court, develop and provide a system to select individuals for testing, conduct the test, notify appropriate authorities regarding test results, and otherwise operate the random testing system in a manner that complies with the requirements of the Treatment Court.

The contractor shall provide routine courier pick-up of urine analysis samples within 24 hours of a Treatment Court drop call.

The contractor shall provide urine analysis results to the Treatment Court within 24 hours of pick-up.

The contractor shall assure for all test readings, the cutoff levels are set at sufficient level to minimize false positive readings. The contractor shall work with the courts to ensure the cutoff levels are set in accordance with industry standard to prevent false positive results.

Quality Review: The contractor shall understand and agree that the accuracy of the contractor's laboratory test findings may be subject to outside laboratory verification at the Treatment Court's discretion.

a. The treatment court shall be responsible for any costs associated with verification of test results.

b. In the event the treatment court determines by verification, the results of the contractor's testing services are inaccurate or unreliable, the contract may be canceled without further cost to the courts in accordance with the applicable provisions and requirements stated herein.

Transportation of Specimens:
The vendor shall provide the Treatment Court with all necessary equipment and supplies for the specimens to be extracted and safely transported from the Treatment Court to the contractor.

a. Such equipment and supplies shall include, but not necessarily be limited to: collection and shipping apparatus, needles, syringes, tubes, labels, urine specimen cups, culture tubes, slides, reagents, and instructions necessary for submission and shipment of laboratory specimens to the contractor's laboratory.

b. All collection and shipping apparatus must be approved by the Treatment Court and meet industry quality control standards.

c. Chain of custody forms shall be provided.

The contractor must maintain specimens in proper condition while being transported in order to ensure accuracy of test performed.

Testing Service Result Reporting:
The contractor must provide test result reports to the Treatment Court, at a minimum with the following information:

- The client's full name,
- Test results,
- Range of normal,
- Indication of abnormal levels/values,
- Chart number,
- Treatment Court type/location,
- Date of specimen collection,
- Date of specimen testing, and
- Date of test result reporting.

Prior to reporting test results to the Treatment Court, the contractor must have a supervisor review the test results and verify that quality control procedures were employed to ensure the accuracy of test results.

The contractor must submit test results to the treatment court, via electronic transmission, within 24 hours following receipt of the specimen unless, according to standard laboratory procedures, more time is required for a specific test because of test complexity. In such instance, test results must be reported to the treatment court promptly upon test completion. The contractor must notify the treatment court if test results cannot be reported within 24 hours.

If requested by the treatment court, **the vendor may report test results by telephone to be followed by either electronic or hard copy.**

Test Order Forms and Billing Forms:
The contractor must provide the Treatment Court with order forms for test kits and/or testing services which must, at a minimum, be formatted as follows:

a. Sufficient space at the top for an addressograph stamp, enabling the Treatment Court to provide client identification including client's full name and chart number;

b. Spaces to accommodate Treatment Court type/location, date ordered, date of specimen collection, time of specimen collection, physician's name, and diagnosis code;

c. A section to record the Treatment Court telephone number, extension; and name of individual designated to receive results;

d. Sufficient number of pages to enable the Treatment Court to retain two (2) copies, and any additional pages the contractor deems necessary to accommodate the contractor's internal needs;

e. The forms must be non-carbon and the subsequent pages must be legible to read.

f. Must be coded to indicate specimen requirements.

Electronic Alcohol Monitoring

Contractor shall provide a service, to include all necessary equipment, for electronic alcohol monitoring of approved court participants. The system shall use web-based software to allow remote electronic monitoring and supervision. The monitoring may be offered in a variety of options. The following are approved systems for this purpose:

- In-home breath alcohol testing sytems – such as iSecure Trac or Smart Start
- transdermal alcohol monitoring – such as SCRAM or Transdermal Alcohol Detector (TAD)

Any system proposed shall have a proprietary secure web-based software to allow random monitoring of participant.

Alcohol testing shall be accurate to within +/- .005% of actual blood alcohol levels and be acceptable as court admissible evidence. Results generated by the system shall stand on their own without secondary or backup testing needed. All systems shall meet the Daubert standard of scientific evidence admissibility.

3.0 CONTRACTUAL REQUIREMENTS

Contract
A binding contract shall consist of: (1) the RFP, amendments thereto, and any Best and Final Offer (BAFO) request(s) with RFP changes/additions, (2) the vendor's proposal including any vendor BAFO response(s), (3) clarification of the proposal, if any, and (4) OSCA acceptance of the proposal by "notice of award". All Exhibits and Attachments included in the RFP shall be incorporated into the contract by reference.

a. A notice of award issued by OSCA does not constitute an authorization for shipment of equipment or supplies or a directive to proceed with services. Before providing equipment, supplies and/or services for OSCA or the Treatment Courts, the vendor must receive an authorized order.

b. The contract expresses the complete agreement of the parties and performance shall be governed solely by the specifications and requirements contained therein.

c. Any change to the contract, whether by modification and/or supplementation, must be accomplished by a formal contract amendment signed and approved by and between the duly authorized representative of the vendor and OSCA. The vendor expressly and explicitly understands and agrees that no other method and/or no other document, including correspondence, acts, and oral communications by or from any person, shall be used or construed as an amendment or modification to the contract.

Contract Period:
The original contract period shall be as stated on the cover page of the Request for Proposal (RFP). The contract shall not bind, nor purport to bind, the state for any contractual commitment in excess of the original contract period.

Renewal Options:
OSCA shall have the right, at its sole option, to renew the contract for five (5) additional one-year periods or any portion thereof. In the event OSCA exercises such right, all terms and conditions, requirements and specifications of the contract shall remain the same and apply during the renewal period, pursuant to applicable option clauses of this document. Prices for each renewal shall be mutually agreed to by both vendor and OSCA.

OSCA does not automatically exercise its option for renewal and reserves the right to offer or to request renewal of the contract at a price less than quoted.

Price:
All prices shall be as indicated on the Pricing Page. OSCA shall not pay nor be liable for any other additional costs including but not limited to taxes, shipping charges, insurance, interest, penalties, termination payments, attorney fees, liquidated damages, etc.

Prices offered shall remain valid for 90 days from proposal opening unless otherwise indicated. If the proposal is accepted, prices shall be firm for the specified contract period.

Invoicing and Payment Requirements:
Immediately upon award of the contract, the vendor needs to submit or must have already submitted a properly completed State Vendor ACH/EFT Application. It is the vendor's responsibility to insure the information is current. OSCA intends to make all contract payments through the use of Electronic Funds Transfer.

a. If not already submitted, the vendor needs to obtain a copy of the State Vendor ACH/EFT Application and completion instructions from the Internet at: http://www.oa.mo.gov/purch/vendorinfo/vendorach.pdf

b. The vendor must submit invoices on the vendor's original descriptive business invoice form and must use a unique invoice number with each invoice submitted. The unique invoice number will be listed on the State of Missouri's EFT addendum record to enable the vendor to properly apply the Treatment Court payment to the invoice submitted.

After acceptance and approval of the vendor's services and after receipt of a properly itemized invoice and required documentation, the Treatment Court shall pay the vendor in accordance with the approved invoice.

The State of Missouri does not pay state or federal taxes unless otherwise required under law or regulation.

Laboratory Tests:
For any laboratory tests provided and reported where the test is listed by the vendor on the Pricing Page, the vendor shall invoice in accordance with the firm, fixed price per test stated on the Pricing Page(s). **The vendor shall not be paid by the Treatment Court more than the firm, fixed price per test stated on the Pricing Page(s).**

Termination:
OSCA reserves the right to terminate the contract at any time for convenience, without penalty or recourse, by giving written notice to the vendor at least thirty (30) calendar days prior to the effective date of such termination. The vendor shall be entitled to receive just and equitable compensation for services and/or supplies delivered to and accepted by the Treatment Courts pursuant to the contract prior to the effective date of termination.

Transition:
Upon award of the contract, the vendor shall work with the Treatment Courts and any other organizations designated by the Treatment Courts to ensure an orderly transition of services and responsibilities under the contract and to ensure the continuity of those services required by the courts.

Upon expiration, termination, or cancellation of the contract, the shall assist the Treatment Courts to ensure an orderly transfer of responsibility and/or the continuity of those services required under the terms of the contract to an organization designated by OSCA, if requested in writing. The vendor shall provide and/or perform any or all of the following responsibilities:

a. The vendor shall deliver, FOB destination, all records, documentation, reports, data, recommendations, or printing elements, etc., which were required to be produced under the terms of the contract to the Treatment Court and/or to the Treatment Court designee within seven (7) days after receipt of the written request in a format and condition that are acceptable to OSCA.

b. The vendor shall agree to continue providing any part or all of the services in accordance with the terms and conditions, requirements and specifications of the contract for a period not to exceed thirty (30) calendar days after the expiration, termination or cancellation date of the contract for a price not to exceed those prices set forth in the contract.

c. The vendor shall discontinue providing service or accepting new assignments under the terms of the contract, on the date specified by OSCA, in order to ensure the completion of such service prior to the expiration of the contract.

Liquidated Damages
Liquidated Damages - The vendor shall agree and understand that the provision of the medical laboratory services in accordance with the requirements and delivery schedules stated is considered critical to the efficient operations of the Treatment Court. However, since the amount of actual damages would be difficult to establish in the event the vendor fails to comply with the requirements and delivery schedules, the vendor shall agree and understand that the amount identified below as liquidated damages shall be reasonable and fair under the circumstances.

a. In the event that the vendor fails to report any specimen's test results within the timeframe required herein, the vendor shall be assessed liquidated damages in the amount of $50.00 per day for each twenty-four (24) hour period thereafter in which the identified requirement is not completed, unless the sample is positive. If the sample is positive, the lab is hereby allotted an additional 48 hours to confirm the tests levels are GC/MS confirmed.

No Actions, Suits, or Proceedings:
The vendor warrants that there are no actions, suits, or proceedings, pending or threatened, that will have a material adverse effect on the vendor's ability to fulfill its obligations under this contract. The vendor further warrants that it will notify the State of Missouri immediately if the vendor becomes aware of any action, suit, or proceeding, pending or threatened, that will have a material adverse effect on vendor's ability to fulfill the obligations under this contract.

Warranty of Vendor
The vendor warrants that it is financially capable of fulfilling all requirements of this contract, that there are no legal proceedings against it that could threaten performance of this contract, and that the vendor is a validly organized entity that has the authority to enter into this contract. The vendor is not prohibited by any loan, contract, financing arrangement, trade covenant, or similar restriction from entering into this contract.

The vendor hereby covenants that at the time of the submission of the proposal the vendor has no other contractual relationships which would create any actual or perceived conflict of interest. The vendor further agrees that during the term of the contract neither the vendor nor any of its employees shall acquire any other contractual relationships which create such a conflict.

Insurance:
The vendor shall understand and agree that the State of Missouri cannot save and hold harmless and/or indemnify the vendor or employees against any liability incurred or arising as a result of any activity of the vendor or any activity of the vendor's employees related to the vendor's performance under the contract.

Therefore, the vendor must acquire and maintain adequate liability insurance in the form(s) and amount(s) sufficient to protect the State of Missouri, its agencies, its employees, its clients, and the general public against any such loss, damage and/or expense related to his/her performance under the contract. The insurance coverage shall include general liability and appropriate professional liability. Written evidence of the insurance shall be provided by the vendor to the state agency. The evidence of insurance shall include, but shall not necessarily be limited to: effective dates of coverage, limits of liability, insurer's name, policy number, endorsement by representatives of the insurance company, etc. Evidence of self-insurance coverage or of another alternative risk financing mechanism may be utilized provided that such coverage is verifiable and irrevocably reliable. The evidence of insurance coverage must be submitted before or upon award of the contract. In the event the insurance coverage is canceled, the state agency must be notified immediately.

Vendor Liability
The vendor shall be responsible for any and all personal injury (including death) or property damage as a result of the vendor's negligence involving any equipment or service provided under the terms and conditions, requirements and specifications of the contract. In addition, the vendor assumes the obligation to save OSCA, including its agencies, employees, and assignees, from every expense, liability, or payment arising out of such negligent act. The vendor also agrees to hold the State of Missouri, including its agencies, employees, and assignees, harmless for any negligent act or

omission committed by any subcontractor or other person employed by or under the supervision of the vendor under the terms of the contract. The vendor shall not be responsible for any injury or damage occurring as a result of any negligent act or omission committed by the State of Missouri, including its agencies, employees, and assignees. Under no circumstances shall the vendor be liable for any of the following: (1) third party claims against the state for losses or damages (other than those listed above); or (2) economic consequential damages (including lost profits or savings) or incidental damages, even if the vendor is informed of their possibility.

Business Compliance
The vendor must be in compliance with the laws regarding conducting business in the State of Missouri. The vendor certifies by signing the signature page of this original document and any amendment signature page(s) that the vendor and any proposed subcontractors either are presently in compliance with such laws or shall be in compliance with such laws prior to any resulting contract award. The vendor shall provide documentation of compliance upon request by OSCA. The compliance to conduct business in the state shall include, but not necessarily be limited to:

a. Registration of business name (if applicable)
b. Certificate of authority to transact business/certificate of good standing (if applicable)
c. Taxes (e.g., city/county/state/federal)
d. State and local certifications (e.g., professions/occupations/activities)
e. Licenses and permits (e.g., city/county license, sales permits)
f. Insurance (e.g., worker's compensation/unemployment compensation)

Vendor Status:
The vendor represents himself or herself to be an independent vendor offering such services to the general public and shall not represent himself/herself or his/her employees to be an employee of the State of Missouri. Therefore, the vendor shall assume all legal and financial responsibility for taxes, FICA, employee fringe benefits, workers compensation, employee insurance, minimum wage requirements, overtime, etc., and agrees to indemnify, save, and hold the State of Missouri, its officers, agents, and employees, harmless from and against, any and all loss; cost (including attorney fees); and damage of any kind related to such matters.

Subcontractors
Any subcontracts for the products/services described herein must include appropriate provisions and contractual obligations to ensure the successful fulfillment of all contractual obligations agreed to by the vendor and OSCA and to ensure that OSCA is indemnified, saved, and held harmless from and against any and all claims of damage, loss, and cost (including attorney fees) of any kind related to a subcontract in those matters described in the contract between OSCA and the vendor.

a. The vendor shall expressly understand and agree that he/she shall assume and be solely responsible for all legal and financial responsibilities related to the execution of a subcontract.

b. The vendor shall agree and understand that utilization of a subcontractor to provide any of the products/services in the contract shall in no way relieve the vendor of the responsibility for providing the products/services as described and set forth herein.

c. The vendor must obtain the approval of OSCA prior to establishing any new subcontracting arrangements and before changing any subcontractors. The approval shall not be arbitrarily withheld.

Substitution of Personnel
The vendor agrees and understands that OSCA's agreement to the contract is predicated in part on the utilization of the specific individual(s) and/or personnel qualifications identified in the proposal. Therefore, the vendor agrees that no substitution of such specific individual(s) and/or personnel qualifications shall be made without the prior written approval of the Treatment Court. The vendor further agrees that any substitution made pursuant to this paragraph must be equal or better than originally proposed and that the Treatment Court's approval of a substitution shall not be construed as an

acceptance of the substitution's performance potential. OSCA agrees that an approval of a substitution will not be unreasonably withheld.

Property of State
All reports, documentation, and material developed or acquired by the vendor as a direct requirement specified in the contract shall become the property of OSCA. Upon expiration, termination, or cancellation of the contract, all documents, data, reports, supplies, equipment, and accomplishments prepared, furnished or completed by the vendor pursuant to the terms of the contract shall become the property of OSCA.

Inventions, Patents and Copyrights

The vendor shall defend, protect, and hold harmless the State of Missouri, its officers, agents, and employees against all suits of law or in equity resulting from patent and copyright infringement concerning the vendor's performance or products produced under the terms of the contract.

Authorized Personnel (Immigrant Responsibility Act):
The vendor understands and agrees that by signing the RFP, the vendor certifies the following:

a. The vendor shall only utilize personnel authorized to work in the United States in accordance with applicable federal and state laws. This includes but is not limited to the Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA) and INA Section 274A.

b. If the vendor is found to be in violation of this requirement or the applicable state, federal and local laws and regulations, and if the State of Missouri has reasonable cause to believe that the vendor has knowingly employed individuals who are not eligible to work in the United States, the state shall have the right to cancel the contract immediately without penalty or recourse and suspend or debar the vendor from doing business with the state.

PROPOSAL SUBMISSION INFORMATION

Submission of Proposals:
When submitting a proposal, the vendor should include the original proposal, one (1) paper copy and one electronic copy. The front cover of the original proposal should be labeled “original” and the front cover of the copy should be labeled “copy”. The electronic copy may be submitted either on a CD or emailed to the buyer of record listed on the cover page.

a. Recycled Products - OSCA recognizes the limited nature of our resources and the leadership role of government agencies in regard to the environment. Accordingly, the vendor is requested, but not required, to print the proposal double sided using recycled paper, if possible, and minimize or eliminate the use of non-recyclable materials such as plastic report covers, plastic dividers, vinyl sleeves, and binding. Lengthy proposals may be submitted using printer or other loose leaf paper in a notebook or binder.

b. Open Records - The vendor’s proposal shall be considered an open record after a contract is executed or all proposals are rejected pursuant to Section RSMo 610.021.

To facilitate the evaluation process, the vendor is encouraged to organize their proposal into sections that correspond with the individual evaluation categories described herein. The vendor is cautioned that it is the vendor’s sole responsibility to submit information related to the evaluation categories and that OSCA is under no obligation to solicit such information if it is not included with the proposal. The vendor’s failure to submit such information may cause an adverse impact on the evaluation of the proposal.

a. Each section should be titled with each individual evaluation category and all material related to that category should be included therein.

b. The proposal should be page numbered.

c. The signed page one from the original RFP and all signed amendments should be placed at the beginning of the proposal.

Questions Regarding the RFP - The vendor and the vendor's agents (including subcontractors, employees, consultants, or anyone else acting on their behalf) must direct all of their questions or comments regarding the RFP, the evaluation, etc., to the buyer of record indicated on the first page of this RFP.

a. The buyer may be contacted via e-mail or phone as shown on the cover page.

b. The vendor is advised that any questions received less than ten calendar days prior to the RFP opening date may not be answered.

c. Except as stated below, the vendor and the vendor's agents may not contact any other state employee regarding the RFP, the evaluation, etc., during the solicitation and evaluation process.

   1) Inappropriate contacts are grounds for suspension and/or exclusion from specific procurements.

   2) Vendors and their agents who have questions regarding this matter should contact the buyer.

Competitive Negotiation of Proposals
The vendor is advised that under the provisions of this Request for Proposal, OSCA reserves the right to conduct negotiations of the proposals received or to award a contract without negotiations. If such negotiations are conducted, the following conditions shall apply**:**

a. Negotiations may be conducted in person, in writing, or by telephone.

Terms, conditions, prices, methodology, or other features of the vendor's proposal may be subject to negotiation and subsequent revision. As part of the negotiations, the vendor may be required to submit supporting financial, pricing and other data in order to allow a detailed evaluation of the feasibility, reasonableness, and acceptability of the proposal.

The mandatory requirements of the Request for Proposal shall <u>not</u> be negotiable and shall remain unchanged unless OSCA determines that a change in such requirements is in the best interest of the State of Missouri

Evaluation of Vendor's Experience, Reliability, and Expertise of Personnel:
OSCA anticipates making multiple contract awards, i.e., more than one award, as a result of this RFP. OSCA reserves the right to reject any offer which is determined unacceptable for reasons which may include but are not necessarily limited to: 1) failure of the vendor to meet mandatory general performance specifications; and/or 2) failure of the vendor to meet mandatory technical specifications; and/or, 3) receipt of any information, from any source, regarding delivery of unsatisfactory product or service by the vendor within the past three years. As deemed in its best interests, OSCA reserves the right to clarify any and all portions of any offer.

The vendor is advised to submit information concerning the vendor's organization and information documenting the vendor's experience in past performances, especially those performances related to the requirements of this RFP. Also, the qualifications of the personnel proposed by the vendor to perform the requirements of this RFP, whether from the vendor's organization or from a proposed subcontractor. Therefore, the vendor should submit detailed information related to the experience and qualifications, including education and training, of proposed personnel.

The vendor should submit a copy of all licenses, certifications, accreditations, and/or permits required by state, federal, and/or local law, statute, or regulation to provide medical laboratory services. If not submitted with the proposal, OSCA reserves the right, prior to contract award, to request and obtain a copy of any licenses, certifications, accreditations, and/or permits required to provide medical laboratory services.

Vendor Information - The vendor should provide information about the vendor's organization on Exhibit A.

Prior Experience - The vendor should provide information related to previous and current services/contracts of the vendor or vendor's proposed subcontractor where performance was similar to the required services of this RFP. The information may be shown on Exhibit B or in a similar manner. In addition:

a. The vendor should include an explanation of available cut off levels which may be requested.

b. The vendor should include an explanation of the testing procedure(s).

Personnel Expertise - The vendor should utilize Exhibit C for summarizing the personnel information for proposed key personnel and may also submit resumes with additional information.

a. The information provided should be structured to emphasize relevant qualifications and experience of the personnel in completing contracts/performing services of a similar size and scope to the requirements of this document.

b. Information submitted should clearly identify previous experience of the person in performing similar services and should include beginning and ending dates, a description of the role of the person in such performances, results of the services performed, and whether the person is proposed for the same services for the Treatment Court.

Personnel Qualifications - If personnel are not yet hired, the vendor should provide detailed descriptions of the required employment qualifications; and detailed job descriptions of the position to be filled, including the type of person proposed to be hired.

Description of Proposed Services - Exhibit D is provided for the vendor's use in providing information about the proposed method of performance. The vendor may also respond to the provisions in the Contractual Requirements by: (1) identifying each specific paragraph and subparagraph of the Contractual Requirements by paragraph number, (2) then writing a description of how, when, by whom, with what, to what degree, why, where, etc. the requirement will be satisfied and otherwise detailing the vendor's understanding of the requirements and ability and methodology to successfully perform.

Organizational Chart - The vendor should provide an organizational chart showing the staffing and lines of authority for the key personnel to be used. The organizational chart should include (1) The relationship of service personnel to management and support personnel, (2) The names of the personnel and the working titles of each, and (3) Any proposed subcontractors including management, supervisory, and other key personnel.

Employee Bidding/Conflict of Interest

Vendors who are employees of the State of Missouri, a member of the General Assembly or a statewide elected official must comply with Sections 105.450 to 105.458 RSMo regarding conflict of interest. If the vendor and/or any of the owners of the vendor's organization are currently an employee of the State of Missouri, a member of the General Assembly or a statewide elected official, please provide the following information.

Name of State Employee, General Assembly Member, or Statewide Elected Official:		
	In what office/agency are they employed?	
	Employment Title:	
Percentage of ownership interest in vendor's organization:		_____ %

LOCAL GOVERNMENT USE (COOPERATIVE PROCUREMENT):
The contractor should indicate agreement to participate in the State of Missouri's Cooperative Procurement Program as described herein.

Yes_____ No_____

PRICING PAGE

The vendor shall provide the pricing information for each product and/or service to be provided in accordance with the provisions and requirements specified herein. All costs associated with providing the products and/or services required herein shall be included in the prices.

PRICE: The vendor shall provide a listing of each product and/or service with a firm, fixed price for each product and/or service.

More lines may be added, if needed.

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

Electronic Alcohol Montoring
Pricing per participant

per day: _____

per week: _____

per month: _____

Is there a minimum number of days? Yes_____ No_____

If yes, please indicate number of days:_____

Deposit or Start Up fee required? Yes_____ How much?_____No_____

Please list system requirements, such as single land phone line, water resistance, range of coverage etc:

_____

Please list counties you will provide this service:

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EXHIBIT_A

VENDOR INFORMATION

The vendor should provide the following information about their organization:

a. Provide a brief company history, including the founding date and number of years in business as currently constituted.

b. Describe the nature of the vendor's business, type of services performed, etc.

c. Provide a list of and a short summary of information regarding the vendor's current contracts/clients. List, identify, and provide reasons for each contract/client gained and lost in the past 2 years.

c. Describe the structure of the organization including any board of directors, partners, top departmental management, corporate organization, corporate trade affiliations, any parent/subsidiary affiliations with other firms, etc.

e. Provide a list summarizing pending litigation, any civil or criminal judgments, any bankruptcy proceedings, etc., that could affect the vendor's ability to perform. Failure to list such litigation may result in rejection of the proposal or in termination of any subsequent contract.

f. Document the vendor's financial solvency in a manner that is acceptable for public review. Audited financial statements for the last year will provide such documentation; however, the statements will become public information. If the vendor is a subsidiary, also provide the documentation for the parent company.

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EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: _____	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	
Dates of Prior Services:	
Dollar Value of Prior Services:	
Description of Prior Services Performed:	

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

_____ _____

Signature of Reference Contact Person *Date of Signature*

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EXHIBIT C
PERSONNEL EXPERTISE SUMMARY
(Complete this Exhibit for personnel proposed. Resumes or summaries of key information may be provided)

Personnel	Background and Expertise of Personnel and Planned Duties
1. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	
2. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	
3. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	
4. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	
5. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	
6. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	

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EXHIBIT D

METHOD OF PERFORMANCE

The vendor should use this Exhibit, or similar format, to present a written plan for performing the requirements specified in this Request for Proposal.

1. Describe what is provided with which to collect the each sample (cups, chain of custody forms, mailing packets).

2. Describe the instruction or training provided to treatment court staff pertaining to properly collecting a sample and completing necessary documentation.

3. Describe how the sample is transported to the testing laboratory (U S Postal, Fed Ex, UPS, etc.).

4. Describe the methods of testing which are employed (LC/MS/MS, GS/MS, LC/MS, and/or Immunoassay methods).

5. Provide the testing cutoff levels which are available (100ng/mL, 250ng/mL, 500ng/mL, 1000 ng/mL). What cutoff level is recommended to safe guard against incidental false positive? _____ng/mL

6. Describe the turnaround time for results.

7. Describe how test results will be reported (telephone, fax, or e-mail).

8. Organizational Chart - The vendor should provide an organizational chart showing the staffing and lines of authority for the key personnel to be used. The organizational chart should include (1) The relationship of service personnel to management and support personnel, (2) The names of the personnel and the working titles of each, and (3) Any proposed subcontractors including management, supervisory, and other key personnel.

   - The organizational chart should outline the team proposed for this project and the relationship of those team members to each other and to the management structure of the vendor's organization.

9. Along with a detailed organizational chart, the vendor should describe the following:

   - How services of the contract will be managed, controlled, and supervised in order to ensure satisfactory contract performance.
   - Total Personnel Resources - The vendor should provide information that documents the depth of resources to ensure completion of all requirements on time and on target. If the vendor has other ongoing contracts that also require personnel resources, the vendor should document how sufficient resources will be provided to the STATE OF MISSOURI.

10. Outside United States - If any products and/or services offered under this RFP are being manufactured or performed at sites outside the United States, the vendor MUST disclose such fact and provide details in the space below or on an attached page.

Are products and/or services being manufactured or performed at sites outside the United States?	Yes ____	No ____
Describe and provide details:		

STATE OF MISSOURI
OFFICE OF STATE COURTS ADMINISTRATOR

TERMS AND CONDITIONS -- REQUEST FOR PROPOSAL

1. TERMINOLOGY/DEFINITIONS

Whenever the following words and expressions appear in a Request for Proposal (RFP) document or any amendment thereto, the definition or meaning described below shall apply.

a. **Agency and/or State Agency** means the statutory unit of state government in the State of Missouri for which the equipment, supplies, and/or services are being purchased. The agency is also responsible for payment.
b. **Amendment** means a written, official modification to an RFP or to a contract.
c. **Attachment** applies to all forms which are included with an RFP to incorporate any informational data or requirements related to the performance requirements and/or specifications.
d. **Proposal Opening Date and Time** and similar expressions mean the exact deadline required by the RFP for the receipt of sealed proposals.
e. **Contractor** means the person or organization that responds to an RFP by submitting a proposal with prices to provide the equipment, supplies, and/or services as required in the RFP document.
f. **Contract** means a legal and binding agreement between two or more competent parties, for a consideration for the procurement of equipment, supplies, and/or services.
g. **Contractor** means a person or organization who is a successful contractor as a result of an RFP and who enters into a contract.
h. **Exhibit** applies to forms which are included with an RFP for the contractor to complete and submit with the sealed proposal prior to the specified opening date and time.
i. **Request for Proposal (RFP)** means the solicitation document issued to potential contractors for the purchase of equipment, supplies, and/or services as described in the document. The definition includes these Terms and Conditions as well as all Pricing Pages, Exhibits, Attachments, and Amendments thereto.
j. **May** means that a certain feature, component, or action is permissible, but not required.
k. **Must** means that a certain feature, component, or action is a mandatory condition. Failure to provide or comply will result in a proposal being considered non-responsive.
l. **Pricing Page(s)** applies to the form(s) on which the contractor must state the price(s) applicable for the equipment, supplies, and/or services required in the RFP. The pricing pages must be completed and submitted by the contractor with the sealed proposal prior to the specified proposal opening date and time.
m. **Shall** has the same meaning as the word must.
n. **Should** means that a certain feature, component and/or action is desirable but not mandatory.

2. APPLICABLE LAWS AND REGULATIONS

a. The contract shall be construed according to the laws of the State of Missouri. The contractor shall comply with all local, state, and federal laws and regulations related to the performance of the contract to the extent that the same may be applic ble.
b. To the extent that a provision of the contract is contrary to the Constitution or laws of the State of Missouri or of the United States, the provisions shall be void and unenforceable. However, the balance of the contract shall remain in force between the parties unless terminated by consent of both the contractor and the Office of State Courts Administrator.
c. The contractor must be registered and maintain good standing with the Secretary of State of the State of Missouri and other regulatory agencies, as may be required by law or regulations.
d. The contractor must timely file and pay all Missouri sales, withholding, corporate and any other required Missouri tax returns and taxes, including interest and additions to tax.
e. The exclusive venue for any legal proceeding relating to or arising out of the RFP or resulting contract shall be in the Circuit Court of Cole County, Missouri.

3. OPEN COMPETITION/REQUEST FOR PROPOSAL DOCUMENT

a. It shall be the contractor's responsibility to ask questions, request changes or clarification, or otherwise advise the Office of State Courts Administrator if any language, specifications or requirements of an RFP appear to be ambiguous, contradictory, and/or arbitrary, or appear to inadvertently restrict or limit the requirements stated in the RFP to a single source. Any and all communication from contractors regarding specifications, requirements, competitive proposal process, etc., must be directed to the Contract and Grant Coordinator, unless the RFP specifically refers the contractor to another contact. Such communication should be received at least ten calendar days prior to the official proposal opening date.

b. Every attempt shall be made to ensure that the contractor receives an adequate and prompt response. However, in order to maintain a fair and equitable procurement process, all contractors will be advised, via the issuance of an amendment to the RFP, of any relevant or pertinent information related to the procurement. Therefore, contractors are advised that unless specified elsewhere in the RFP, any questions received less than ten calendar days prior to the RFP opening date may not be answered.
c. Contractors are cautioned that the only official position of the State of Missouri is that which is issued in the RFP or an amendment thereto. No other means of communication, whether oral or written, shall be construed as a formal or official response or statement.
d. The Office of State Courts Administrator monitors all procurement activities to detect any possibility of deliberate restraint of competition, collusion among contractors, price-fixing by contractors, or any other anticompetitive conduct by contractors which appears to violate state and federal antitrust laws. Any suspected violation shall be referred to the Missouri Attorney General's Office for appropriate action.
e. The Office of State Courts Administrator reserves the right to officially amend or cancel an RFP after issuance.

4. PREPARATION OF PROPOSALS

a. Contractors **must** examine the entire RFP carefully. Failure to do so shall be at contractor's risk.
b. Unless otherwise specifically stated in the RFP, all specifications and requirements constitute minimum requirements. All proposals must meet or exceed the stated specifications and requirements.
c. Unless otherwise specifically stated in the RFP, any manufacturer's names, trade names, brand names, information and/or catalog numbers listed in a specification and/or requirement are for informational purposes only and are not intended to limit competition. The contractor may offer any brand which meets or exceeds the specification for any item, but must state the manufacturer's name and model number for any such brands in the proposal. In addition, the contractor shall explain, in detail, (1) the reasons why the proposed equivalent meets or exceeds the specifications and/or requirements and (2) why the proposed equivalent should not be considered an exception thereto. Proposals which do not comply with the requirements and specifications are subject to rejection without clarification.
d. Proposals lacking any indication of intent to offer an alternate brand or to take an exception shall be received and considered in complete compliance with the specifications and requirements as listed in the RFP.
e. In the event that the contractor is an agency of state government or other such political subdivision which is prohibited by law or court decision from complying with certain provisions of an RFP, such a contractor may submit a proposal which contains a list of statutory limitations and identification of those prohibitive clauses which will be modified via a clarification conference between the Office of State Courts Administrator and the contractor, if such contractor is selected for contract award. The clarification conference will be conducted in order to agree to language that reflects the intent and compliance of such law and/or court order and the RFP. Any such contractor needs to include in the proposal, a complete list of statutory references and citations for each provision of the RFP which is affected by this paragraph.
f. All equipment and supplies offered in a proposal must be new, of current production, and available for marketing by the manufacturer unless the RFP clearly specifies that used, reconditioned, or remanufactured equipment and supplies may be offered.
g. Prices shall include all packing, handling and shipping charges FOB destination, freight prepaid and allowed unless otherwise specified in the RFP.
h. Prices offered shall remain valid for 90 days from proposal opening unless otherwise indicated. If the proposal is accepted, prices shall be firm for the specified contract period.

5. SUBMISSION OF PROPOSALS

a. Proposals must be submitted hard copy, delivered to the Office of State Courts Administrator, Contract and Grant Coordinator. All proposals must (1) be submitted by a duly authorized representative of the contractor's organization, (2) contain all information required by the RFP, and (3) be priced as required. Delivered proposals must be sealed in an envelope or container, and received in the Office of State Courts Administrator no later than the exact opening time and date specified in the RFP.
b. The sealed envelope or container containing a proposal should be clearly marked on the outside with (1) the official RFP number and (2) the official opening date and time. Different proposals should not be placed in the same envelope, although copies of the same proposal may be placed in the same envelope.
c. A proposal which has been delivered to the Office of State Courts Administrator may be modified by signed, written notice which has been received by the Contract and Grant Coordinator prior to the official opening date and time specified. A proposal may also be modified in person by the contractor or its authorized representative, provided proper identification is presented before the official opening date and time. Telephone or telegraphic requests to modify a proposal shall not be honored.
d. A proposal which has been delivered to the Office of State Courts Administrator may only be withdrawn by a signed, written notice or facsimile which has been received by the Contract and Grant Coordinator prior to the official opening date and time specified. A proposal may also be withdrawn in person by the contractor or its authorized representative, provided proper identification is presented before the official opening date and time. Telephone or telegraphic requests to withdraw a proposal shall not be honored.

e. Contractors delivering a hard copy proposal to Office of State Courts Administrator must sign and return the RFP cover page or, if applicable, the cover page of the last amendment thereto in order to constitute acceptance by the contractor of all RFP terms and conditions. Failure to do so may result in rejection of the proposal unless the contractor's full compliance with those documents is indicated elsewhere within the contractor's response.

6. PROPOSAL OPENING

a. Proposal openings are public on the opening date and at the opening time specified on the RFP document. Only the names of the respondents shall be read at the proposal opening. The contents of the responses shall not be disclosed at this time.
b. It is the contractor's responsibility to ensure that the proposal is received by Office of State Courts Administrator by the official opening date and time.
c. Proposals which are not received by the Office of State Courts Administrator prior to the official opening date and time shall be considered late, regardless of the degree of lateness, and normally will not be opened. Late proposals may only be opened under extraordinary circumstances in accordance with 1 CSR 40-1.050.

7. PREFERENCES

a. By virtue of statutory authority, a preference will be given to materials, products, supplies, provisions and all other articles produced, manufactured, made or grown within the state of Missouri. Such preference shall be given when quality is equal or better and delivered price is the same or less.
b. In accordance with Executive Order 98-21, contractors are encouraged and may be required per the RFP to utilize certified minority and women-owned businesses in selecting subcontractors.

8. EVALUATION/AWARD

a. Any clerical error, apparent on its face, may be corrected by the Contract and Grant Coordinator before contract award. Upon discovering an apparent clerical error, the Contract and Grant Coordinator shall contact the contractor and request clarification of the intended proposal. The correction shall be incorporated in the notice of award. Examples of apparent clerical errors are: 1) misplacement of a decimal point; and 2) obvious mistake in designation of unit.
b. Any pricing information submitted by a contractor shall be subject to evaluation if deemed by the Office of State Courts Administrator to be in the best interest of the State of Missouri.
c. Unless otherwise stated in the RFP, cash discounts for prompt payment of invoices shall not be considered in the evaluation of prices. However, such discounts are encouraged to motivate prompt payment.
d. Awards shall be made to the contractor whose proposal (1) complies with all mandatory specifications and requirements of the RFP and (2) is the lowest and best proposal, considering price, responsibility of the contractor, and all other evaluation criteria specified in the RFP and any subsequent negotiations.
e. In the event all contractors fail to meet the same mandatory requirement in an RFP, the Office of State Courts Administrator reserves the right, at its sole discretion, to waive that requirement for all contractors and to proceed with the evaluation. In addition, the Office of State Courts Administrator reserves the right to waive any minor irregularity or technicality found in any individual proposal.
f. The Office of State Courts Administrator reserves the right to reject any and all proposals.
g. When evaluating a proposal, the State of Missouri reserves the right to consider relevant information and fact, whether gained from a proposal, from a contractor, from contractor's references, or from any other source.
h. Any information submitted with the proposal, regardless of the format or placement of such information, may be considered in making decisions related to the responsiveness and merit of a proposal and the award of a contract.
i. Negotiations may be conducted with those contractors who submit potentially acceptable proposals. Proposal revisions may be permitted for the purpose of obtaining best and final offers. In conducting negotiations, there shall be no disclosure of any information submitted by competing contractors.
j. Any award of a contract shall be made by notification from the Office of State Courts Administrator to the successful contractor. The Office of State Courts Administrator reserves the right to make awards by item, group of items, or an all or none basis. The grouping of items awarded shall be determined by Office of State Courts Administrator based upon factors such as item similarity, location, administrative efficiency, or other considerations in the best interest of the State of Missouri.
k. Pursuant to Section 610.021 RSMo, proposals and related documents shall not be available for public review until after a contract is executed or all proposals are rejected.
l. The Office of State Courts Administrator reserves the right to request clarification of any portion of the contractor's response in order to verify the intent of the contractor. The contractor is cautioned, however, that its response may be subject to acceptance or rejection without further clarification.

9. CONTRACT/PURCHASE ORDER

a. By submitting a proposal, the contractor agrees to furnish any and all equipment, supplies and/or services specified in the RFP, at the prices quoted, pursuant to all requirements and specifications contained therein.
b. A binding contract shall consist of: (1) the RFP, amendments thereto, and/or Best and Final Offer (BAFO) request(s) with RFP changes/additions, (2) the contractor's proposal including the contractor's BAFO, and (4) Office of State Courts Administrator's acceptance of the proposal by "notice of award" or by "purchase order."
c. A notice of award does not constitute an authorization for shipment of equipment or supplies or a directive to proceed with services. Before providing equipment, supplies and/or services, the contractor must receive a properly authorized purchase order.
d. The contract expresses the complete agreement of the parties and performance shall be governed solely by the specifications and requirements contained therein. Any change, whether by modification and/or supplementation, must be accomplished by a formal contract amendment signed and approved by and between the duly authorized representative of the contractor and the Contract and Grant Coordinator or by a modified purchase order prior to the effective date of such modification. The contractor expressly and explicitly understands and agrees that no other method and/or no other document, including correspondence, acts, and oral communications by or from any person, shall be used or construed as an amendment or modification.

10. INVOICING AND PAYMENT

a. The State of Missouri does not pay state or federal taxes unless otherwise required under law or regulation.
b. The statewide financial management system has been designed to capture certain receipt and payment information. Therefore, each invoice submitted must reference the purchase order number and must be itemized in accordance with items listed on the purchase order. Failure to comply with this requirement may delay processing of invoices for payment.
c. The contractor shall not transfer any interest in the contract, whether by assignment or otherwise, without the prior written consent of the Office of State Courts Administrator.
d. Payment for all equipment, supplies, and/or services required herein shall be made in arrears. The State of Missouri shall not make any advance deposits.
e. The State of Missouri assumes no obligation for equipment, supplies, and/or services shipped or provided in excess of the quantity ordered. Any unauthorized quantity is subject to the State's rejection and shall be returned at the contractor's expense.
f. All invoices for equipment, supplies, and/or services purchased by the State of Missouri shall be subject to late payment charges as provided in Section 34.055 RSMo.

11. DELIVERY

Time is of the essence. Deliveries of equipment, supplies, and/or services must be made no later than the time stated in the contract or within a reasonable period of time, if a specific time is not stated.

12. INSPECTION AND ACCEPTANCE

a. No equipment, supplies, and/or services received pursuant to a contract shall be deemed accepted until the Office of State Courts Administrator has had reasonable opportunity to inspect said equipment, supplies, and/or services.
b. All equipment, supplies, and/or services which do not comply with the specifications and/or requirements or which are otherwise unacceptable or defective may be rejected. In addition, all equipment, supplies, and/or services which are discovered to be defective or which do not conform to any warranty of the contractor upon inspection (or at any later time if the defects contained were not reasonably ascertainable upon the initial inspection) may be rejected.
c. The State of Missouri reserves the right to return any such rejected shipment at the contractor's expense for full credit or replacement and to specify a reasonable date by which replacements must be received.
d. The State of Missouri's right to reject any unacceptable equipment, supplies, and/or services shall not exclude any other legal, equitable or contractual remedies the State may have.

13. WARRANTY

a. The contractor expressly warrants that all equipment, supplies, and/or services provided shall: (1) conform to each and every specification, drawing, sample or other description which was furnished to or adopted by the Office of State Courts Administrator, (2) be fit and sufficient for the purpose expressed in the RFP, (3) be merchantable, (4) be of good materials and workmanship, and (5) be free from defect.
b. Such warranty shall survive delivery and shall not be deemed waived either by reason of the State's acceptance of or payment for said equipment, supplies, and/or services.

14. CONFLICT OF INTEREST

a. Officials and employees of the state agency, its governing body, or any other public officials of the State of Missouri must comply with Sections 105.452 and 105.454 RSMo regarding conflict of interest.

b. The contractor hereby covenants that at the time of the submission of the proposal the contractor has no other contractual relationships which would create any actual or perceived conflict of interest. The contractor further agrees that during the term of the contract neither the contractor nor any of its employees shall acquire any other contractual relationships which create such a conflict.

15. REMEDIES AND RIGHTS

a. No provision in the contract shall be construed, expressly or implied, as a waiver by the State of Missouri of any existing or future right and/or remedy available by law in the event of any claim by the State of Missouri of the contractor's default or breach of contract.
b. The contractor agrees and understands that the contract shall constitute an assignment by the contractor to the State of Missouri of all rights, title and interest in and to all causes of action that the contractor may have under the antitrust laws of the United States or the State of Missouri for which causes of action have accrued or will accrue as the result of or in relation to the particular equipment, supplies, and/or services purchased or procured by the contractor in the fulfillment of the contract with the State of Missouri.

16. CANCELLATION OF CONTRACT

a. In the event of material breach of the contractual obligations by the contractor, the Office of State Courts Administrator may cancel the contract. At its sole discretion, the Office of State Courts Administrator may give the contractor an opportunity to cure the breach or to explain how the breach will be cured. The actual cure must be completed within no more than 10 working days from notification, or at a minimum the contractor must provide the Office of State Courts Administrator within 10 working days from notification a written plan detailing how the contractor intends to cure the breach.
b. If the contractor fails to cure the breach or if circumstances demand immediate action, the Office of State Courts Administrator will issue a notice of cancellation terminating the contract immediately.
c. If the Office Of State Courts Administrator cancels the contract for breach, the Office of State Courts Administrator reserves the right to obtain the equipment, supplies, and/or services to be provided pursuant to the contract from other sources and upon such terms and in such manner as the Office of State Courts Administrator deems appropriate and charge the contractor for any additional costs incurred thereby.
d. The contractor understands and agrees that funds required to fund the contract must be appropriated by the General Assembly of the State of Missouri for each fiscal year included within the contract period. The contract shall not be binding upon the State for any period in which funds have not been appropriated, and the State shall not be liable for any costs associated with termination caused by lack of appropriations.

17. COMMUNICATIONS AND NOTICES

Any notice to the contractor shall be deemed sufficient when deposited in the United States mail postage prepaid, transmitted by facsimile, transmitted by e-mail or hand-carried and presented to an authorized employee of the contractor.

18. BANKRUPTCY OR INSOLVENCY

a. Upon filing for any bankruptcy or insolvency proceeding by or against the contractor, whether voluntary or involuntary, or upon the appointment of a receiver, trustee, or assignee for the benefit of creditors, the contractor must notify the Office of State Courts Administrator immediately.
b. Upon learning of any such actions, the Office of State Courts Administrator reserves the right, at its sole discretion, to either cancel the contract or affirm the contract and hold the contractor responsible for damages.

19. INVENTIONS, PATENTS AND COPYRIGHTS

The contractor shall defend, protect, and hold harmless the State of Missouri, its officers, agents, and employees against all suits of law or in equity resulting from patent and copyright infringement concerning the contractor's performance or products produced under the terms of the contract.

20. NON-DISCRIMINATION AND AFFIRMATIVE ACTION

In connection with the furnishing of equipment, supplies, and/or services under the contract, the contractor and all subcontractors shall agree not to discriminate against recipients of services or employees or applicants for employment on the basis of race, color, religion, national origin, sex, age, disability, or veteran status. If the contractor or subcontractor employs at least 50 persons, they shall have and maintain an affirmative action program which shall include:

a. A written policy statement committing the organization to affirmative action and assigning management responsibilities and procedures for evaluation and dissemination;

b. The identification of a person designated to handle affirmative action;
c. The establishment of non-discriminatory selection standards, objective measures to analyze recruitment, an upward mobility system, a wage and salary structure, and standards applicable to layoff, recall, discharge, demotion, and discipline;
d. The exclusion of discrimination from all collective bargaining agreements; and
e. Performance of an internal audit of the reporting system to monitor execution and to provide for future planning.

If discrimination by a contractor is found to exist, the Office of State Courts Administrator shall take appropriate enforcement action which may include, but not necessarily be limited to, cancellation of the contract, suspension, or debarment by the Office of State Courts Administrator until corrective action by the contractor is made and ensured, and referral to the Attorney General's Office, whichever enforcement action may be deemed most appropriate.

21. AMERICANS WITH DISABILITIES ACT

In connection with the furnishing of equipment, supplies, and/or services under the contract, the contractor and all subcontractors shall comply with all applicable requirements and provisions of the Americans with Disabilities Act (ADA).

22. TITLES

Titles of paragraphs used herein are for the purpose of facilitating reference only and shall not be construed to infer a contractual construction of language.

OFFICE OF STATE COURTS ADMINISTRATOR
P.O. Box 104480
2112 Industrial Drive
Jefferson City, MO 65110-4480

RFP NO. OSCA 11-029-00
AMENDMENT: 001
TITLE: Drug/Alcohol Testing Equipment & Services
ISSUE DATE: January 28, 2011

CONTACT: Russell Rottmann
PHONE NO.: (573) 522-6766
E-MAIL: osca.contracts@courts.mo.gov

RETURN PROPOSAL NO LATER THAN: February 10, 2011 AT 5:00 PM

MAILING INSTRUCTIONS: Print or type **RFP Number** and **Return Due Date** on the lower left hand corner of the envelope or package.

RETURN PROPOSAL TO:

(U.S. Mail)
Office of State Courts Administrator
Contracts Unit
PO Box 104480
Jefferson City Mo 65110 - 4480

or

(Courier Service)
Office of State Courts Administrator
Contracts Unit
2112 Industrial Dr
Jefferson City Mo 65109

CONTRACT PERIOD: JULY 1, 2011 THROUGH JUNE 30, 2012

DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:

MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI

The vendor hereby declares understanding, agreement and certification of compliance to provide the items and/or services, at the prices quoted, in accordance with all requirements and specifications contained herein and the Terms and Conditions Request for Proposal. The vendor further agrees that the language of this RFP shall govern in the event of a conflict with his/her proposal. The vendor further agrees that upon receipt of an authorized purchase order from the Office of State Courts Administrator or when this RFP is countersigned by an authorized official of the Office of State Courts Administrator, a binding contract shall exist between the vendor and the Office of State Courts Administrator.

SIGNATURE REQUIRED

AUTHORIZED SIGNATURE		DATE 02/09/11
PRINTED NAME Barry C. Chapman		TITLE Chief Financial Officer
COMPANY NAME Redwood Toxicology Laboratory, Incl		
MAILING ADDRESS 3650 Westwind Boulevard		
CITY, STATE, ZIP Santa Rosa, CA 95403		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 68-0332937
PHONE NO. 800.255.2159	FAX NO. 707.569.0121	E-MAIL ADDRESS smcintosh@redwoodtoxicology.com

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS:		
CONTRACT NO.	CONTRACT PERIOD	
CONTACTS COORDINATOR	DATE	STATE COURTS ADMINISTRATOR

OFFICE OF STATE COURTS ADMINISTRATOR
P.O. Box 104480
2112 Industrial Drive
Jefferson City, MO 65110-4480

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PO Box 104480		2112 Industrial Dr
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CONTRACT NO.	CONTRACT PERIOD	
CONTACTS COORDINATOR	DATE	STATE COURTS ADMINISTRATOR

The following changes were made under this amendment:

Page 4 under General Requirements

All testing devices, **except the units being proposed under the electronic alcohol monitoring section of this RFP**, must be previously approved by the U.S. Food and Drug Administration (FDA) for commercial distribution as a medical device. The contractor must provide a copy of the active FDA 510K-notification document.

Page 4 under Accreditation

The contractor must comply with all state laws concerning licensing, accreditation, and regulations and must meet the following accreditation requirements and provide documentation of such credentials. **This requirement does not apply to the electronic alcohol monitoring section of this RFP.**

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Attachments

Attachments

Lab Overview & Licensure

Lab DOA Testing (Urine)

Designer Stimulants

Lab Synthetic Marijuana Testing

Lab EtG Testing (Urine)

Comp Panel (Urine)

Lab DOA Steriod Testing (Urine)

Lab GHB Testing (Urine)

Oral Fluid Lab Testing

Chain of Custody Forms

Reporting Options

Third Party Billing

On-Site Devices

iCup

RediCup

Panel Dip

Cassette

Integrated EZ Cup

On-Site Oral

iScreen OFD

OrAlert

Alcohol

reditest®

SUBSTANCE ABUSE SCREENING DEVICES

Are they on drugs? We'll find out.

Reditest® on-site urine and oral fluid drug testing devices from the name you can count on—Redwood Toxicology Laboratory.

Confidence in testing.

REDITEST® SUBSTANCE ABUSE SCREENING DEVICES

Redwood Toxicology Laboratory, Inc. (RTL) sells millions of instant urine and oral fluid drugs of abuse screening devices each year. With our Reditest® on-site screening devices, you get more than the highest quality, most cost-effective devices in the industry, you get reliability.

The Reditest screening devices, in combination with RTL's lab services, provide our clients with a comprehensive and convenient drug testing solution. Reditest screening devices are ideal for a variety of testing environments. Turn to RTL for confidence in testing—we'll find out.

BENEFITS INCLUDE:

- *Multiple drugs and configurations available*
- *Toll-free customer support services with access to board certified toxicologists*
- *Collection and confirmation kits available*
- *Affordable pricing (ask about GC/MS confirmations)*

PRODUCT LINE:

Reditest® RediCup®—*all inclusive urine collection and test*
Available tests include: *AMP, M-AMP, BAR, BZO, COC, MDMA, MTD, OPI, OXY, PCP, TCA and THC

Reditest® Panel-Dip—*accurate dip test for multiple drugs in urine*
Available tests include: *AMP, M-AMP, BAR, BZO, COC, MDMA, MTD, OPI, OXY, PCP, TCA and THC

Reditest® On-site Oral—*reliable and unobtrusive saliva test*
Drugs detected: *AMP, M-AMP, THC, COC, OPI, PCP

iScreen™ OFD—*saliva drug detection, anywhere anytime*
Available tests include: *AMP, M-AMP, COC, OPI, PCP, THC.

OrAlert—*saliva drug detection, with BZO & improved THC sensitivity*
Available tests include: *AMP, M-AMP, BZO, COC, OPI, PCP, THC.

Reditest® 6 Cassette—*CLIA waived and ideal for clinical use*
Drugs detected: *AMP, COC, THC, M-AMP, OPI and PCP

Reditest® Alcohol-Saliva—*rapidly detect ethyl alcohol in saliva*
*Semi-quantitative interpretations at 0.0%, 0.02%, 0.08% and 0.30% SAC.

Reditest® Alcohol-Breath—*self contained, non intrusive test*
Available in .02 gm/dL cut-off level.

Reditest® Smoke Cassette—*urine screen for smoking status*
Cotinine (nicotine metabolite) in urine at 200 ng/mL.

* Alcohol (SAC), Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine Metabolite (COC), Cotinine (COT), Marijuana (THC), Ecstasy (MDMA), Methadone (MTD), Opiates—300 or 2,000 ng/mL cut-off (OPI), Oxycodone (OXY), Phencyclidine (PCP), and Tricyclic Antidepressants (TCA).

REDWOOD TOXICOLOGY LABORATORY

an Inverness medical company

Call Now: **800-255-2159**

or visit: www.redwoodtoxicology.com/0309

FREQUENTLY ASKED QUESTIONS

Complete list of FAQ's available online at www.redwoodtoxicology.com

What devices do you offer?
Redwood Toxicology Laboratory provides an extensive selection of on-site screening devices for urine and saliva. In addition to our popular Reditest® RediCup® device, we offer the Reditest® Panel-Dip for urine testing. Both are affordable options for your agency. Gender neutral, saliva testing devices include the Reditest® On-Site Oral, iScreen™ OFD, and OrAlert for drugs of abuse detection, and the Reditest® Alcohol-Saliva device for the alcohol detection. Other specialty tests include the Reditest® Smoke Cassette, Buprenorphine Cassette, CLIA-Waived Reditest® 6 Cassette and the Adulteration Strips.
Call us toll-free to place your order (800) 255-2159.

What training and support services does RTL provide?
RTL provides many support services to make your drug testing program a success. This includes telephonic training, toll-free access to Client Services staff members and laboratory GC/MS confirmation. Our toll-free number is (800) 255-2159.

Do the results hold up in court?
The Reditest on-site devices provide preliminary analytical test results. Industry standards require that a more specific analytical method be used in order to obtain a confirmed analytical result. RTL offers gas chromatography/mass spectrometry (GC/MS) confirmation services at its state of the art laboratory.

Reditest® RediCup® Procedure

** See product insert for complete instructions, limitations, and warnings.*

Collect urine sample in RediCup®.

Screw cap onto cup, ensure cap is tightly secured.

Turn cup upside-down, on flat surface, for approximately 30 seconds.

After 30 seconds, flip upright and wait for results to appear.

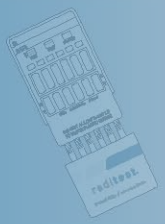
Read results in 5 minutes.

Reditest® Panel-Dip Procedure

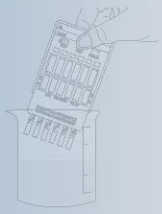
** See product insert for complete instructions, limitations, and warnings.*

Collect urine sample in clean container.

Remove plastic cap from bottom of device.

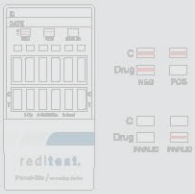


Dip revealed pads into urine sample for a minimum of 15-30 seconds until urine is seen wicking into reading zone.



Replace cap on device. Lay flat.

Read results in 5 minutes.

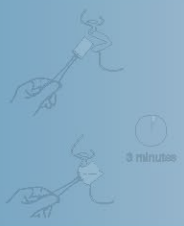


Reditest® On-Site Oral Procedure

** See product insert for complete instructions, limitations, and warnings.*

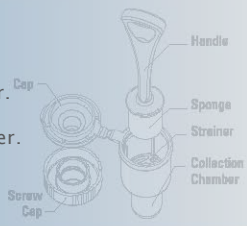
Insert the sponge collection device into the donor's mouth.

Actively swab mouth for 3 minutes.

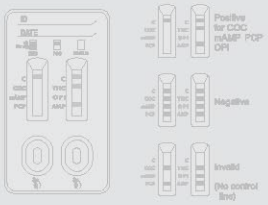


Open collection chamber and place the saturated collector into chamber. Press the sponge fully against strainer.

Discard collector and snap cap shut.



Add 3 drops of oral fluid into each sample well. Read results in 10 minutes



Reditest® Alcohol – Saliva Procedure

** See product insert for complete instructions, limitations, and warnings.*

Tear open the foil pouch and remove the test strip.

Saturate the reactive pad on the end of the stick with saliva in the mouth or a cup for 10 seconds.

Remove stick from mouth or cup.

After exactly 2 minutes, match the color on the pad to color chart.

11 000 0309 REV4

redicup® // panel-dip // on-site oral // iscreen ofd // oralert // 6 cassette // alcohol-saliva // alcohol-breath // smoke cassette

REDWOOD TOXICOLOGY LABORATORY™

800-255-2159
Screening Devices: 877-444-0049 // Laboratory: 800-255-2159 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

RediCup®, Panel-Dip, and 6 Cassette devices are for professional in vitro diagnostic use only. On-Site Oral, Alcohol-Saliva Strips, iScreen™ OFD, OrAlert, and Alcohol-Breath Test are for forensic use only. Reditest® Smoke Cassette is for determination of smoking status only. The assays provide only a preliminary test result. Any positive result obtained with these drug screens are presumptive and should be confirmed by an alternate method such as GC/MS.

See the difference reditest® can make.

Equip your drug test program with reliable and rapid on-site screening devices.

To place an order, call: 1-877-444-0049. *Can't find what your looking for? Just ask us!*

With Reditest, we offer you more than the highest quality, most cost-effective devices in the industry. We offer complete drug testing confidence.

Reditest® Panel-Dip URINE SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	PANEL-DIP CONFIGURATIONS — *25 per box*	PART NUMBER
1	AMPHETAMINES (AMP)	01 102 0018
1	BARBITURATES (BAR)	01 102 0019
1	BENZODIAZEPINES (BZO)	01 102 0022
1	BUPRENORPHINE (BUP)	01 102 1955
1	COCAINE (COC)	01 102 0001
1	EDDP (Methadone Metabolite)	01 102 2143
1	OPIATES (300) (OPI)	01 102 0003
1	OXYCODONE (OXY)	01 102 0037
1	TRICYCLIC ANTIDEPRESSANTS (TCA)	01 102 0023
1	MARIJUANA (THC)	01 102 0004
1	MDMA (Ecstasy)	01 102 0036
1	METHADONE (MTD)	01 102 0020
1	METHAMPHETAMINES (M-AMP)	01 102 0002
1	PHENCYCLIDINE (PCP)	01 102 0021
2	COC/M-AMP	01 102 0007
2	COC/OPI(300)	01 102 0005
2	COC/THC	01 102 0006
2	M-AMP/THC	01 102 0008
2	M-AMP/OPI(300)	01 102 0030
3	COC/M-AMP/THC	01 102 0009
3	COC/THC/OPI(300)	01 102 0010
3	M-AMP/THC/OPI(300)	01 102 0011
3	M-AMP/COC/OPI(300)	01 102 0014
4	COC/M-AMP/THC/OPI(300)	01 102 0012
4	COC/AMP/THC/OPI(300)	01 102 0032
5	COC/M-AMP/THC/OPI(300)/BZO	01 102 0015
5	COC/M-AMP/THC/OPI(300)/PCP	01 102 0013
5	COC/AMP/THC/OPI(300)/PCP	01 102 0033
5	COC/AMP/M-AMP/THC/OPI(300)	01 102 0034
5	COC/AMP/THC/OPI2(2000)/PCP	01 102 0047
6	COC/M-AMP/THC/OPI(300)/PCP/BZO	01 102 0016
6	COC/M-AMP/THC/MTD/OPI(300)/BZO	01 102 0017
6	COC/M-AMP/THC/OPI(300)/BAR/BZO	01 102 0024
6	COC/M-AMP/THC/OPI(300)/OXY/BZO	01 102 0119
7	COC/AMP/THC/OPI(300)/PCP/BZO/TCA	01 102 0035
8	COC/AMP/M-AMP/THC/OPI(300)/OXY/BZO/MDMA	01 102 0169
10	COC/AMP/M-AMP/THC/MTD/OPI(300)/PCP/BAR/BZO/TCA	01 102 0025
10	COC/M-AMP/THC/MTD/MDMA/OPI(300)/OXY/PCP/BAR/BZO	01 102 0138
12	COC/AMP/M-AMP/THC/MTD/MDMA/OPI(300)/OXY/PPX/PCP/BAR/BZO	01 102 0141

Reditest® RediCup® URINE SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	REDICUP® CONFIGURATIONS — *25 per box*	PART NUMBER
4	M-AMP/COC/THC/OPI(300)	01 102 0026
5	M-AMP/COC/THC/OPI(300)/BZO	01 102 0027
5	M-AMP/COC/THC/OPI(300)/PCP	01 102 0028
5	M-AMP/COC/THC/OPI(300)/AMP	01 102 0121
6	M-AMP/COC/THC/AMP/OPI2(2000)/BZO	01 102 0135
6	M-AMP/COC/THC/OPI(300)/PCP/BZO	01 102 0029
10	AMP/COC/THC/M-AMP/OPI2(2000)/PCP/BZO/TCA/BAR/MTD	01 102 0058
10	M-AMP/COC/THC/BZO/TCA/BAR/PCP/AMP/OPI(300)/MTD	01 102 0059
10	M-AMP/COC/THC/BZO/MTD/BAR/MDMA/OPI(300)/PCP/OXY	01 102 0137

iCup® URINE SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	ICUP A.D CONFIGURATIONS *(with Specimen Validity Test)* — *25 per box*	PART NUMBER
4	COC/THC/OPI(2000)/M-AMP—*CLIA Waived*	01 102 2032
4	COC(150)/THC/AMP/M-AMP(500)	01 102 2033
5	COC/THC/OPI(2000)/AMP/M-AMP—*CLIA Waived*	01 102 2034
5	COC/THC/MOP(300)/AMP/M-AMP	01 102 2021
6	COC/THC/OPI(2000)/AMP/M-AMP/BZO	01 102 2022
6	COC/THC/OPI(2000)/AMP(300)/OXY/MDMA	01 102 2037
8	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/BAR	01 102 2038
8	COC/THC/MOP(300)/AMP/M-AMP/BZO/OXY/PCP	01 102 2069
9	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/BAR/MTD	01 102 2039
10	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/BAR/MTD/TCA	01 102 2129
10	COC/THC/OPI(2,000)/AMP/M-AMP/BZO/BAR/OXY/MTD/PPX	01 102 2074
12	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/BAR/MTD/TCA/OXY/PPX	01 102 2027
13	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/ BAR/MTD/TCA/OXY/PPX/BUP	01 102 2028

PANEL	ICUP ALL INCLUSIVE CUP CONFIGURATION	PART NUMBER
10	COC/THC/OPI(2000)/AMP/M-AMP/BZO/BAR/OXY/MDMA/PPX	01 102 2020

QuikScreen™ Cup URINE SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	QUICKSCREEN® CUP CONFIGURATIONS — *25 per box*	PART NUMBER
11	COC/THC/OPI/AMP/M-AMP/PCP/BZO/BAR/OXY/MTD/TCA	01 357 6001

E-Z Split Key Cup II URINE SUBSTANCE ABUSE SCREENING DEVICES

PANEL	EZ SPLIT KEY CUP II CONFIGURATION *(with Specimen Validity Test) — 25 per box*	PART NUMBER
5	COC/THC/OPI(2000)/AMP/PCP—*CLIA Waived*	01 102 1974

PANEL(S)	EZ SPLIT KEY CUP II CONFIGURATIONS *— 25 per box*	PART NUMBER
6	COC/THC/OPI(2000)/AMP/M-AMP/BZO	01 102 1984
10	COC/THC/OPI(2000)/AMP/M-AMP/PCP/BZO/BAR/MTD/MDMA	01 102 1985
12	COC/THC/MOP(300)/AMP/M-AMP/BZO/BAR/MTD/MDMA/OXY/BUP/PPX	01 102 2096

Reditest® 6 Cassette **CLIA WAIVED** URINE SUBSTANCE ABUSE SCREENING DEVICE

PANEL	REDITEST® 6 CASSETTE CONFIGURATION *— 25 per box*	PART NUMBER
6	AMP/COC/M-AMP/OPI2(2000)PCP/THC—*CLIA Waived*	01 102 0166

Reditest® On-Site Oral ORAL FLUID SUBSTANCE ABUSE SCREENING DEVICE

PANEL	REDITEST® ON-SITE ORAL CONFIGURATION *— 25 per box*	PART NUMBER
6	AMP/COC/M-AMP/OPI2(2000)/PCP/THC	01 102 0127

iScreen® OFD ORAL FLUID SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	ISCREEN® OFD CONFIGURATIONS *— 25 per box*	PART NUMBER
5	COC/THC/OPI(2000)/M-AMP/AMP	01 102 2024
6	COC/THC/OPI(2000)/M-AMP/AMP/PCP	01 102 2025

OrAlert™ ORAL FLUID SUBSTANCE ABUSE SCREENING DEVICES

PANEL(S)	ORALERT CONFIGURATIONS *— 25 per box*	PART NUMBER
6	AMP/COC/M-AMP/OPI(2000)/PCP/THC	01 102 1960
6	AMP/COC/M-AMP/OPI(2000)/BZO/THC	01 102 2083

Reditest® Alcohol-Saliva Test ORAL FLUID ALCOHOL SCREENING DEVICE

DEVICE	**REDITEST® ALCOHOL-SALIVA TEST STRIP** — *25 per box*	PART NUMBER
TEST STRIP	DETECTS 0.02%/ 0.08%/ AND 0.30% SAC	01 362 0001

Reditest® Alcohol-Breath Test BREATH ALCOHOL SCREENING DEVICE

DEVICE	**REDITEST® ALCOHOL-BREATH TEST DEVICE** — *25 per box*	PART NUMBER
TEST STRIP	DETECTS 0.02%/ 0.08%/ AND 0.30% SAC	01 215 0004

ALCO-SCREEN® ORAL FLUID ALCOHOL SCREENING DEVICES

DEVICE	**ALCO-SCREEN® // ALCO-SCREEN® 02**— *25 per box*	PART NUMBER
TEST STRIP	DETECTS 0.02%/ 0.08%/ AND 0.30% SAC	01 094 0055
TEST STRIP	DETECTS 0.02%—*DOT APPROVED*	01 094 0056

Reditest® Smoke Cassette URINE COTININE SCREENING DEVICES

DEVICE	**REDITEST® SMOKE CASSETTE** — *25 per box*	PART NUMBER
CASSETTE	COTININE (200 NG/ML)—*DETECTS NICOTINE METABOLITE*	01 102 0140

Adulteration Strips SPECIMEN VALIDITY TEST (SVT)

DEVICE	**ADULTERATION STRIPS** — *25 strips per canister*	PART NUMBER
TEST STRIP	1-STEP VALIDITY TEST. SCREENS 6 PARAMETERS FOR SPECIMEN VALIDITY, DILUTION & TAMPERING. *Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, and Oxidants/Pyridinium Chlorochromate*	01 102 1910

screening device cut-off levels

The Reditest devices detect a wide range of drugs and drug metabolites in urine or oral fluids at the following cut-off concentrations:

URINE SCREENING DEVICE CUT-OFF LEVELS

DRUG	CALIBRATOR	CUT-OFF LEVEL
Amphetamine (AMP 1000)	d-Amphetamine	*1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL[1]
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	*300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL[2]
EDDP (Methadone Metabolite)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	*50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (M-AMP)	d-Methamphetamine	1000 ng/mL
Methamphetamine (M-AMP 500)	d-Methamphetamine	500 ng/mL[2]
Opiates (OPI 300 / MOP 300)	Morphine	300 ng/mL
Opiates (OPI2 2000 / OPI 2000)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	*25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

**Meets SAMHSA cut-off levels.*

SALIVA SCREENING DEVICE CUT-OFF LEVELS

DRUG	CALIBRATOR	CUT-OFF LEVEL
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (M-AMP)	d-Methamphetamine	50 ng/mL
Benzodiazepines (BZO)	Oxazepam	10 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12 ng/mL
Marijuana (THC)	Δ9-THC	100 ng/mL[3]
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

1. iScreen® iCup® P/N: 01 102 2037, AMP detection at 300 ng/mL.
2. iScreen® iCup® P/N: 01 102 2033, COC detection at 150 ng/mL, AMP detection at 500 ng/mL.
3. OrAlert THC detection. Includes improved sensitivity of parent THC.

RediCup®, Panel-Dip, 6 Cassette devices, EZ-Split Key Cup, iCup® and Alcohol-Breath Test are for professional in vitro diagnostic use only. On-Site Oral, Alcohol-Saliva Strips, iScreen™ OFD, OrAlert™ and ALCO-SCREEN are for forensic use only. Reditest® Smoke Cassette is for determination of smoking status only. ALCO-SCREEN 02 is for DOT use. The assays provide only a preliminary test result. Any positive result obtained with these drug screens are presumptive and should be confirmed by an alternate method such as GC/MS.

11 000 0135 REV17

REDWOOD TOXICOLOGY LABORATORY™

Laboratory: 800-255-2159 // Screening Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com
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iScreen™ iCup® / substance abuse screening device

The iScreen™ **iCup®** is the **all inclusive on-site** device for all of your urine drug **screening** needs.

FEATURES/BENEFITS

- *Self contained cup minimizes collector exposure to urine*
- *Easy to use device*
- *Results in 2 - 5 minutes*
- *Screens up to 15 different drugs with optional adulteration strips.*
- *FDA 510k cleared to market*

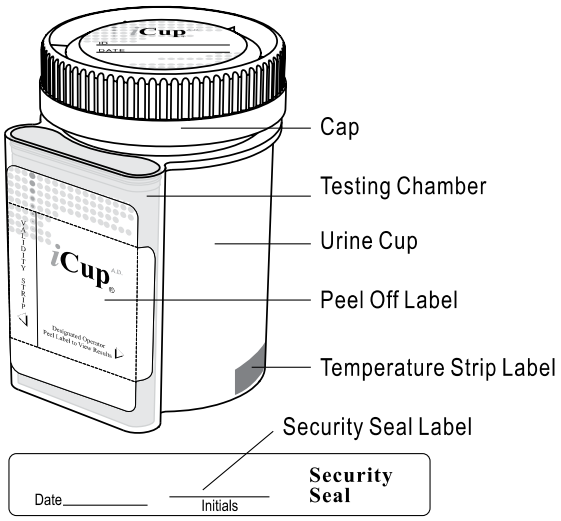
15 AVAILABLE DRUGS TO SCREEN

**AMP, BAR, BUP, BZO, COC, MDMA, THC, MTD, M-AMP, MOP, OPI, OXY, PCP, PPX and TCA*

REDWOOD TOXICOLOGY LABORATORY™

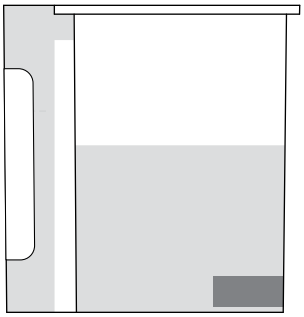
PRODUCT OVERVIEW

iSCREEN iCUP COMPONENTS

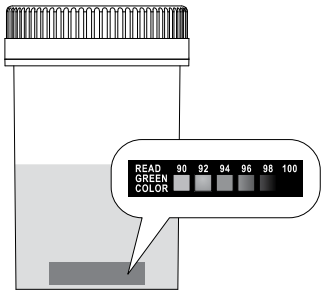


iSCREEN iCUP TESTING PROCEDURE

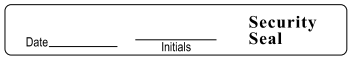
1 Donor provides specimen and replaces lid.



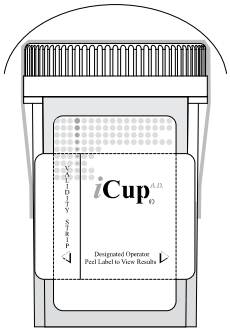
2 Temperature is read between 2-4 minutes to verify range between 90-100°F.



3 Check cap for tight seal. Donor dates and initials the security seal and places security seal over cap.

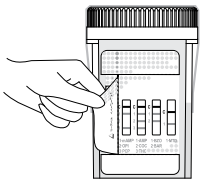


Place security seal over cup



4 Technician peels off label to reveal drug test strips.

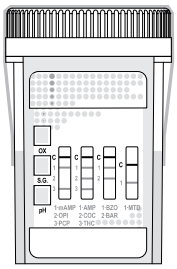
Technician peels off label to reveal adulteration strip(s), if applicable.



Note: The order can be reversed.

5 Read adulteration test results between 2 - 5 minutes, if applicable.

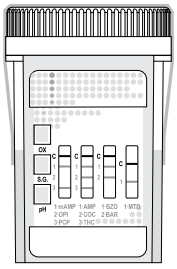
This illustration is an example of a 9 drug cup. Other configurations available but not shown.



2 - 5 minutes.
2 minutes
5 minutes

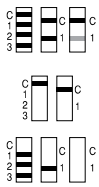
Adulteration Strip
See color chart and package insert for interpretation.

6 Read drug test results at 5 minutes.**



5 minutes. 60 minutes.

Read the drug strip results at 5 minutes. Test results stable up to 60 minutes.



**NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For professional in vitro diagnostic use only.

*Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, MDMA (Ecstasy), Marijuana, Methadone, Methamphetamine, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants

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11 000 0366 REV2

Instant Technologies

One Step Multi-Drug Screen Test Card with the Integrated iCup® / iCup® A.D.

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BUP/BZO/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

Available with Specimen Validity Test (S.V.T.) for Oxidants/PCC, pH and Creatinine

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D. come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

AMPHETAMINE (AMP 300)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.[3] The plasma half life of Buprenorphine is 2-4 hours.[3] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.[4,5] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[5]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

COCAINE (COC 150)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

OPIATE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[7] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[8]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

S.V.T. SUMMARY

The strip contains chemically treated reagent pads. 2-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), pH and creatinine in human urine which can help assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and to detect the presence of oxidants/PCC, pH, and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is commonly used adulterant.[8] Normal human urine should not contain oxidants or PCC.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
pH	0.06%	99.94%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

For best results, test specimens immediately following collection. Storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to testing.

MATERIALS

Materials Provided

- **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Adulteration color chart (if applicable)
- Security seal label
- Package insert
- Procedure card

Materials Required But Not Provided

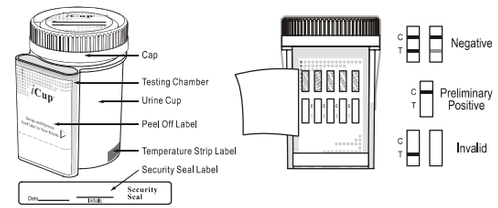
- A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External controls

DIRECTIONS FOR USE

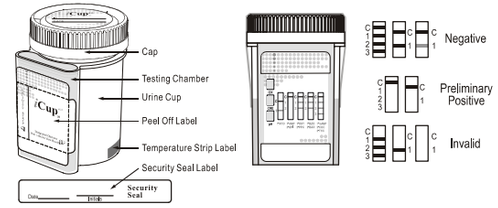
Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Donor dates and initials the security seal and attaches the security seal over the cup cap.
5. Technician peels off label to reveal adulteration strip, if applicable.
6. Technician peels off the label on the multi-drug test card to view results.
7. The adulteration strip, if applicable, should be read between 2-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.
8. If results do not indicate adulteration, read the drug test result at 5 minutes. The drug test results remain stable for up to sixty minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card and Color Chart.
9. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

Cup without SVT



Cup with SVT



INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,4,3]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests, included with this product, are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BUP	Buprenorphine
BZO	Oxazepam, Nordiazepam, α-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.	AMP 1,000	Positive	129	0	>99%
		Negative	0	172	>99%
	AMP 300	Positive	127	0	>99%
		Negative	0	173	>99%
	BAR	Positive	126	1	>99%
		Negative	0	166	>99%
	BUP	Positive	*	*	*
		Negative	*	*	*
	BZO	Positive	131	0	>99%
		Negative	1	162	>99%
	COC 300	Positive	112	1	>99%
		Negative	0	186	99%
	COC 150	Positive	141	0	>99%
		Negative	0	159	>99%
	mAMP 1,000	Positive	121	0	99%
		Negative	1	174	>99%
	mAMP 500	Positive	108	39**	>99%
		Negative	0	153	80%
	MDMA	Positive	86	0	>95%
		Negative	4	152	>99%
	MOP	Positive	125	0	95%
		Negative	7	150	>99%
	MTD	Positive	120	0	89%
		Negative	18	168	>99%
	OPI	Positive	131	0	98%
		Negative	2	164	>99%
	OXY	Positive	142	0	97%
		Negative	4	154	>99%
	PCP	Positive	71	0	99%
		Negative	1	160	>99%
	PPX	Positive	157	0	>99%
		Negative	0	157	>99%
	TCA	Positive	45	0	92%
		Negative	4	177	>99%
	THC	Positive	124	1	>99%
		Negative	0	175	99%

* Commercial kit unavailable for BUP

** 32 specimens showed >500 ng/mL concentration by GC/MS

Method		GC/MS					
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP 1,000	Positive	0	1	8	18	114	97%
	Negative	149	1	5	4	0	95%
BAR	Positive	0	0	4	5	117	92%
	Negative	150	1	5	1	9	98%
BUP	Positive	0	0	0	5	50	98%
	Negative*	150	15	5	1	0	>99%
BZO	Positive	0	7	1	5	26	97%
	Negative	149	7	1	3	1	95%
COC 300	Positive	0	2	15	16	103	96%
	Negative	150	5	7	1	1	90%
THC	Positive	0	13	9	12	109	96%
	Negative	150	6	0	0	1	97%
MTD	Positive	0	0	10	10	112	99%
	Negative	150	17	0	0	1	94%
mAMP 1,000	Positive	0	0	10	9	126	99%
	Negative	150	0	4	1	0	94%
MDMA	Positive	0	0	3	6	82	98%
	Negative	147	0	2	0	0	>99%
MOP	Positive	0	2	7	10	131	>99%
	Negative	150	0	0	0	0	94%
OPI	Positive	0	0	16	18	116	>99%
	Negative	150	0	0	0	0	90%
PCP	Positive	0	0	6	10	40	>99%
	Negative	150	6	0	0	0	97%
*TCA	Positive	0	12	8	15	20	>99%
	Negative	150	17	0	0	0	89%

* When compared with HP/LC at a cut-off of 1,000ng/ml, the following results were tabulated:

Method		GC/MS					
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
*BUP	Positive	0	0	0	5	50	98%
	Negative	150	15	5	1	0	>99%
PPX	Positive	0	0	2	7	158	94%
	Negative	152	5	18	10	0	99%
AMP 300	Positive	0	1	1	2	123	99%
	Negative	150	18	5	0	0	99%

* Negative samples were confirmed negative using LC/MS by pooling these samples into groups of 15.

Method		GC/MS				
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.		Neg.	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
COC 150	Positive	0	0	10	131	>99%
	Negative	150	7	0	2	98%
OXY	Positive	0	5	2	135	98%
	Negative	147	8	2	1	97%

Method		GC/MS		
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.		Neg.	Pos.	% agreement with GC/MS
mAMP 500	Positive	7	140	>99%
	Negative	153	0	96%

Forty (40) clinical samples for each drug were run using each of the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

Precision

A study was conducted at three physician offices for Amphetamine (1,000 ng/mL), Cocaine (300 ng/mL), Marijuana, Methamphetamine (1,000 ng/mL), Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	90	0	88	2	89	1
-25% Cut-off	90	80	10	70	20	70	20
+25% Cut-off	90	34	56	13	77	12	78
+50% Cut-off	90	5	85	5	85	3	87

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	83	7	87	3	90	0
-25% Cut-off	90	67	23	75	15	80	10
+25% Cut-off	90	28	62	30	60	22	68
+50% Cut-off	90	1	89	0	90	2	88

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	0	15	1	14	0	15
15	15	0	15	0	15	0	15

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	25	5	25	5
Cut-off	30	17	13	13	17	13	17	14	16
+25% Cut-off	30	5	25	4	26	7	23	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	24	6	27	3	20	10
Cut-off	30	19	11	14	16	14	16	19	11
+25% Cut-off	30	3	27	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		MOP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	23	7	20	10	27	3
Cut-off	30	18	12	13	17	18	12	17	13
+25% Cut-off	30	5	25	8	22	10	20	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4	24	6	25	5
Cut-off	30	17	13	18	12	14	16	17	13	18	12
+25% Cut-off	30	4	26	6	24	6	24	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** at 5 minutes.

Compound	**ng/mL**
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390

Compound	ng/mL
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8–THC	15,000
Δ^9–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250

Compound	ng/mL
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®A.D.** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine
Acetophenetidin	Deoxycorticosterone	Labetalol	Quinacrine
N-Acetylprocainamide	Dextromethorphan	Loperamide	Quinine
Acetylsalicylic acid	Diclofenac	Meperidine	Quindine
Aminopyrine	Diflunisal	Meprobamate	Rantidine*
Amoxicillin	Digoxin	Methoxyphenamine	Salicylic acid
Ampicillin	Diphenhydramine	Methylphenidate	Serotonin
l-Ascorbic acid	l -Ψ-Ephedrine	Nalidixic acid	Sulfamethazine
Apomorphine	β-Estradiol	Naproxen	Sulindac
Aspartame	Estrone-3-sulfate	Niacinamide	Tetracycline
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Tetrahydrocortisone
Benzilic acid	l (-)-Epinephrine	Norethindrone	3-acetate
Benzoic acid	Erythromycin	Noscapine	Tetrahydrocortisone
Benzphetamine*	Fenoprofen	d,l-Octopamine	3-(β-D-glucuronide)
Bilirubin	Furosemide	Oxalic acid	Tetrahydrozoline
d,l-Brompheniramine	Gentisic acid	Oxolinic acid	Thiamine
Caffeine	Hemoglobin	Oxymetazoline	Thioridazine
Cannabidol	Hydralazine	Papaverine	d,l-Tyrosine
Chloralhydrate	Hydrochlorothiazide	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrocortisone	Pentazocine	Triamterene
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	Trifluoperazine
d,l-Chlorophenirameine	p-Hydroxytyramine	Phenelzine	Trimethoprim
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo	Tryptamine
Cholesterol	Iproniazid	propylamine	d,l-Tryptophan
Clonidine	d,l-Isoproterenol	Prednisolone	Uric acid
Cortisone	Isoxsuprine	Prednisone	Verapamil
l-Cotinine	Ketamine	d,l-Propranolol	Zomepirac

*Parent compound only.

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DN: 1155990701
Effective. Date: 2010-07-23

Integrated E-Z Cup / substance abuse screening device

A **reliable** and **all-inclusive** drug screen solution, ideal for a variety of situations.

FEATURES/BENEFITS

- *All-inclusive collection cup and test panel (multiple drug configurations available)*
- *Minimizes collector exposure to urine*
- *Performance comparable to laboratory screening methods*
- *Secure activation key limits donor access to test*
- *Collector can test at own convenience*
- *FDA 510(k) cleared to market*

TWO CUP DESIGNS TO CHOOSE FROM

E-Z Cup I *— separate key*
Available tests: AMP, BAR, BZO, COC, M-AMP, MDMA, MTD, OPI, PCP, TCA, THC, OXY

E-Z CUP II *— key included with cap*
Available tests: AMP, BAR, BZO, BUP, COC, M-AMP, MDMA, MTD, OPI, PCP, PPX, TCA, THC, OXY

Also available with Specimen Validity Tests or CLIA waived drug analytes.

REDWOOD TOXICOLOGY LABORATORY™

PRODUCT OVERVIEW

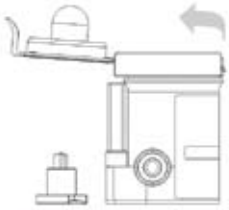
COMPONENTS

***CUP II** diagram shown below. **CUP I** key packaged separately with cup.*

TESTING PROCEDURE

***CUP II** with adulterant test shown, except where indicated.*

1 Remove the key by twisting it from the center of the cup cap. Open cap with the Pull Tab. (Key is held by technician.)



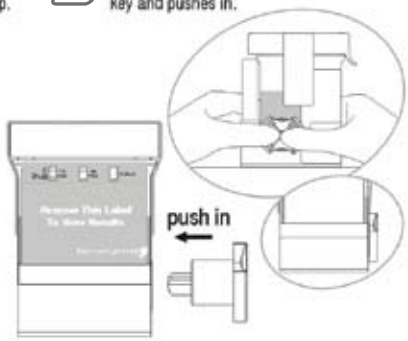
** NOTE: CUP I key packaged with cup*

2 Donor provides specimen and secures cap. Note: Secure cap by pressing down on the Pull Tab until an audible click is heard.

3 Check cap for tight seal. Technician dates and initials the security seal and places security seal over cap.

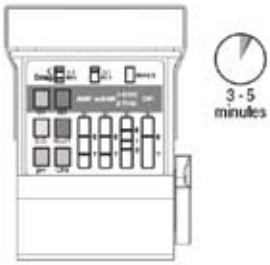
Place security seal over cup

4 On a flat surface, technician inserts key and pushes in.



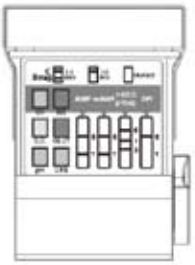
5 Peel off the label to view results.

6 If the test cup includes S.V.T., read adulteration test results between 3 - 5 minutes.

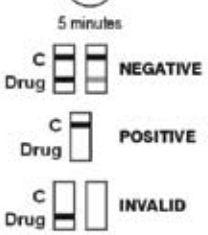


Adulteration Strips
See color chart and package insert for interpretation.

7 Read drug test results at 5 minutes.

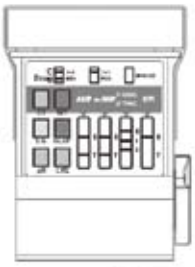


Example: Test shows positive for OPI.



All positive results are presumptive and should be confirmed by an alternative method. (e.g. GC/MS)

8 A photocopy of the drug test results can be made by placing the entire cup with the card face down on the copier.



*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For professional in vitro diagnostic use only.

*Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methamphetamine, Marijuana (THC), MDMA (Ecstasy), Methadone, Opiates (300 or 2,000 ng/mL cut-off), Phencyclidine, and Tricyclic Antidepressants (TCA). Available with specimen validity tests (S.V.T.).

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11 000 0357 REV2

Integrated E-Z Split Key® Cup II

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

Available with Specimen Validity Tests (S.V.T.) for Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The **Integrated E-Z Split Key® Cup II** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the Integrated E-Z Split Key® Cup II come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **Integrated E-Z Split Key® Cup II** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

AMPHETAMINE (AMP 300)

The **Integrated E-Z Split Key® Cup II** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.[3,4] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[4]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

COCAINE (COC 150)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[2]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[5] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

OPIATE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[6] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[7]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

S.V.T. SUMMARY

The strip contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[5] Normal human urine should not contain oxidants or PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[8] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE

The **Integrated E-Z Split Key® Cup II** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°-30°C (36°-86°F). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

For best results, test specimens immediately following collection. Storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to testing.

MATERIALS

Materials Provided

- **Integrated E-Z Split Key® Cup II** [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Keys
- Security seals
- Package insert
- Procedure cards
- SVT/Adulterant color charts (Optional)

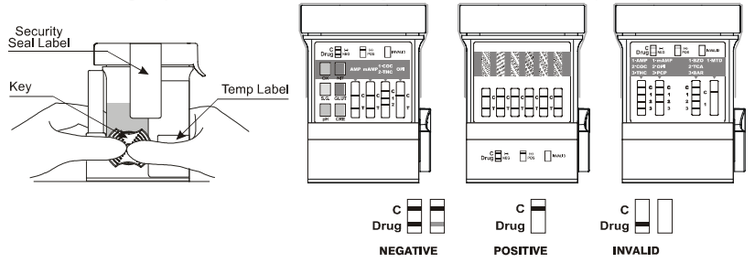
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Remove the key by twisting it from the center of the cup cap.
3. **Collect specimen in the cup** and secure cap tightly by pressing down on the pull tab until an audible click is heard.
4. Technician dates and initials the security seal and attaches the security seal over the cup cap.
5. Place the cup on a flat surface and **push the key to a fully closed position** to initiate the test. Start the timer.
6. Remove the peel off label covering the test results.
7. If adulteration is included on the test cup, read the adulteration strip(s) between 3 and 5 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.
8. **Read the drug strip results at 5 minutes**. The drug test results remain stable for up to sixty minutes.



INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart, if applicable)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **Integrated E-Z Split Key® Cup II** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,4,10]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests, if included with this product, are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **Integrated E-Z Split Key® Cup II** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, α-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

	AMP	AMP 300	BAR	BZO	COC 300	COC 150	THC	MTD	mAMP 1,000
Positive Agreement	97%	>99%	>99%	90%	95%	>99%	98%	>99%	98%
Negative Agreement	>99%	>99%	99%	97%	>99%	>99%	>99%	>99%	>99%
Total Results	98%	>99%	99%	94%	98%	>99%	99%	>99%	99%

	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA
Positive Agreement	>99%	>99%	>99%	>99%	96%	98%	>99%	95%
Negative Agreement	80%	99%	>99%	>99%	99%	>99%	>99%	>99%
Total Results	87%	99%	>99%	>99%	98%	99%	>99%	99%

% Agreement with GC/MS

	AMP 1,000	AMP 300	BAR	BZO	COC 300	COC 150	THC	MTD	mAMP 1,000
Positive Agreement	97%	>99%	92%	97%	96%	99%	97%	99%	99%
Negative Agreement	95%	99%	98%	95%	90%	>99%	88%	94%	94%
Total Results	96%	99%	95%	96%	93%	99%	91%	96%	96%

	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA*
Positive Agreement	>99%	>99%	>99%	>99%	98%	>99%	94%	>99%
Negative Agreement	96%	98%	94%	90%	99%	96%	99%	89%
Total Results	98%	99%	97%	95%	99%	97%	96%	91%

Forty (40) clinical samples for each drug were run using each of the **Integrated E-Z Split Key® Cup II** by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel. *Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	5	10	7	8	10	5
375	15	2	13	5	10	5	10
450	15	0	15	1	14	1	14

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	13	2	13	2
225	15	6	9	7	8	13	2
375	15	0	15	1	14	3	12
450	15	0	15	0	15	0	15

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14

*Note:One invalid result was obtained.

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

MARIJUANA (THC)

11-nor-Δ^9-THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

OPIATE (MOP 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	13	2	15	0
225	15	3	12	7	8	10	5
375	15	1	14	0	15	1	14
450	15	0	15	1	14	0	15

OPIATE (OPI 2,000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1,000	15	15	0	15	0	14	1
1,500	15	13	2	11	4	7	8
2,500	15	4	11	1	14	2	13
3,000	15	0	15	0	15	2	13

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	15	0
750	15	14	1	11	4	14	1
1,250	15	8	7	2	13	6	9
1,500	15	1	14	0	15	1	14

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	22	8	27	3	27	3	27	3
Cut-off	30	12	18	13	17	22	8	11	19
+25% Cut-off	30	2	28	4	26	7	23	5	25
+50% Cut-off	30	0	30	0	30	2	28	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	29	1
-25% Cut-off	30	30	0	24	6	12	18	24	6
Cut-off	30	4	26	14	16	1	29	21	9
+25% Cut-off	30	0	30	7	23	1	29	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		MOP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	23	7	26	4	25	5
Cut-off	30	18	12	13	17	17	13	17	13
+25% Cut-off	30	1	29	8	22	4	26	1	29
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		OXY		PCP		PPX	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	19	11	24	6
Cut-off	30	13	17	18	12	16	14	17	13
+25% Cut-off	30	4	26	6	24	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	TCA	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	22	8
Cut-off	30	12	18
+25% Cut-off	30	7	23
+50% Cut-off	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **Integrated E-Z Split Key® Cup II** at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8–THC	15,000
Δ^9–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Integrated E-Z Split Key® Cup II** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Integrated E-Z Split Key® Cup II**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **Integrated E-Z Split Key® Cup II** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine
Acetophenetidin	Deoxycorticosterone	Labetalol	Quinacrine
N-Acetylprocainamide	Dextromethorphan	Loperamide	Quinine
Acetylsalicylic acid	Diclofenac	Meperidine	Quindine
Aminopyrine	Diflunisal	Meprobamate	Ranitidine*
Amoxicillin	Digoxin	Methoxyphenamine	Salicylic acid
Ampicillin	Diphenhydramine	Methylphenidate	Serotonin
l-Ascorbic acid	l -Ψ-Ephedrine	Nalidixic acid	Sulfamethazine
Apomorphine	β-Estradiol	Naproxen	Sulindac
Aspartame	Estrone-3-sulfate	Niacinamide	Tetracycline
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Tetrahydrocortisone
Benzilic acid	l (-)-Epinephrine	Norethindrone	3-acetate
Benzoic acid	Erythromycin	Noscapine	Tetrahydrocortisone
Benzphetamine*	Fenoprofen	d,l-Octopamine	3-(β-D-glucuronide)
Bilirubin	Furosemide	Oxalic acid	Tetrahydrozoline
d,l-Brompheniramine	Gentisic acid	Oxolinic acid	Thiamine
Caffeine	Hemoglobin	Oxymetazoline	Thioridazine
Cannabidol	Hydralazine	Papaverine	d,l-Tyrosine
Chloralhydrate	Hydrochlorothiazide	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrocortisone	Pentazocine	Triamterene
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	Trifluoperazine
d,l-Chloropheniramine	p-Hydroxytyramine	Phenelzine	Trimethoprim
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo	Tryptamine
Cholesterol	Iproniazid	propylamine	d,l-Tryptophan
Clonidine	d,l-Isoproterenol	Prednisolone	Uric acid
Cortisone	Isoxsuprine	Prednisone	Verapamil
l-Cotinine	Ketamine	d,l-Propranolol	Zomepirac
Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine

*Parent compound only.

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DN: 1150349202
Eff. Date 2006-02-16

6 Cassette / substance abuse screening device

Drugs tested:

- *Amphetamine*
- *Cocaine*
- *Marijuana*
- *Methamphetamine*
- *Opiates*
- *Phencyclidine*

Reliable and convenient **CLIA waived** on-site **drug screening.**

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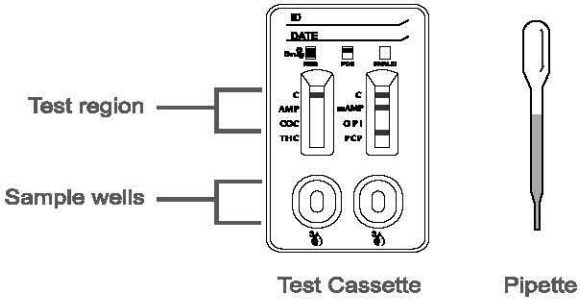
PRODUCT OVERVIEW

6 CASSETTE COMPONENTS

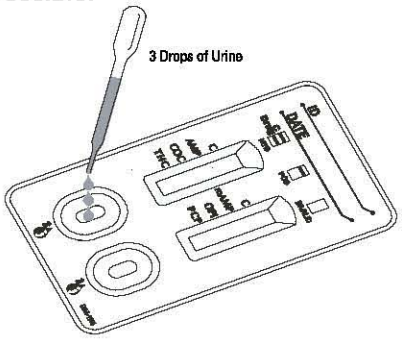


TESTING PROCEDURE

Allow the test device, urine sample, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch. Use test device as soon as possible.

2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL total volume) to each of the sample well (S) of the test device.



Start the timer. Avoid trapping air bubbles in the sample well (S). See illustration.

3. Wait for the colored line(s) to appear. The results should be read at 5 minutes or up to 4 hours after test initiation.

RESULT KEY

*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For professional in vitro diagnostic use only.

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CLIA WAIVED
Multi-Drug,Multi-Line Screen Test Device

Instruction Sheet for testing of any combination of the following drugs: AMP/COC/THC/mAMP/OPI/PCP

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The Multi-Drug, Multi-line Screen Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	**d-Amphetamine**	**1,000 ng/mL**
Cocaine (COC)	**Benzoylecgonine**	**300 ng/mL**
Marijuana (THC)	**11-nor-Δ^9-THC-9 COOH**	**50 ng/mL**
Methamphetamine (mAMP)	**d-Methamphetamine**	**1,000 ng/mL**
Opiates (OPI 2000)	**Morphine**	**2,000 ng/mL**
Phencyclidine (PCP)	**Phencyclidine**	**25 ng/mL**

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The Multi-Drug, Multi-Line Screen Test Device is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA). [4]

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.
Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[2,3] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[3]
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA).

MARIJUANA (THC)

THC (Δ^9--tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA). [4]

METHAMPHETAMINE (mAMP)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.
The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

OPIATES (OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.
Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[1]
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA).

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.
Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.
PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]
The Multi-Drug, Multi-Line Screen Test Device yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA).

PRINCIPLE

The Multi-Drug, Multi-Line Screen Test Device is an immunoassay based on the principle of competitive binding. Drugs, which may be present in the urine sample, compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a urine sample migrates upward by capillary action. A drug, if present in the urine sample below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.
A drug-positive urine sample will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine sample will generate a line in the test line region because of the absence of drug competition.
To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of sample has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates on the test line, goat polyclonal antibody against gold-protein conjugate at the control line and dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, THC, Methamphetamine, Morphine or Phencyclidine.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Sample Storage

Urine samples may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20°C. Frozen samples should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable droppers
- Package insert

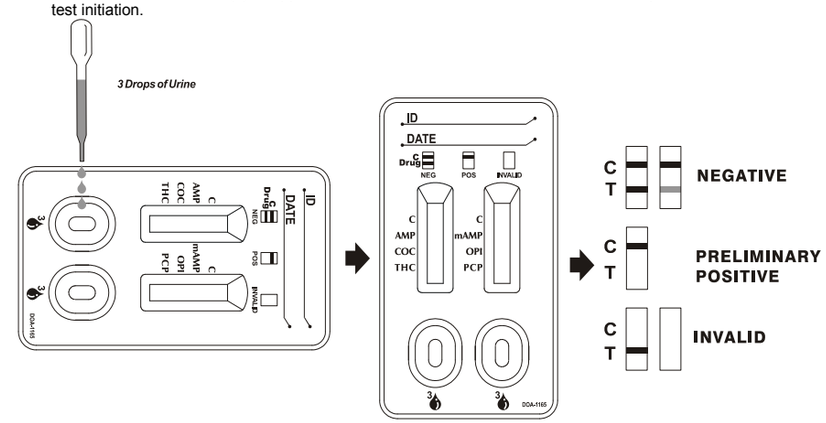
Materials Required But Not Provided

- Sample collection container
- External Positive and Negative Controls
  (Please contact your manufacturer for a list of suggested external control suppliers)
- Timer

DIRECTIONS FOR USE

Allow the test device, urine sample, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch. Use test device as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 ul total volume) to the sample well (S) of the test device. Start the timer. Avoid trapping air bubbles in the sample well (S). See the illustration below.
3. Wait for the colored lines(s) to appear. The results should be read at 5 minutes or up to 4 hours after test initiation.



RESULT INTERPRETATION

(Please refer to the illustration above)

POSITIVE: A colored line appears in the control region (C). NO line appears in the test region next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.
NEGATIVE:* A colored line appears in the control region (C) and a colored line appears in the test region (T). Up to four colored lines may appear in each result window. One line will be in the control region (C). Up to three lines will be next to the drug names in the test region. This negative result means that the drug concentration in the urine sample is below the designated cut-off for a specific drug.
***NOTE:** The shade of color in the test region (T) may vary. The result should be considered negative whenever there is even a faint colored line.
INVALID: No line appears in the control region (C). If this occurs read the directions again and repeat the test with a new panel. If the result is still invalid stop using the test kit and contact your distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

It is recommended that external positive and negative controls be tested with each new opened kit, new lot or shipment of product, with each change in operator within the test kit, weekly as a check on continued storage conditions, and as otherwise required by your laboratory's internal quality system procedures. Control specimens should be performed the same as patient specimens (refer to Directions for Use and Interpretation of Results). If unexpected results are seen when running the external positive or negative controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another device. If the problem persists, discontinue use of the test kit immediately and contact your Distributor at (877) 444-0049.

LIMITATIONS

1. The Multi-Drug, Multi-Line Screen Test Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [3,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine sample may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine samples may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine sample.
4. A Positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug, Multi-Line Screen Test Device and commercially available drug rapid tests. Testing was performed on approximately 1,000 samples previously collected from subjects presenting for Drug Screen Testing. Some samples in the +/- 25% cut-off levels were prepared by diluting from the more concentrated clinical samples with the neat urine. Presumptive positive results were confirmed by GC/MS. Negative urine samples were screened initially by Predicate test. Approximately 10% negative samples were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested in the following clinical studies:

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
mAMP	Methamphetamine
OPI	Morphine, Codeine
PCP	Phencyclidine

The following results were tabulated:

Method		GC/MS					
Multi-Drug Multi-Line		Neg.*	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP	Positive	0	0	1	14	114	97%
	Negative	150	2	12	8	0	
COC	Positive	0	0	1	13	99	98%
	Negative	150	8	22	4	2	
THC	Positive	0	6	3	12	114	95%
	Negative	150	13	6	2	4	
mAMP	Positive	0	0	0	4	117	96%
	Negative	150	0	12	6	7	
OPI	Positive	0	0	2	18	111	98%
	Negative	150	0	14	2	1	
PCP	Positive	0	0	1	6	64	96%
	Negative	150	0	3	3	5	

*Negative urine samples were screened by predicate tests.

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
Multi-drug Multi-line Test Device	AMP	Positive	129	0	>99%
		Negative	0	172	
	COC	Positive	112	1	>99%
		Negative	0	186	
	THC	Positive	124	1	>99%
		Negative	0	175	
	mAMP	Positive	121	0	>99%
		Negative	1	174	
	OPI	Positive	131	0	99%
		Negative	2	164	
	PCP	Positive	71	0	>99%
		Negative	1	160	

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations. >99% agreement with expected results was found at +/- 50% cut-off for each drug tested (with a 95% confidence interval.

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug, Multi-Line Screen Test Device at 5 minutes.

AMPHETAMINE	ng/mL
d-Amphetamine	1,000
d,l-Amphetamine sulfate	3,000
l-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine	2,000
Phentermine	3,000
COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
METHAMPHETAMINE	
d-Methamphetamine	1,000
ρ-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
(±)-3,4-Methylenedioxymethamphetamine	2,000
Mephentermine	50,000
OPIATES	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levophanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PCP	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

Precision

A study was conducted at three physician offices for Amphetamine, Cocaine, Marijuana, Methamphetamine, Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded samples, containing drugs at the concentration of +/-50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug, Multi-Line Screen Test Device was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug, Multi-Line Screen Test Device. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cocaine, Amphetamine, Methamphetamine, Marijuana, Opiate or Phencyclidine positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug, Multi-Line Screen Test Device at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine*
Bilirubin	d,l-Brompheniramine
Caffeine	Cannabidol
Chloral hydrate	Chloramphenicol
Chlorothiazide	d,l-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	l-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diflunisal	Digoxin
Diphenhydramine	Ecgonine methyl ester
l -Ψ-Ephedrine	β-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine	l(–)-Epinephrine
Erythromycin	Fenoprofen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone
O-Hydroxyhippuric acid	p-Hydroxyamphetamine
p-Hydroxytyramine	Ibuprofen
Iproniazid	d,l-Isoproterenol
Isoxsuprine	Ketamine
Ketoprofen	Labetalol
Loperamide	Meperidine
Meprobamate	Methoxyphenamine
Methylphenidate	Nalidixic acid
Naloxone	Naltrexone
Naproxen	Niacinamide
Nifedipine	Norethindrone
d-Norpropoxyphene	Noscapine
d,l-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G
Pentazocine	Perphenazine
Phenelzine	Trans-2-phenylcyclo-propylamine
l-Phenylephrine	β-Phenylethylamine
Phenylpropanolamine	Prednisolone
Prednisone	d,l-Propranolol
d-Propoxyphene	d-Pseudoephedrine
Quinacrine	Quinine
Quindine	Ranitidine
Salicylic acid	Serotonin
Sulfamethazine	Sulindac
Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (β-D-glucuronide)	Tetrahydrozoline
Thiamine	Thioridazine
d,l-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine
Trimethoprim	Tryptamine
d,l-Tryptophan	Tyramine
Uric acid	Verapamil
Zomepirac	

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

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REDWOOD TOXICOLOGY LABORATORY

Reditest® substance abuse screening devices are manufactured in China for Redwood Toxicology Laboratory, Inc.

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Smoke Cassette / cotinine screening device

A **reliable** and cost **effective** on-site **cotinine screening** solution.

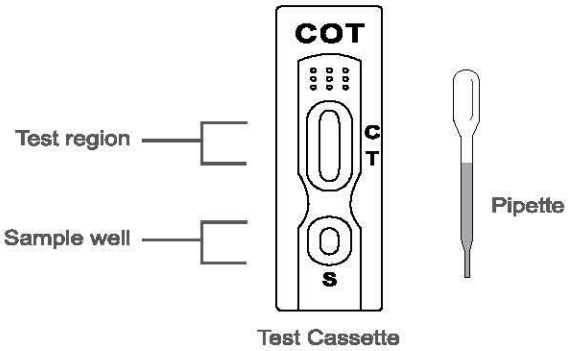
Determine smoking status:

- *Detects Cotinine, a Nicotine metabolite, in urine.*

reditest®

PRODUCT OVERVIEW

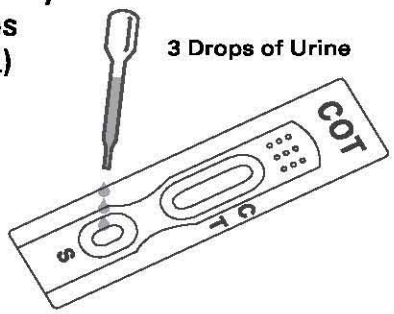
SMOKE CASSETTE COMPONENTS



TESTING PROCEDURE

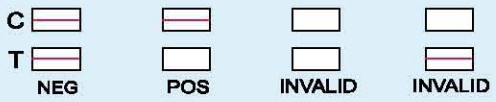
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µL) to the sample well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration.



3. Wait for the colored line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

RESULT KEY



*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For determination of smoking status only.

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COT

One Step
Cotinine Test Device
Package Insert

A rapid, one step test for the qualitative detection of Cotinine (nicotine metabolite) in human urine.
For Determination of Smoking Status Only.

INTENDED USE

The COT One Step Cotinine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Cotinine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT One Step Cotinine Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The COT One Step Cotinine Test Device (Urine) yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE

The COT One Step Cotinine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains mouse monoclonal anti-Cotinine antibody-coupled particles and Cotinine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Package insert

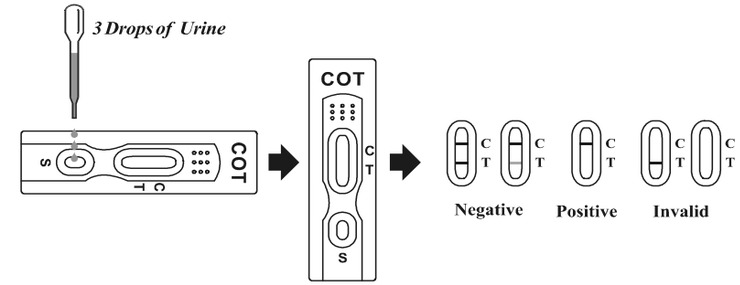
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test device, urine specimen to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The result should be **read at 5 minutes**. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Cotinine concentration is below the detectable level (200 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Cotinine concentration exceeds the detectable level (200 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION

1. The COT One Step Cotinine Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates only that the presence of Cotinine is above the cut-off concentration. It does not indicate or measure level of consumption.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the COT One Step Cotinine Test Device (Urine) and a leading commercially available COT rapid test. Testing was performed on 300 clinical specimens collected from smoking and non-smoking volunteers. The following results were tabulated:

Method		Other COT Rapid Test		Total Results
COT One Step Test Device	Results	Positive	Negative	
	Positive	103	12	115
	Negative	0	185	185
Total Results		103	197	300
% Agreement		>99%	94%	96%

Analytical Sensitivity

A drug-free urine pool was spiked with Cotinine at the following concentrations: 0 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 250 ng/mL, 300 ng/mL and 400 ng/mL. The result demonstrates > 99% accuracy at 100% above and 50% below the cut-off concentration. The data are summarized below:

Cotinine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	90	90	0
100	-50%	90	90	0
150	-25%	90	90	0
200	Cut-off	90	63	27
250	+25%	90	40	50
300	+50%	90	16	74
400	+100%	90	0	90

Analytical Specificity

The following table lists compounds that are positively detected in urine by the COT One Step Cotinine Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
(-)-Cotinine	200
(-)-Nicotine	6,250

Precision

A study was conducted by trained operators using 2 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Cotinine, 50% Cotinine below cut-off level and 100% Cotinine above the 200 ng/mL cutoff level were used. The following results were tabulated:

Cotinine Concentration (ng/mL)	n per lot	Lot A		Lot B	
		-	+	-	+
0	30	30	0	30	0
100	30	30	0	30	0
400	30	0	30	0	30

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 100 ng/mL and 400 ng/mL of Cotinine. The COT One Step Cotinine Test Device (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Cotinine to 100 ng/mL and 400 ng/mL. The spiked, pH-adjusted urine was tested with the COT One Step Cotinine Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cotinine positive urine. The following compounds show no cross-reactivity when tested with the COT One Step Cotinine Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	Acetone	Acetophenetidin	Acetylsalicyclic acid
Albumin	Aminopyrine	Amitryptyline	Amobarbital
Amoxapine	Amoxicillin	l-Amphetamine	Ampicillin
Apomorphine	Aspartame	Atropine	Benzilic acid
Benzoic acid	Benzoylecgonine	Benzphetaminne	Bilirubin
Brompheniramine	Buspirone	Caffeine	Cannabidiol
Cannabinol	Chloral Hydrate	Chloramphenicol	Chlordiazepoxide
Chloroquine	(+)-Chlorpheniramine	(±)Chlorpheniramine	Chlorpromazine
Chlorprothixene	Cholestrol	Cimetidine	Clomipramine
Clonidine	Cocaine	Codeine	Cortisone
Creatinine	Cyclobarbital	Cyclobenzaprine	Deoxycorticosterone
(-) Deoxyephedrine	R(-) Deprenyl	Dextromethorphan	Diazepam
Diclofenac	Digoxin	4-Dimethylaminoantipyrine	Diphenhydramine
5,5-Diphenylhydantoin	Disopyramide	Doxylamine	Ecgonine
Ecgonine Methylester	EDDP	Efavirenz (Sustiva)	EMDP
Ephedrine	(1r,2s)-(-) Ephedrine	(-)ψ-Ephedrine	(±)Epinephrine
Erythromycin	B-Estradiol	Estrone 3-sulfate	Ethanol
Ethyl-p-aminobenzoate	Etodolac	Famprofazone	Fenfluramine
Fenoprofen	Fentanyl	Fluoxetine	Furosemide
Gentisic acid	d (+) Glucose	Guaiacol Glyceryl Ether	Hemoglobin
Hydralazine	Hydrochlorothiazide	Hydrocodone	Hydrocortisone
Hydromorphone	p-Hydroxyamphetamine	o-Hydroxyhippuric acid	p-Hydroxymethamphetamine
p-Hydroxynorephedrine	Hydroxyzine	3-Hydroxytyramine	Ibuprofen
Imipramine	Iproniazid	(-)Isoproterenol	Isoxsuprine
Kanamycin	Ketamine	Ketoprofen	Labetalol
l-Ascorbic acid	l-Ephedrine	l-Epinephrine	Levorphanol
Lidocaine	Lindane	Lithum Carbonate	Loperamide
Maprotiline	Meperidine	Mephentermine	Meprobamate
Methadone	d-Methamphetamine	l-Methamphetamine	Methaqualone
Methoxyphenamine	MDA*	MDMA**	Methylphenidate
Methyprylon	Metoprolol	Morphine Sulfate	Morphine 3-β-d-glucuronide
Nalidixic acid	Nalorphine	Naloxone	Naltrexone
Nimesulide	Norcodeine	a-Naphthaleneactetic acid	Norethindrone
Normorphine	d-Norpropoxyphene	Noscapine	d,l-Octopamine
Orphenadrine	Oxalic acid	Oxazepam	Oxolinic acid
Oxycodone	Oxymetazoline	Oxymorphone	Papaverine
Pemoline	Penicillin-G	Pentazocine	Pentobarbital
Perphenazine	Phencyclidine	Phenelzine	Pheniramine
Phenobarbital	Phenothiazine	Phentermine	Trans-2-phenylcyclopropylamine
l-Phenylephrine	B-Phenylethylamine	d,l Norephedrine	(±)Phenylpropanolamine
Prednisolone	Prednisone	Procaine	Promazine
Promethazine	d,l-Propanolol	d-Propoxyphene	d-Pseudoephedrine
Quinacrine	Quinidine	Quinine	Ranitidine
Riboflavin	Salicylic acid	Secobarbital	Serotonin
Sodium Chloride	Sulfamethazine	Sulindac	Temazepam
Tetracycline	Tetrahydrocortisone	3-acetate Tetrahydrozoline	Thebaine
Theophylline	Thiamine	Thioridazine	l-Thyroxine
Tolbutamine	Cis-Tramadol	Trazodone	Trimterene
Trifluoperazine	Trimethobenzamide	Trimethoprim	Trimipramine
Tryptamine	d,l-Tryptophan	Tyramine	d,l-Tyrosine
Uric Acid	Verapmil	Zomepirac	

*MDA= 3,4-Methylenedioxyamphetamine **MDMA = 3,4-Methylenedioxymethamphetamine

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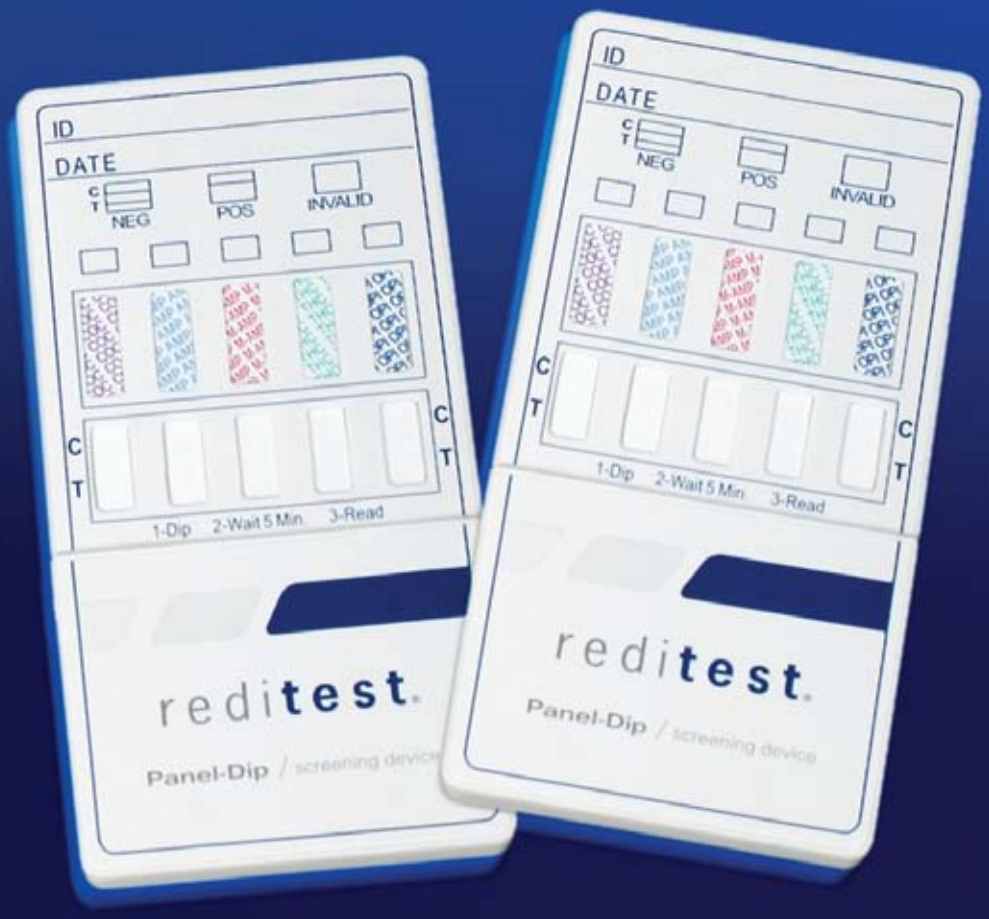
Printed in China

DN: 1150311801
Eff. Date: 2005-04-30

Panel-Dip / substance abuse screening device



A **reliable** and cost **effective** on-site **drug screening** solution.

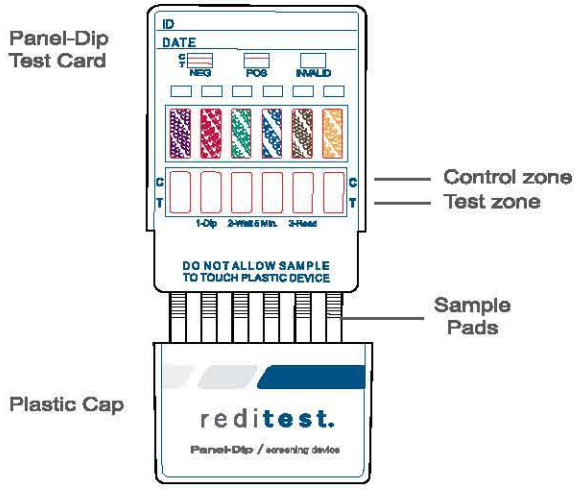
Available tests include:

- *Amphetamine*
- *Methamphetamine*
- *Barbiturates*
- *Benzodiazepines*
- *Buprenorphine*
- *Cocaine*
- *Marijuana (THC)*
- *MDMA (Ecstasy)*
- *Methadone*
- *Opiates*
- *Oxycodone*
- *Phencyclidine (PCP)*
- *Propoxyphene*
- *Trycyclic Anti-depressants*

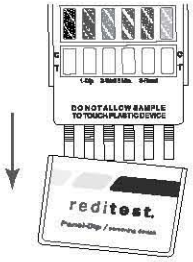
reditest®

PRODUCT OVERVIEW

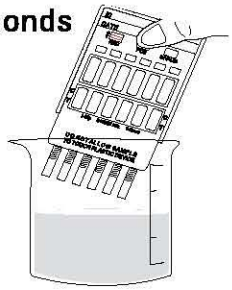
PANEL-DIP COMPONENTS



TESTING PROCEDURE



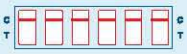
1. Remove device from foil pouch.
2. Pull plastic cap from test device.
3. Dip revealed sample pads into urine sample for a minimum of 15-30 seconds until urine is seen wicking into the reading zone.



4. Remove the device from the urine and replace the plastic cap. Place on a flat surface.
5. Read test results at 5 minutes. (Do not interpret results after 4 hours as false results may occur. Note: Any line at all in the test zone is to be interpreted as negative.)

RESULT KEY

NEGATIVE
Colored line appears in Test (T) Zone



POSITIVE
NO Colored line in Test (T) Zone

INVALID
Colored line must appear in Control (C) Zone for test to be valid

*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For professional in vitro diagnostic use only.

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One Step Drug Screen Test Card

Package Insert for Single and Multi Drug Screen Test Cards

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The **One Step Drug Screen Test Card** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA) Ecstasy	d,l Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Drug Screen Test Card can consist of any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **One Step Drug Screen Test Card** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.
The **One Step Drug Screen Test Card** yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

AMPHETAMINE (AMP 300)

The AMP 300 One Step Amphetamine Test Strip yields a positive result when Amphetamines in urine exceed 300 ng/mL.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.
Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.
Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.
The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[1]

The **One Step Drug Screen Test Card** yields a positive result when the Barbiturates in urine exceed 300 ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.
Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.
Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in urine is 3-7 days.
The **One Step Drug Screen Test Card** yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.
Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in urine in a short time primarily as Benzoylecgonine.[2,3] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[3]
The **One Step Drug Screen Test Card** yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

COCAINE (COC 150)

The COC-150 One Step Cocaine Test Strip yields a positive result when the cocaine metabolite in urine exceeds 150 ng/mL.

MARIJUANA (THC)

THC (Δ^9--tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).
The **One Step Drug Screen Test Card** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.
Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[1]
The **One Step Drug Screen Test Card** yields a positive result when the Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.
The **One Step Drug Screen Test Card** yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The mAMP 500 One Step Methamphetamine Test Strip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The mAMP 500 One Step Methamphetamine Test Strip yields a positive result when the Methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for a summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) ECSTASY

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[8] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.
The **One Step Drug Screen Test Card** yields a positive result when Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATE (OPI 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.
Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in urine for several days after an opiate dose.[1]
The **One Step Drug Screen Test Card** yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (OPI 2,000)

The **One Step Drug Screen Test Card** yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4] See opiate (OPI 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.
Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%)1. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.
The OXYCODONE One Step Oxycodone Test Strip yields a positive result when the oxycodone level in urine exceeds 100 ng/mL.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.
Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.
PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]
The **One Step Drug Screen Test Card** yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The One Step Propoxyphene Test Strip yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **One Step Drug Screen Test Card** yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The **One Step Drug Screen Test Card** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°-30°C (36°-86°F). The test is stable through the expiration date printed on the sealed pouch. The test card must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- **One Step Drug Screen Test Card**
- Package insert

Materials Required But Not Provided

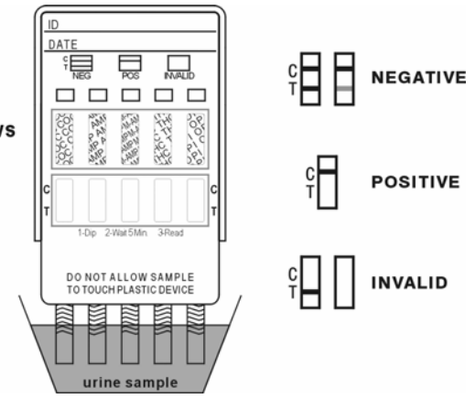
- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

Allow the test card, urine specimen, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Remove the test card from the sealed pouch and use it as soon as possible. Remove the cap from the end of the test card. Immerse the strip(s) of the test card vertically in the urine specimen for at least 10-15 seconds. **Immerse the test card to at least the level of the wavy lines on the strip(s), but not above the arrow(s) on the test card. See the illustration below.**
2. Replace cap and place the test card on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear. The results should be read at 5 minutes. Results remain stable for up to 4 hours after test initiation.

Note: This illustration shows a 5-drug test card



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. **A colored line appears in the Control region (C) and a colored line appears in the Test region (T)**. This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **One Step Drug Screen Test Card** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. [1,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **One Step Drug Screen Test Card** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, OH-Alprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

Method		GC/MS					
Multi-Drug Single-Line Test Card		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP	Positive	0	1	8	18	114	97%
	Negative	149	1	5	4	0	95%
BAR	Positive	0	0	4	5	117	92%
	Negative	150	1	5	1	9	98%
BZO	Positive	0	7	1	5	26	97%
	Negative	149	7	1	3	1	95%
COC	Positive	0	2	15	16	103	96%
	Negative	150	5	7	1	1	90%
THC	Positive	0	13	9	12	109	96%
	Negative	150	6	0	0	1	97%
MTD	Positive	0	0	10	10	112	99%
	Negative	150	17	0	0	1	94%
mAMP	Positive	0	0	10	9	126	99%
	Negative	150	0	4	1	0	94%
MDMA	Positive	0	0	3	6	82	98%
	Negative	147	0	2	0	0	>99%
OPI 300	Positive	0	2	7	10	131	>99%
	Negative	150	0	0	0	0	94%
OPI 2,000	Positive	0	0	16	18	116	>99%
	Negative	150	0	0	0	0	90%
PCP	Positive	0	0	6	10	40	>99%
	Negative	150	6	0	0	0	97%
*TCA	Positive	0	12	8	15	20	>99%
	Negative	150	17	0	0	0	89%

%Agreement with Commercial Kit

	AMP 1,000	AMP 300	BAR	BZO	COC 300	COC 150	THC	MTD	mAMP 1,000
Positive Agreement	97%	>99%	>99%	90%	95%	>99%	98%	99%	98%
Negative Agreement	>99%	>99%	>99%	97%	>99%	>99%	>99%	>99%	>99%
Total Results	98%	>99%	99%	94%	98%	>99%	99%	>99%	99%

	mAMP 500	MDMA	OPI 300	OPI 2,000	OXY	PCP	PPX	TCA
Positive Agreement	>99%	>99%	>99%	>99%	97%	98%	>99%	95%
Negative Agreement	80%	99%	>99%	>99%	97%	>99%	>99%	>99%
Total Results	87%	99%	>99%	>99%	97%	99%	>99%	99%

%Agreement with GC/MS

	AMP 1,000	AMP 300	BAR	BZO	COC 300	COC 150	THC	MTD	mAMP 1,000
Positive Agreement	97%	>99%	92%	97%	96%	>99%	96%	99%	99%
Negative Agreement	95%	99%	98%	95%	90%	98%	97%	>94%	94%
Total Results	96%	99%	95%	96%	93%	98%	96%	>96%	96%

	mAMP 500	MDMA	OPI 300	OPI 2,000	OXY	PCP	PPX	TCA*
Positive Agreement	99%	98%	>99%	>99%	98%	100%	94%	>99%
Negative Agreement	96%	>99%	94%	>90%	97%	97%	99%	89%
Total Results	98%	99%	97%	>95%	97%	98%	96%	94%

Forty (40) clinical samples for each drug were run using each of The **One Step Drug Screen Test Card** by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.
*Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	5	10	7	8	10	5
375	15	2	13	5	10	5	10
450	15	0	15	1	14	1	14

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	14	1	14	1	15	0
225	15	11	4	14	1	14	1
375	15	0	15	1	14	3	12
450	15	0	15	0	15	0	15

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14

*Note: One invalid result was obtained.

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

MARIJUANA (THC)

11-nor-Δ^9 -THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) ECSTASY

Methylenedioxymeth-amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

OPIATE (OPI 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	13	2	15	0
225	15	3	12	7	8	10	5
375	15	0	15	1	14	0	15
450	15	0	15	0	15	0	15

OPIATE (OPI 2,000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1,000	15	15	0	15	0	14	1
1,500	15	13	2	11	4	7	8
2,500	15	4	11	1	14	2	13
3,000	15	0	15	0	15	2	13

OXYCODONE (OXY)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	14	1
75	15	15	0	14	1	5	10
125	15	15	0	3	12	2	13
150	15	0	15	0	15	0	15

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

PROPOXYPHENE (PPX)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
750	15	14	1	11	4	14	1
1,250	15	8	7	2	13	6	9
1,500	15	1	14	0	15	1	14

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	22	8	27	3	27	3	27	3
Cut-off	30	12	18	13	17	22	8	11	19
+25% Cut-off	30	2	28	4	26	7	23	5	25
+50% Cut-off	30	0	30	0	30	2	28	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	29	1
-25% Cut-off	30	30	0	24	6	12	18	24	6
Cut-off	30	4	26	14	16	1	29	21	9
+25% Cut-off	30	0	30	7	23	1	29	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		OPI 300	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	23	7	26	4	25	5
Cut-off	30	18	12	13	17	17	13	17	13
+25% Cut-off	30	1	29	8	22	4	26	1	29
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI 2,000		OXY		PCP		PPX	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	23	7	19	11	24	6
Cut-off	30	13	17	13	17	16	14	17	13
+25% Cut-off	30	4	26	8	22	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	TCA	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	22	8
Cut-off	30	12	18
+25% Cut-off	30	7	23
+50% Cut-off	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by **One Step Drug Screen Test Card** at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000	
d-Amphetamine	1,000
d,l-Amphetamine sulfate	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300	
d-Amphetamine	300
d/l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d/l-Norephedrine	100,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	

Compound	ng/mL
METHADONE	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000	
d-Methamphetamine	1,000
ρ-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500	
dl-Methamphetamine	500
d-Amphetamine	50,000
d/l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine	1,000
P-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE (OPI 300)	
Morphine	300
Codeine	300
Ethylmorphine	6,250

Oxazepam	300
Alprazolam	196
Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlordiazepoxide	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE 300	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300
PCP	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1500
6-Monoacetylmorphine	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE (2,000)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levophanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,562
Hydromorphone	12,500
Oxymorphone	1,562
Thebaine	50,000
TCA	
Notriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **One Step Drug Screen Test Card** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with **One Step Drug Screen Test Card**. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with **One Step Drug Screen Test Card** at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin	N-Acetylprocainamide
Acetylsalicylic acid	Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid	Apomorphine
Aspartame	Atropine	Benzilic acid
Benzoic acid	Benzphetamine*	Bilirubin
d/l-Brompheniramine	Caffeine	Cannabidol
Chloral-hydrate	Chloramphenicol	Chlorothiazide
d/l-Chloropheniramine	Chlorpromazine	Chloroquine
Cholesterol	Clonidine	Cortisone
l-Cotinine	Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac	Diflunisal
Digoxin	Diphenhydramine	Ecgonine methyl ester
l -Ψ-Ephedrine	β-Estradiol	Estrone-3-sulfate
Ethyl-p-aminobenzoate	[1R,2S] (-) Ephedrine	l(–)-Epinephrine
Erythromycin	Fenoprofen	Furosemide
Gentisic acid	Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone	o-Hydroxyhippuric acid
p-Hydroxyamphetamine	p-Hydroxytyramine	Ibuprofen
Iproniazid	d/l-Isoproterenol	Isoxsuprine
Ketamine	Ketoprofen	Labetalol
Loperamide	Meperidine	Meprobamate
Methoxyphenamine	Methylphenidate	Nalidixic acid
Naloxone	Naltrexone	Naproxen
Niacinamide	Nifedipine	Norethindrone
d-Norpropoxyphene	Noscapine	d/l-Octopamine
Oxalic acid	Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G	Pentazocine hydrochloride
Perphenazine	Phenelzine	l-Phenylephrine
Trans-2-phenylcyclo-propylamine hydrochloride	β-Phenylethylamine	Phenylpropanolamine
Prednisolone	Prednisone	d/l-Propranolol
d-Propoxyphene	d-Pseudoephedrine	Quinacrine
Quinine	Quindine	Rantidine
Salicylic acid	Serotonin	Sulfamethazine
Sulindac	Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (β-D-glucuronide)	Tetrahydrozoline	Thiamine
Thioridazine	d/l-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine	Trimethoprim
Tryptamine	d/l-Tryptophan	Tyramine
Uric acid	Verapamil	Zomepirac

*Parent compound only.

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1) Source: 2009 National Drug Threat Assessment, National Drug Intelligence Center, U.S. Department of Justice

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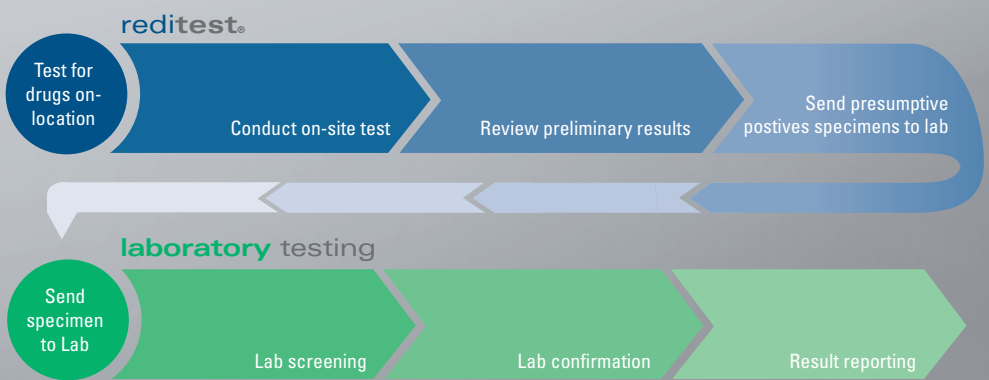

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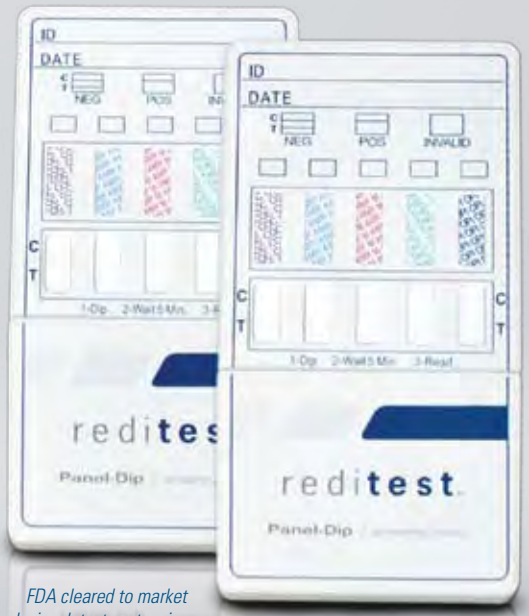

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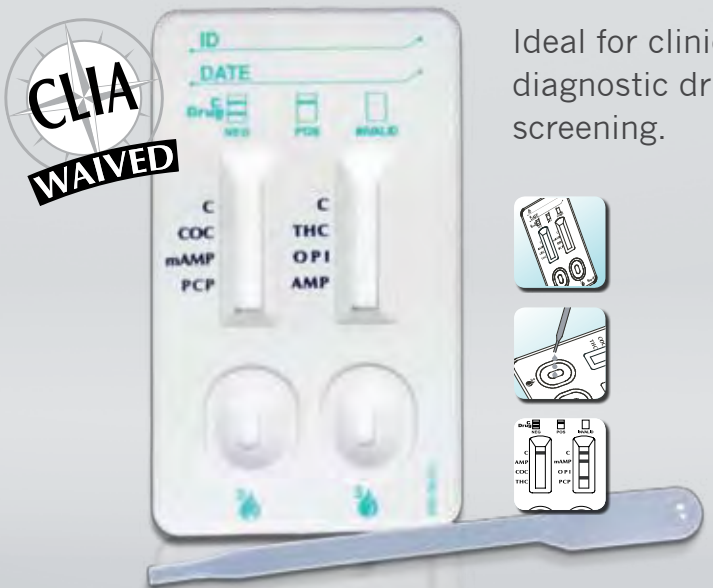
- FDA 510(k) cleared to market *(NIDA 5 cut-off levels meet SAMHSA guidelines)*
- Fast test results in 5 minutes
- Simple procedure: collect, dip, read results
- Built in procedural controls for negative, positive or invalid results
- 25 test devices per box *(long shelf life)*

**See pages 16-17 for available panel configurations, cut-offs and procedures.*



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- Results in 5 minutes

See page 20-21 for available panels, cut-offs and procedure

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- Tests 6 commonly abused drugs: AMP, M-AMP, THC, COC, OPI, PCP
- Ideal for recent drug use detection
- Eliminates collection site fees, same sex administrator and complex training
- Adequate saliva collections every time
- Results in 10 minutes
- Reliable on-site test and collector for sending specimens to the lab

See page 18-19 for available panels, cut-offs and procedure

Assurance and reliability in one screening device.

iscreen™ ofd

*3 test configurations**

The iScreen™ OFD (Oral Fluid Device) offers you a reliable and affordable saliva drug test solution. Screening devices are now widely available, but few manufacturers offer RTL's quality, flexibility, and superior support.

- Tests include: AMP, M-AMP, COC, OPI, PCP and THC
- Eliminates the need for a controlled urine collection site
- Use anywhere, anytime—eliminating privacy concerns and same sex administrators
- Results in under 10 minutes

*See page 18-19 for available panels, cut-offs and procedure

Dependable results for the presence of drugs in saliva.

Now available with benzodiazepine detection.
P/N: 01 102 2083

oralert™

*2 test configurations**

OrAlert™ combines proven technology and screening accuracy. Look no further than OrAlert to provide reliable saliva drug screening. Ideal for most testing environments.

- Tests include: AMP, M-AMP, BZO, COC, OPI, PCP and THC
- Improved sensitivity of parent THC
- Zero collector exposure to specimen
- Split specimen well
- Results in under 10 minutes

*See page 18-19 for available panels, cut-offs and procedure

REDWOOD TOXICOLOGY LABORATORY™

*Not sure yet? Try a **FREE** sample.*

Instant alcohol saliva screening made simple.

redi**test**® **alcohol-**saliva test

P/N 01 362 0001

Test for alcohol presence more confidently and more efficiently with this inexpensive solution. Alcohol-Saliva Test Strips offers a rapid preliminary method to detect a saliva alcohol concentration (SAC†) greater than 0.02%. Now you'll know.

- Semi-quantitative interpretations at 0.0%, 0.02%, 0.08% and 0.30% SAC
- Easy to use
- Gender-neutral, observed collection
- Affordable pricing
- Quick results in two minutes

Immediate breath alcohol screening results.

redi**test**® **alcohol-**breath test

P/N 01 215 0004

The Reditest® Alcohol-Breath Test is self-contained, unobtrusive and easy to administer. Tests are portable, and can be administered quickly anywhere. In a few simple steps, you can perform an initial screening for alcohol.

- Available in .02 gm/dL cut-off level
- Non-intrusive method for alcohol screening
- Ideal solution for on-site testing
- Fast results at 2 minutes

† Saliva alcohol concentration. It has been published that SAC is approximately equal to blood alcohol concentration.

reditest® substance abuse screening devices

Determine smoking status—instantly.

reditest® smoke cassette

P/N 01 102 0140

Now you can easily and quickly find out if they smoke cigarettes. The Reditest® Smoke Cassette qualitatively detects Cotinine (nicotine metabolite) in a simple one-step urine test.

- Detects Cotinine, a Nicotine metabolite, in urine at 200 ng/mL
- Convenient to use and interpret
- Fast on-site results in 5 minutes

Detect if specimens are valid.

adulteration strips

P/N 01 102 1910

A rapid one step validity test for the simultaneous detection of: Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, and Oxidants/Pyridinium Chlorochromate (PCC) in human urine.

- Screens 6 parameters for specimen validity, dilution and tampering
- Screens for chemicals and reagents not normally found in human urine
- 25 strips per canister *(long shelf life)*

REDWOOD TOXICOLOGY LABORATORY™

*Not sure yet? Try a **FREE** sample.*

what our customers say!

★★★★★

"We have been very pleased with the devices offered by Redwood. They are simple to use, very accurate and cost effective."

— Costa Mesa, CA

"RTL has provided excellent drug detection services over the past nine years. Your support staff is always available by phone and responds promptly to any information we need. We receive regular shipments of supplies and appreciate the seamless chain-of-custody from our collection site to your testing facility."

— Chemical Dependency Counselor

"RTL's urine screening panels provide us important information we use when making clinical decisions. RTL's accurate and timely reporting enables us to respond quickly and help our participants challenge their drug/alcohol abuse."

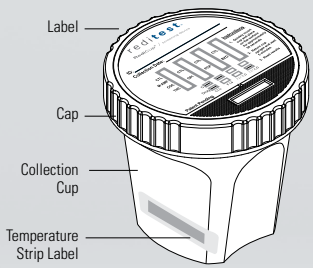
— Drug Treatment Court

"Our staff has been very satisfied with the performance of the four Panel-Dip screen device. The test is quick and the results are easy to interpret."

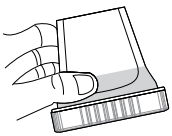
— Probation Office, NY

reditest® urine screening devices

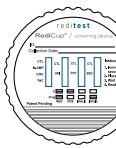
Reditest® RediCup®



Collect urine sample in RediCup®. Screw cap onto cup, ensure cap is tightly secured.

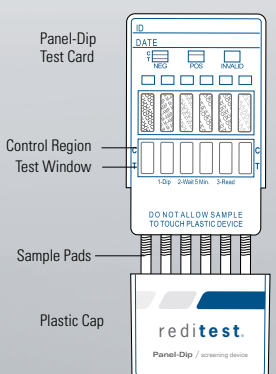


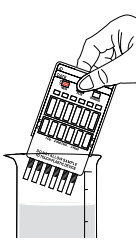
Turn cup upside-down for 30 seconds. Flip upright and wait for results to appear.

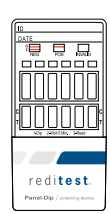


Read result in 5 minute

Reditest® Panel-Dip







RediCup® and Panel-Dip, are for professional in vitro diagnostic use only. The assays provide only a preliminary test result. Any positive result obtained with these drug screens is presumptive and should be confirmed by an alternate method such as GC/MS.

CUT-OFF LEVELS — URINE DRUG SCREENING DEVICES

Amphetamine (AMP)	d-Amphetamine	*1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	*300 ng/mL
Methylenedioxymeth-amphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	*50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methampheta-mine (M-AMP)	D-Methampheta-mine	1000 ng/mL
Opiates (OPI 300)	Morphine	300 ng/mL
Opiates (OPI 2000)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	*25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

* Meets SAMHSA cut-off levels

REDWOOD TOXICOLOGY LABORATORY™

4 Panel Drug Test Device	Part Number
M-AMP/COC/THC/OPI (300)	RC 01 102 0026

5 Panel Drug Test Device(s)	Part Number
M-AMP/COC/THC/OPI (300)/BZO	RC 01 102 0027
M-AMP/COC/THC/OPI (300)/PCP	RC 01 102 0028
M-AMP/COC/THC/OPI (300)/AMP	RC 01 102 0121

6 Panel Drug Test Device(s)	Part Number
M-AMP/COC/THC/AMP/OPI (2000)/BZO	RC 01 102 0135
M-AMP/COC/THC/OPI (300)/PCP/BZO	RC 01 102 0029

10 Panel Drug Test Device(s)	Part Number
AMP/COC/THC/M-AMP/OPI (2000)/ PCP/BZO/TCA/BAR/MTD	RC 01 102 0058
M-AMP/COC/THC/BZO/TCA/BAR/ PCP/AMP/OPI (300)/MTD	RC 01 102 0059
M-AMP/COC/THC/BZO/MTD/BAR/ MDMA/OPI (300)/PCP/OXY	RC 01 102 0137

25 devices per box *(long shelf life)*

Collect sample. Remove plastic cap at bottom.

Dip revealed pads into sample for 15-30 seconds.

Replace cap on device. Lay flat.

Read results in 5 minutes.

1 Panel Drug Test Device(s)	Part Number
AMP	01 102 0018
M-AMP	01 102 0002
BAR	01 102 0019
BUP	01 102 1955
BZO	01 102 0022
COC	01 102 0001
MTD	01 102 0020
MDMA	01 102 0036
OPI (300)	01 102 0003
OXY	01 102 0037
TCA	01 102 0023
THC	01 102 0004
PCP	01 102 0021

2 Panel Drug Test Device(s)	Part Number
COC/M-AMP	01 102 0007
COC/OPI (300)	01 102 0005
COC/THC	01 102 0006
M-AMP/THC	01 102 0008
M-AMP/OPI	01 102 0030

3 Panel Drug Test Device(s)	Part Number
COC/M-AMP/THC	01 102 0009
COC/THC/OPI (300)	01 102 0010
M-AMP/THC/OPI (300)	01 102 0011
M-AMP/COC/OPI (300)	01 102 0014

25 devices per box *(long shelf life)*

4 Panel Drug Test Device(s)	Part Number
COC/M-AMP/THC/OPI (300)	01 102 0012
COC/AMP/THC/OPI (300)	01 102 0032

5 Panel Drug Test Device(s)	Part Number
COC/M-AMP/THC/OPI (300)/BZO	01 102 0015
COC/M-AMP/THC/OPI (300)/PCP	01 102 0013
COC/AMP/THC/OPI (300)/PCP	01 102 0033
COC/AMP/M-AMP/THC/OPI (300)	01 102 0034
COC/AMP/THC/OPI (2000)/PCP	01 102 0047

6 Panel Drug Test Device(s)	Part Number
COC/M-AMP/THC/OPI (300)/PCP/BZO	01 102 0016
COC/M-AMP/THC/MTD/OPI (300)/BZO	01 102 0017
COC/M-AMP/THC/OPI (300)/BAR/BZO	01 102 0024
COC/M-AMP/THC/OPI (300)/OXY/BZO	01 102 0119

7 Panel Drug Test Device	Part Number
COC/AMP/THC/OPI (300)/PCP/BZO/TCA	01 102 0035

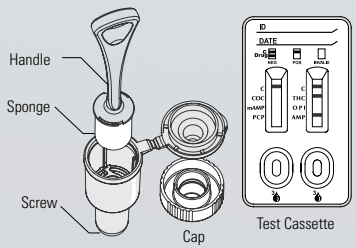
10 Panel Drug Test Device(s)	Part Number
COC/AMP/M-AMP/THC/MTD/OPI (300)/ PCP/BAR/BZO/TCA	01 102 0025
COC/M-AMP/THC/MTD/MDMA/ OPI (300)/OXY/PCP/BAR/BZO	01 102 0138

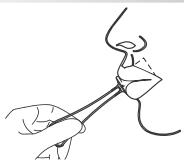
12 Panel Drug Test Device	Part Number
COC/AMP/M-AMP/THC/MTD/MDMA/ OPI(300)/OXY/PPX/PCP/BAR/BZO	01 102 0141

PRODUCT PROCEDURE NOTE: Refer to product insert for complete instructions, limitations, and warnings.

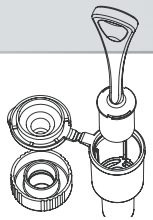
reditest® saliva screening devices

Reditest® On-Site Oral



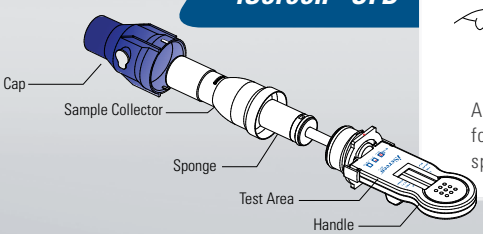


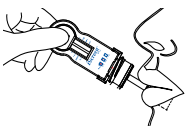
Swab mouth for 3 minutes with sponge collector.



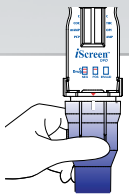
Place saturated collector into chamber. Press sponge against strainer. Snap cap shut.

iScreen™ OFD





Actively swab mouth for 3 minutes with sponge collector.



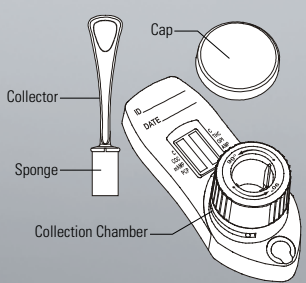
Insert the collector vertically into cap. Plunge the collector 3 times. Twist handle to close the chamber.

CUT-OFF LEVELS — SALIVA DRUG SCREENING DEVICES

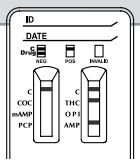
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (M-AMP)	d-Methamphetamine	50 ng/mL
Benzodiazepines (BZO)	Oxazepam	10 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12[1] ng/mL
Marijuana (THC)	Δ^9-THC	100[2] ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

1) Reditest On-Site Oral and iScreen OFD THC detection
2) OrAlert THC detection. Includes improved sensitivity of parent THC.

OrAlert



REDWOOD TOXICOLOGY LABORATORY™

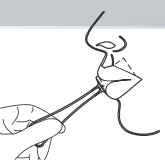


Add 3 drops of oral fluid into each sample well. Read results in 10 minutes.

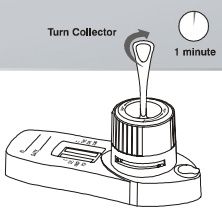
6 Panel Drug Test Device *(25 per box)*	**Part Number**
AMP/COC/M-AMP/OPI (300)/PCP/THC	01 102 0127

Place test horizontally on a level surface. Read results in 10 minutes.

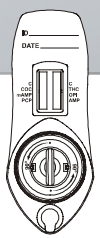
4 Panel Drug Test Device *(25 per box)*	**Part Number**
COC/THC/OPI (300)/M-AMP	01 102 2029
5 Panel Drug Test Device *(25 per box)*	**Part Number**
COC/THC/OPI (300)/M-AMP/AMP	01 102 2024
6 Panel Drug Test Device *(25 per box)*	**Part Number**
COC/THC/OPI (300)/M-AMP/AMP/PCP	01 102 2025



Swab mouth for 3 minutes with sponge collector.



Insert collector into device. Turn clockwise to lock. Wait 1 minute. Rotate collection chamber.



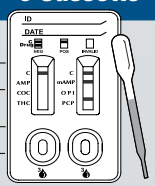
Wait 9 minutes and read results.

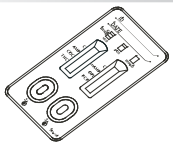
6 Panel Drug Test Device *(25 per box)*	**Part Number**
AMP/M-AMP/BZO/COC/THC/OPI (300)	01 102 2083
AMP/M-AMP/COC/THC/OPI (300)/PCP	01 102 1960

PRODUCT PROCEDURE NOTE: Refer to product insert for complete instructions, limitations, and warnings.

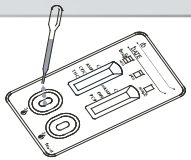
On-Site Oral, iScreen™ OFD, and OrAlert are for forensic use only. The assays provide only a preliminary test result. Any positive result obtained with these drug screens is presumptive and should be confirmed by an alternate method such as GC/MS.

Reditest® 6 Cassette



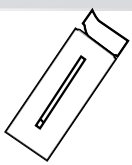


Place test device on a clean flat surface.



Transfer 3 full drops of urine to each of the sample wells.

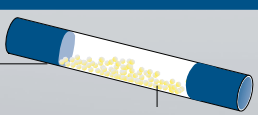
Reditest® Alcohol-Saliva Strips



Tear open foil pouch and remove test strip.

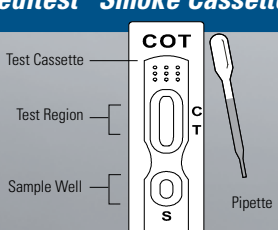
Saturate reactive pad with saliva for 10 seconds.

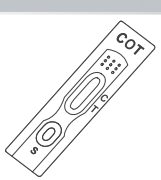
Reditest® Alcohol-Breath Test



Squeeze the middle of tester to break inner glass tube.

Reditest® Smoke Cassette





Remove the test device from the sealed pouch.

6 Cassette device is for professional in vitro diagnostic use only. Alcohol-Saliva Strips and Alcohol-Breath Test are for forensic use only. Reditest® Smoke Cassette is for determination of smoking status only. The assays provide only a preliminary test result. Any positive result obtained with these drug screens is presumptive and should be confirmed by an alternate method such as GC/MS.

REDWOOD TOXICOLOGY LABORATORY™

Wait 5 minutes
and read results.

6 Panel Drug Test Device *(25 per box)* **Part Number**

AMP/COC/M-AMP/OPI (2000)/PCP/THC - CLIA WAIVED 01 102 0166

Cut-off Levels

Amphetamine (AMP)	*d-Amphetamine*	*1,000 ng/mL*
Cocaine (COC)	*Benzoylecgonine*	*300 ng/mL*
Marijuana (THC)	*11-nor-Δ9-THC-9 COOH*	*50 ng/mL*
Methamphetamine	*d-Methamphetamine*	*1,000 ng/mL*
Opiates (OPI 2)	*Morphine*	*2,000 ng/mL*
Phencyclidine (PCP)	*Phencyclidine*	*25 ng/mL*

After 2 minutes, match the
color on the pad to color chart.

Saliva Test Strip *(25 per box)* **Part Number**

Ethanol (Alcohol) 01 362 0001

Cut-off Level

Semi-quantitative interpretations at 0.0%, 0.02%, 0.08% and 0.30% SAC

Blow into tube for 12
consecutive seconds.

Read results in
2 minutes.

Breath Test Device *(25 per box)* **Part Number**

Ethanol (Alcohol) 01 215 0004

Cut-off Level

Available in .02 gm/dL cut-off level

Transfer 3 full drops of
urine to the sample well.

Read results in
5 minutes.

Cotinine Cassette Device *(25 per box)* **Part Number**

Cotinine (Nicotine). 01 102 0140

Cut-off Level

Detects Cotinine, a Nicotine metabolite, in urine at 200 ng/mL

PRODUCT PROCEDURE NOTE: Refer to product insert for complete instructions, limitations, and warnings.

support services

ESSENTIAL RESOURCES FOR YOUR DRUG SCREENING PROGRAM.

CUSTOMER SERVICE—Trained, professional customer support representatives are ready at our toll-free number to assist you promptly and courteously. When you call RTL, an actual person greets you—not a recording. Because our business is about people, we prefer to provide personal customer service.

EDUCATION AND TRAINING—Most testing errors occur during specimen collection and packaging. RTL provides effective education and training resources critical to your program's success. Need to train a team of people? We offer comprehensive training via telephone or web seminar sessions.

RESULT REPORTING—You can retrieve your results from RTL by U.S. mail, by fax or online. RTL's internet reporting application is the most efficient solution for managing and reviewing drug test results. Internet reports are available at no charge to our clients. *(See inset for details)*

SPECIMEN COLLECTION & SHIPPING SUPPLIES—Our complete set of supplies allow efficient and precise specimen collection and shipments to the lab. *(See inset for details)*

LAB TEST REQUEST FORM—Test requisition forms are created upon request for all new accounts. Pre-printed forms are prepared with your organization's information, ready for routing specimens directly to us. For your convenience, RTL offers 2-part and 3-part forms. Also available now, web chain of custody forms for seamless drug test collections and online reporting.

RANDOM SELECTION—RTL can generate a random selection of names or IDs for clients who require random pool drug tests.

THIRD PARTY INSURANCE BILLING—We offer convenient, third-party government insurance billing service to all qualifying clients. RTL is a Medicare and Medicaid provider for medical laboratory services.

INFORMATIONAL MATERIALS—RTL constantly communicates with our clients via website updates, newsletters, customer support materials, invoice inserts and e-mails. We always provide timely information regarding new tests and support services—to keep our clients up-to-date on the latest drug test options.

LITIGATION SERVICES—RTL offers expert witness services by affidavit, by telephone, or in court. RTL's board certified, licensed toxicologists are court-approved (federal and state) experts in forensic toxicology, urine drug testing and oral fluid drug testing. Court testimony is available on any GC/MS or LC/MS/MS-confirmed drug test.

COLLECTION NETWORK—If you are a collection site or third party administrator and wish to work directly with RTL, please join our referral network. We'll work with your organization to develop a comprehensive drug test program that works for you and your clients.

SPECIMEN VALIDITY/ADULTERATION—RTL provides creatinine levels on every test. For additional fees, RTL will run the following tests: pH, nitrate and specific gravity. Your organization can be confident that specimens are valid and unaffected.

POSITIVE SPECIMEN STORAGE—Positive specimens are retained for up to 6 months, and 2 months for methadone accounts.

REDWOOD TOXICOLOGY LABORATORY™

New! Web chain of custody collection forms

webtoxicology.com

ONLINE RESULT REPORTING

- Results posted immediately after lab completes testing
- Advanced search options to view, manage and print test results
- Schedule donor testing, manage collections and track specimens shipped to the lab
- Secure, HIPAA compliant environment
- Enhanced donor data management: organize by test groups, manage frequency of testing, and view collection roster or no-show list
- Raw data transfers also available for internal/statistical reporting needs

testing supplies

COLLECTION & SHIPPING MATERIALS

- Collection devices or bottles
- Pre-assigned lab test request forms, security seals and sample bags
- Pre-paid lab shipping packs
- Training and support materials

laboratory drug testing

Redwood Toxicology Laboratory, Inc. (RTL) is one of the largest single-location drug testing laboratories in the United States. Our mission is to help you create a reliable, cost-effective and scalable drug test program. We process more than 75,000 drug tests a week—providing confidence to thousands of clients nationwide. We never stop working to ensure your drug test program is a success.

THESE INDUSTRIES RELY ON US

- Criminal justice drug courts, corrections, probation, parole, and law enforcement
- Addiction treatment facilities, and dual-diagnosis counseling programs
- Medical facilities, clinics, hospitals, and behavioral health centers
- Schools, universities, colleges and athletic programs
- Small businesses, enterprises, staffing agencies and occupational centers
- Third party drug test administrators, and resellers

REDWOOD TOXICOLOGY LABORATORY™

CERTIFICATES & LICENSES

RTL is licensed and accredited by several state and federal agencies. To maintain our licensure, RTL undergoes regular on-site inspections and proficiency testing challenges.

+ *U.S. Department of Health & Human Services/ Centers for Medicare & Medicaid Services*
+ *State of California Dept. of Health Services*
+ *American Association of Bioanalysts (AAB)**
+ *College of American Pathologists (CAP)**
+ *U.S. Department of Justice, Drug Enforcement Admin.*
+ *State of Florida Agency for Health Care Administration*
+ *Maryland Department of Health & Mental Hygiene*
+ *Pennsylvania Department of Health*
+ *State of Rhode Island and Providence Plantations*
+ *Drug & Alcohol Testing Industry Association (DATIA)*

**Proficiency Testing Providers*

"FIND OUT" IN 5 EASY STEPS

CREATE an account with RTL → **ORDER** supplies & training info → **COLLECT** donor specimen → **SEND** specimen to RTL → **REVIEW** drug test report

Whether you perform 10 or 10,000 drug tests per month, we will provide your agency with exceptional products, service & support.

Need to be sure? Try us for **FREE.**

SEE BACK PAGE FOR FREE TRIAL OFFER

You need to know. We'll find out.

$10 off your first device order — Haven't tried Reditest® on-site screening devices yet? With Redwood Toxicology Laboratory, Inc. (RTL), complete confidence is just a phone call away. Call now, and receive $10 off your first order.

Try lab testing free — When you call RTL, don't forget to ask about combining Reditest screening devices with industry leading lab confirmation services. We offer these free introductory lab services:

- 1 **FREE** Drugs of Abuse Urine Test (8 panel)
- 1 **FREE** Drugs of Abuse Saliva Test (7 panel)
- 1 **FREE** EtG/EtS Alcohol Test
- 1 **FREE** Steroid Test

REDWOOD TOXICOLOGY LABORATORY™

an inverness medical company

Call **800-255-2159**

or visit: www.redwoodtoxicology.com/findout

Laboratory: 800-255-2159 // Screening Devices: 877-444-0049 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

11 000 0375 REV1

lab services catalog

drugs of abuse testing – *urine*

drugs of abuse testing – *saliva*

comprehensive drug testing

etg/ets alcohol testing

fentanyl testing

steroid testing

ghb testing

hcg testing

REDWOOD TOXICOLOGY LABORATORY™

an inverness medical company

Are they abusing?

Drug and alcohol abuse deteriorates a person's physical and mental health. Abuse also burdens public safety, the workplace, the healthcare industry, and the nation's economy. In 2007, more than 35 million people abused illicit drugs or prescriptions, and more than 1 million of those entered addiction treatment programs. Fifty-two percent (52%) of all inmates were sentenced for drug offenses. A 2009 report[1] on drug abuse indicates cocaine is still the leading threat to society. Methamphetamine is the second leading threat, followed by marijuana, heroin, pharmaceutical drugs, and ecstasy (MDMA) respectively. RTL is committed to helping you detect and prevent abuse. **We'll find out.**

WHY CHOOSE REDWOOD TOXICOLOGY LABORATORY?

- *Federally certified through Dept. of Health & Human Services*
- *Secure & convenient toxicology reports*
- *Laboratory analysis provides confirmative evidence of use*
- *State-of-the-art instrumentation & world-class test methods*
- *Comprehensive & affordable menu of laboratory drug tests*
- *Extensive experience in analytical & forensic drug testing*

**Source: 2009 National Drug Threat Assessment, National Drug Intelligence Center, U.S. Department of Justice*

REDWOOD TOXICOLOGY LABORATORY™

WHO TESTED POSITIVE?

Now you'll know.

TESTED POSITIVE

COCAINE cut-off level exceeded
Positive test device & lab confirmation
Drug test result available online

TESTED POSITIVE

OXYCODONE cut-off level exceeded
Positive lab screen & confirmation
Drug test result available online

TESTED POSITIVE

AMPHETAMINE cut-off level exceeded
Positive lab screen & confirmation
Drug test result available online

+ Confirmation with industry "gold standard"—GC/MS

Quality support & access to certified toxicologists

Call **800-255-2159**

or visit: www.redwoodtoxicology.com/findout

the confidence of science

COMPANY OVERVIEW

Redwood Toxicology Laboratory, Inc. (RTL) is one of the largest single-location drug testing laboratories in the United States. Our mission is to help you create a reliable, cost-effective, scalable drug test program. We process more than 75,000 drug tests a week—providing confidence to thousands of clients nationwide. We never stop working to ensure your drug test program is a success. RTL's expert staff completes all of your drug tests in our own laboratory. Whether you need 10 or 10,000 drug tests per month, RTL provides fast, reliable results, exceptional products, and outstanding customer service. You need to be certain.

THESE INDUSTRIES RELY ON US

- Criminal justice drug courts, corrections, probation, parole, and law enforcement
- Addiction treatment facilities, and dual-diagnosis counseling programs
- Medical facilities, clinics, hospitals, and behavioral health centers
- Schools, universities, colleges and athletic programs
- Small businesses, enterprises, staffing agencies and occupational centers
- Third party drug test administrators, and resellers

ARE THEY ABUSING DRUGS?

We'll find out.

REDWOOD TOXICOLOGY LABORATORY

CERTIFICATES & LICENSES

RTL is licensed and accredited by several state and federal agencies. To maintain our licensure, RTL undergoes regular on-site inspections and proficiency testing challenges.

- *U.S. Department of Health & Human Services/ Centers for Medicare & Medicaid Services*
- *State of California Dept. of Health Services*
- *American Association of Bioanalysts (AAB)**
- *College of American Pathologists (CAP)**
- *U.S. Department of Justice, Drug Enforcement Admin.*
- *State of Florida Agency for Health Care Administration*
- *Maryland Department of Health & Mental Hygiene*
- *Pennsylvania Department of Health*
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**Proficiency Testing Providers*

"FIND OUT" IN 5 EASY STEPS

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Need to be sure?
Try us for **FREE.** SEE BACK PAGE FOR FREE TRIAL OFFER

Call **800-255-2159**
or visit: www.redwoodtoxicology.com/findout

"RTL's urine screening panels provide us important information we use when making clinical decisions. RTL's accurate and timely reporting enables us to respond quickly and help our participants challenge their drug/alcohol abuse."

—Drug Treatment Court

drugs of abuse testing–*urine*

RTL's most popular laboratory drug test is also cost-effective, reliable and legally admissible. You can choose from many urine test options, in many drug configurations.

Our professional toxicologists perform screening and confirmation with state-of-the-art technology in two stages: 1) Initial screening by enzyme immunoassay (EIA); and 2) Confirmation testing by thin layer chromatography (TLC), radioimmunoassay (RIA), gas chromatography (GC), or gas chromatography/mass spectrometry (GC/MS).

See page 12-13 for standard urine test panels and cut-off levels by method.

- Urine screening and confirmation with fast, accurate results
- Wide selection of drug test panels
- Minimally invasive procedure
- Lab analysis provides confirmative evidence of use and defensible results
- Fast result reporting (24 hours[1] negative, 48-72 hours positive)

1. Excludes specimens received Saturday

REDWOOD TOXICOLOGY LABORATORY™

confidence through legally defensible test methods

drugs of abuse testing–*saliva*

Organizations that require convenient, gender-neutral collection and lab-accurate results frequently prefer RTL-Oral™ saliva testing. RTL's saliva tests unobtrusively detect recent drug abuse, and protect you from exposure to the specimen. Choose from a wide selection of cost-effective RTL-Oral solutions, covering many commonly abused drugs. With RTL-Oral, you can find out fast (48 hours[1] negative, 48-72 hours positive).

- Convenient, gender-neutral collections
- Limits exposure to donor sample
- Excellent indication of recent drug use
- Protection against sample adulteration
- Increased THC recovery and stability
- Provides sufficient collection volume every time (1 mL [+/- 10%])

See page 12-13 for standard saliva test panels and cut-off levels by method.

RTL-Oral Collector with saliva volume indicator

Call **800-255-2159**
or visit: www.redwoodtoxicology.com/findout

confidence
and quality

"RTL has provided excellent drug detection services over the past nine years. Your support staff is always available by phone and respond promptly to any information we need. We receive regular shipments of supplies and appreciate the seamless chain-of-custody from our collection site to your test facility."

—*Chemical Dependency Counselor*

comprehensive drug testing

"Most people take prescription medications responsibly; however, an estimated 48 million people have used prescription drugs for non-medical reasons[1]."

RTL's Comprehensive Drug Test detects over 600 brand name prescriptions, illicit drugs and alcohol. Our tests target a wide range of commonly abused prescriptions that pass most standard urine tests. Comprehensive Testing is perfect when specific drug detection and monitoring are critical. Demand more from your drug test.

See page 14-15 for panel configuration.

- Detects over 600 brand name Rx drugs, illicit drugs and alcohol
- Includes expanded opiates/narcotics
- High specificity—GC/MS analysis provides confirmative evidence of use
- Highly sensitive—includes quantitative, semi-quantitative, or qualitative data
- Fast turn-around time (48 hours[2] negative, 48-72 hours positive)

REDWOOD TOXICOLOGY LABORATORY™

through experience
support services

etg/ets alcohol testing

EtG is a direct metabolite of alcohol (ethanol). Its presence in urine may be used to detect recent alcohol ingestion, even after ethanol is no longer measurable. EtG is detectable in urine for up to 80 hours after the ingestion of alcohol.

RTL utilizes the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry), to screen confirm and quantitate EtG/EtS.

See page 12-13 for panel configuration and cut-off levels.

- Detects recent ingestion more accurately and for a longer period of time than standard alcohol tests
- Provides greater sensitivity and accuracy by measuring both EtG/EtS
- Ideal for zero tolerance treatment programs and abstinence enforcement
- EtG/EtS tests may be run conveniently with other RTL drug screens
- Fast results (48 hours[2] negative, 48-72 hours positive)

1. Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, "Prescription Drugs—Abuse and Addiction", NIDA Research Report, 2005
2. Excludes specimens received Saturday

Call **800-255-2159**
or visit: www.redwoodtoxicology.com/findout

"Redwood Toxicology Laboratory's chief toxicologist is easily accessible and has provided our legal & clinical team with expertise when needed. Thank you again for the excellent products and service you provide us."

—Drug Court Coordinator

confidence
equipment

steroid testing

When awards and accreditations are at stake, you need to be certain. RTL offers a comprehensive and affordable performance enhancing drug test that is comparable to WADA[1] testing. In addition, RTL also offers a diuretics & stimulant test panel.

- Detect prescription androgenic anabolic steroids, prohormones, designer anabolic steroids, essential masking, anti-estrogen agents and diuretics.
- Ideal for sports organizations, colleges and high schools, certified athletic trainers, coaches, corrections and law enforcement.
- Performed on state of the art GC/MS equipment
- Fast results (48 hours[2] negative, 48-72 hours positive)

fentanyl testing

Fentanyl (Duragesic, Sublimaze) is a fast-acting synthetic narcotic analgesic, originally created for chronic pain. With similar dependency properties to those of morphine, Fentanyl abuse is rising, but most standard drug tests fail to detect it. RTL offers conclusive, accurate Fentanyl laboratory test results.

- Detects therapeutic and illicitly synthesized forms of fentanyl
- Lab analysis provides conclusive evidence of use
- Tests performed using state-of-the-art GC/MS equipment

REDWOOD TOXICOLOGY LABORATORY™

through highly sensitive
& proven test processes

ghb drug testing

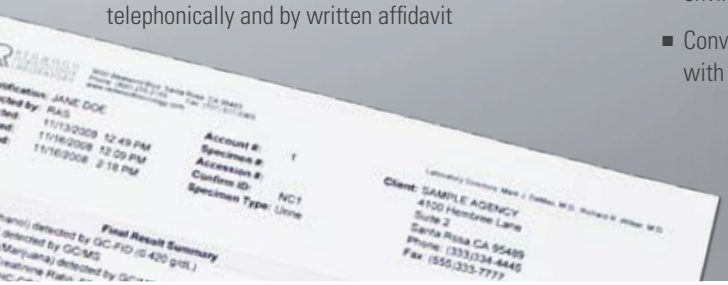
Gamma-Hydroxybutyric acid (GHB) is often associated with sexual assault, as a "date rape" drug, because of its severe hypnotic and sedative effect at high dosage. RTL's proven GC/MS method accurately measures GHB levels.

- Strong indicator of GHB ingestion within 12 hours
- Expert witness services provided in court, telephonically and by written affidavit

hcg testing

RTL also offers pregnancy testing. When you need to be absolutely certain, the accuracy of human chorionic gonadotropin (hCG) lab testing is preferable to over-the-counter devices. We can simultaneously run hCG tests from the same samples collected for drug tests.

- Screens conducted in a dependable laboratory environment by experienced staff
- Convenience—request hCG in conjunction with your RTL drug screen on the same sample



1. World Anti-Doping Agency
2. Excludes samples received on Saturdays

popular urine lab tests (many other test panels to choose from).

Urine Drugs of Abuse Testing

Many test panels available.
A complete list of cut-off levels, test methods, classifications and drug metabolites are available online at: redwoodtoxicology.com

Urine 5 Panel *H39*

Amphetamines
Cocaine
Opiates
THC (Marijuana)
Phencyclidine (PCP)*

Available with **Benzodiazepines in place of Phencyclidine. Panel code P28 (Creatinine and THC/Creatinine ratio screens not included)*

Urine 8 Panel *R53*

Alcohol (Ethanol)
Amphetamines
Barbiturates
Benzodiazepines
Cocaine
Opiates
Phencyclidine (PCP)
THC (Marijuana)

Urine 10 Panel *R57*

Alcohol (Ethanol)
Amphetamines
Barbiturates
Benzodiazepines
Cocaine
Methadone
Opiates
Phencyclidine (PCP)
Propoxyphene
THC (Marijuana)

Includes Creatinine and THC/Creatinine ratio screens

1. *Cocaine Metabolite (Benzoylecgonine)*
2. *Agency has the ability to choose cut-off levels indicated.*
3. *Test performed by Gas Chromatography Flame Ionization Detection.*
4. *Test performed by Liquid Chromatography / Mass Spectrometry / Mass*

popular saliva lab tests (many other test panels to choose from).

Oral Fluid Drugs of Abuse Testing

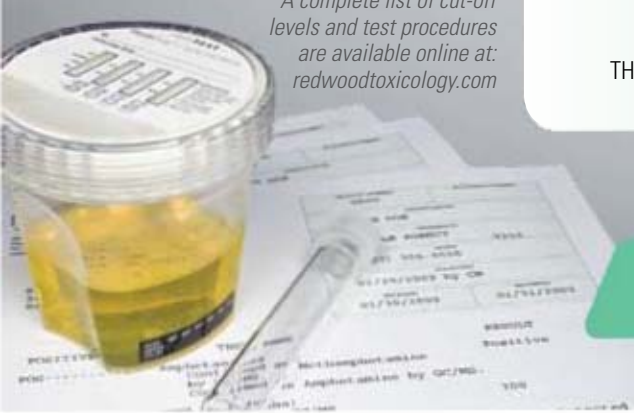
Many test panels available.
A complete list of cut-off levels and test procedures are available online at: redwoodtoxicology.com

Oral Fluid 6 Panel *9003*

Amphetamines
Cocaine
Methamphetamine
Opiates
PCP
THC (Marijuana)

Oral Fluid 7 Panel *9017*

Amphetamines
Benzodiazepines
Cocaine
Methadone
Methamphetamine
Opiates
THC (Marijuana)



EtG/EtS Alcohol Testing

EtG/EtS Alcohol Panel

Ethyl glucuronide (EtG)
Ethyl sulfate (EtS)

REDWOOD TOXICOLOGY LABORATORY

SCREENING CUT-OFFS	*EIA*
Alcohol (Ethanol)	0.04 gm/dL
Amphetamines	1000 ng/mL
Barbiturates	200 ng/mL
Benzodiazepines	200 ng/mL
Buprenorphine	5 ng/mL
Cocaine[1]	300 ng/mL
Methadone	150 ng/mL
Methamphetamine	1000 ng/mL
Methaqualone	300 ng/mL
Opiates	300 ng/mL
Oxycodone	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene	300 ng/mL
THC *(cannabinoids)*	20/50 ng/mL[2]

s Spectrometry.

CONFIRMATION CUT-OFFS	*TLC*	*RIA*	*GC/MS*
Alcohol (Ethanol)			.02 gm/dL[3]
Amphetamines			
- Amphetamine/Methamphetamine/ MDMA & MDA	<500 ng/mL		100 ng/mL
Barbiturates	< 500 ng/mL		200 ng/mL
Benzodiazepines		200 ng/mL	50 ng/mL (LC/MS/MS)[4]
Buprenorphine			0.5 ng/mL
Cocaine[1]		150 ng/mL	50 ng/mL
Fentanyl			5 ng/mL
GHB			10 mcg/mL
Marijuana Metabolite (THC-COOH)		25 ng/mL	5 ng/mL
Methadone	< 500 ng/mL		100 ng/mL
Opiates			
- Total Morphine/Codeine	< 500 ng/mL		100 ng/mL
- 6-Monoacetylmorphine			5 ng/mL
- Hydrocodone/Hydromorphone/ Hydromorphone & Oxycodone	1000 ng/mL		100 ng/mL
Phencyclidine (PCP)			10 ng/mL
Propoxyphene	< 500 ng/mL		200 ng/mL
Tricyclic Antidepressants			
- Amitriptyline/ Desipramine/Imipramine/ Nortriptyline & Maprotiline			50 ng/mL
- Doxepin			100 ng/mL

SCREENING CUT-OFFS	*ELISA*
Amphetamines	50 ng/mL
Barbiturates	50 ng/mL
Benzodiazepines	20 ng/mL
Cocaine[1]	20 ng/mL
Methadone	50 ng/mL
Methamphetamine	50 ng/mL
Opiates	40 ng/mL
Phencyclidine (PCP)	10 ng/mL
THC *(cannabinoids)*	4 ng/mL

CONFIRMATION CUT-OFFS	*GC/MS*
Amphetamines	15 ng/mL
Barbiturates	20 ng/mL
Benzodiazepines	15 ng/mL
Cocaine[1]	8 ng/mL
Methadone	10 ng/mL
Methamphetamine	15 ng/mL
Opiates	
- Codeine/Hydrocodone/Hydromorphone/ Morphine/Oxycodone	*20 ng/mL*
- 6-monacetylmorphine	*4 ng/mL*
Phencyclidine (PCP)	5 ng/mL
THC *(Δ - 9 THC)*	1 ng/mL

EtG/EtS Alcohol Test Panel	CONFIRMATION CUT-OFFS *LC/MS/MS*
EtG	100 ng/mL
EtS	25 ng/mL

Cut-off list updated periodically.

Comprehensive Drug Testing

A complete list of prescription brand names covered, cut-off levels and test procedures are available online at: redwoodtoxicology.com

Comprehensive Drug Test Panel

Alcohol (Ethanol)

Antidepressants

Amitriptyline	Bupropion	Citalopram	Desipramine
Doxepin	Escitalopram	Fluoxetine	Imipramine
Maprotiline	Paroxetine	Sertraline	Trazodone/Nefazodone
Venlafaxine			

Anticonvulsants

Carbamazepine	Oxcarbazepine

Barbiturates

Amobarbital	Butabarbital	Butalbital	Pentobarbital
Phenobarbital	Secobarbital		

Benzodiazepines

Alprazolam	Clonazepam	Flunitrazepam	Flurazepam
Lorazepam	Midazolam	Nordiazepam	Oxazepam
Temazepam	Triazolam		

Includes specimen validity (Creatinine). List updated periodically.

Steroid Testing

A complete list of cut-off levels and test procedures are available online at: redwoodtoxicology.com

Steroid Test Panel (performance enhancing drug test)

1-Androstendiol	Clenbuterol (anabolic agent)	Formestane (anti-estrogen)
1-Androstendione	Clostebol	Formebolone
4-Androstendiol	Danazol	Furazabol
4-Androstendione	Dehydrochlormethyl-testosterone	Halodrol
5-Androstendiol	Desoxymethyltestosterone	4-Hydroxy-testosterone
5-Androstendione	5α-Dihydrotestos-terone/Drostandiol	Mestanolone
Bolandiol (Norandro-stendiol)	Drostanolone	Mesterolone
Bolasterone	Epitestosterone (masking agent)	Methandriol
Boldenone	Ethisterone	Methandrostenolone
Boldione	Ethylestrenol	Methasterone
Calusterone	Fluoxymesterone	Methenolone

Includes specimen validity (Creatinine). List updated periodically.

REDWOOD TOXICOLOGY LABORATORY™

Narcotics/Opiates

Buprenorphine	Codeine	Fentanyl	Hydrocodone
Ketamine	Meperidine	Methadone	Nalbuphine
Oxycodone	Oxymorphone	Propoxyphene	Tramadol

Phencyclidine (PCP)

Sedative/Hypnotic Agents

Carisoprodol	Meprobamate	Zolpidem

Stimulants

Amphetamine	Cocaine	Methamphetamine	Methylenedioxyamphetamine (MDA)
Methylenedioxymethamphetamine (MDMA)	Methylenedioxyethylamphetamine (MDEA)	Methylphenidate	

THC (Marijuana)

6-Methylandrostendione	Oxabolone	Testosterone
Methyl-1-testosterone	Oxandrolone	Trenbolone
Methylnortestosterone	Oxymesterone	
Methyltestosterone	Oxymetholone	
Mibolerone	Probenecid (masking agent)	
Nandrolone	Prostanozol	
19-Norandrostadiendione	Quinbolone	
19-Norandrostendione	Stanozolol	
Norbolethone	Stenbolone	
Norclostebol	Testolactone (anti-estrogen)	
Norethandrolone	1-Testosterone	

Diuretic Panel and Stimulants Panel

Add 16 performance enhancing diuretics, and 42 commonly abused stimulants.

A complete list of diuretics and stimulants are available online at: redwoodtoxicology.com

support services

ESSENTIAL RESOURCES FOR YOUR DRUG SCREENING PROGRAM.

CUSTOMER SERVICE—Trained, professional customer support representatives are ready at our toll-free number to assist you promptly and courteously. When you call RTL, an actual person greets you—not a recording. Because our business is about people, we prefer to provide personal customer service.

EDUCATION AND TRAINING—Most testing errors occur during specimen collection and packaging. RTL provides effective education and training resources critical to your program's success. Need to train a team of people? We offer comprehensive training via telephone or web seminar sessions.

RESULT REPORTING—You can retrieve your results from RTL by U.S. mail, by fax or online. RTL's internet reporting application is the most efficient solution for managing and reviewing drug test results. Internet reports are available at no charge to our clients. *(See inset for details)*

SPECIMEN COLLECTION & SHIPPING SUPPLIES—Our complete set of supplies allow efficient and precise specimen collection and shipments to the lab. *(See inset for details)*

LAB TEST REQUEST FORM—Test requisition forms are created upon request for all new accounts. Pre-printed forms are prepared with your organization's information, ready for routing specimens directly to us. For your convenience, RTL offers 2-part and 3-part forms. Also available now, web chain of custody forms for seamless drug test collections and online reporting.

RANDOM SELECTION—RTL can generate a random selection of names or IDs for clients who require random pool drug tests.

THIRD PARTY INSURANCE BILLING—We offer convenient, third-party government insurance billing service to all qualifying clients. RTL is a Medicare and Medicaid provider for medical laboratory services.

INFORMATIONAL MATERIALS—RTL constantly communicates with our clients via website updates, newsletters, customer support materials, invoice inserts and e-mails. We always provide timely information regarding new tests and support services—to keep our clients up-to-date on the latest drug test options.

LITIGATION SERVICES—RTL offers expert witness services by affidavit, by telephone, or in court. RTL's board certified, licensed toxicologists are court-approved (federal and state) experts in forensic toxicology, urine drug testing and oral fluid drug testing. Court testimony is available on any GC/MS or LC/MS/MS-confirmed drug test.

COLLECTION NETWORK—If you are a collection site or third party administrator and wish to work directly with RTL, please join our referral network. We'll work with your organization to develop a comprehensive drug test program that works for you and your clients.

SPECIMEN VALIDITY/ADULTERATION—RTL provides creatinine levels on every test. For additional fees, RTL will run the following tests: pH, nitrate and specific gravity. Your organization can be confident that specimens are valid and unaffected.

POSITIVE SPECIMEN STORAGE—Positive specimens are retained for up to 6 months, and 2 months for methadone accounts.

REDWOOD TOXICOLOGY LABORATORY™

webtoxicology.com

ONLINE RESULT REPORTING

New! *Web chain of custody collection forms*

- Results posted immediately after lab completes testing
- Advanced search options to view, manage and print test results
- Schedule donor testing, manage collections and track specimens shipped to the lab
- Secure, HIPAA compliant environment
- Enhanced donor data management: organize by test groups, manage frequency of testing, and view collection roster or no-show list
- Raw data transfers also available for internal/statistical reporting needs

testing supplies

COLLECTION & SHIPPING MATERIALS

- Collection devices or bottles
- Pre-assigned lab test request forms, security seals and sample bags
- Pre-paid lab shipping packs
- Training and support materials

reditest®

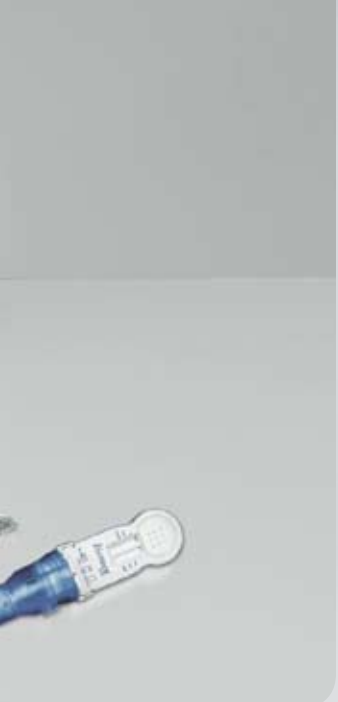
substance abuse screening devices

In addition to top-notch lab testing, RTL also offers instant urine and saliva screening devices. Combined with RTL's lab testing, Reditest® devices provide your organization the most comprehensive, cost-effective drug test solution available. We sell millions of quality on-site screening tests each year. They are ideal for situations where you need to know immediately. You can rely on Reditest to help you find out who is abusing and who isn't. Be confident. Take the first step in drug detection with Reditest screening devices.

- Test results available instantly on-location
- Over 70 screening devices available, to detect a broad range of drugs or alcohol
- Easy to perform and interpret results
- Select from FDA 510(k) cleared to market, CLIA waived or for forensic use devices
- Collection and confirmation kits available
- Competitive pricing (ask about combining on-site tests with GC/MS confirmations)

REDWOOD TOXICOLOGY LABORATORY™

Call **800-255-2159**
or visit: www.redwoodtoxicology.com/findout

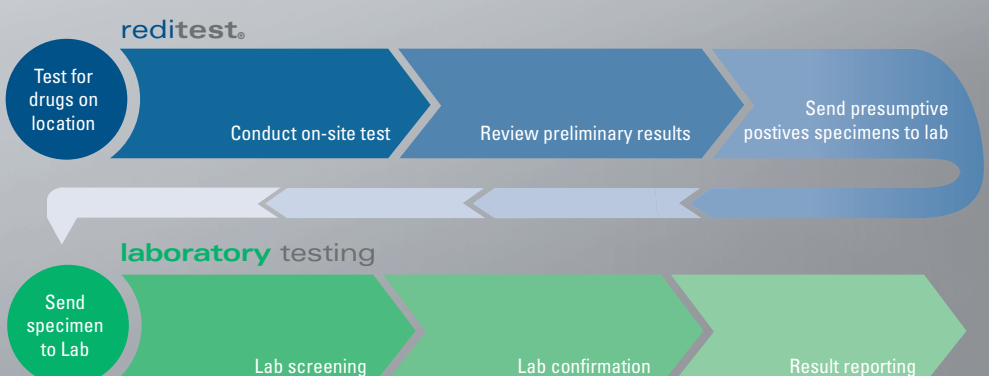


"Our staff has been very satisfied with the performance of the Reditest® four Panel-Dip on-site screening device. The test is quick and the results are easy to interpret."

—Probation Office, NY

Instant tests + lab tests = the perfect pair.

RTL offers you instant screening devices plus lab testing services, all in one integrated, cost-effective solution. With RTL, your organization can perform initial Reditest® screens, and order further lab testing—all from one company. Are you testing with combined confidence?



WHEN YOU NEED TO KNOW. WE'LL FIND OUT.

You need to know. We'll find out.

Try us free — Haven't tried RTL's lab services yet? Sign up for a free trial offer by calling the number below. We utilize the most sensitive, sophisticated, and modern equipment for all of your drug tests. Complete confidence is now simpler than ever with Redwood Toxicology Laboratory, Inc. When you call, ask about combining lab services with our instant Reditest® screening devices.

- 1 **FREE** Drugs of Abuse Urine Test (8 panel)
- 1 **FREE** Drugs of Abuse Saliva Test (7 panel)
- 1 **FREE** EtG/EtS Alcohol Test
- 1 **FREE** Steroid Test

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an inverness medical company

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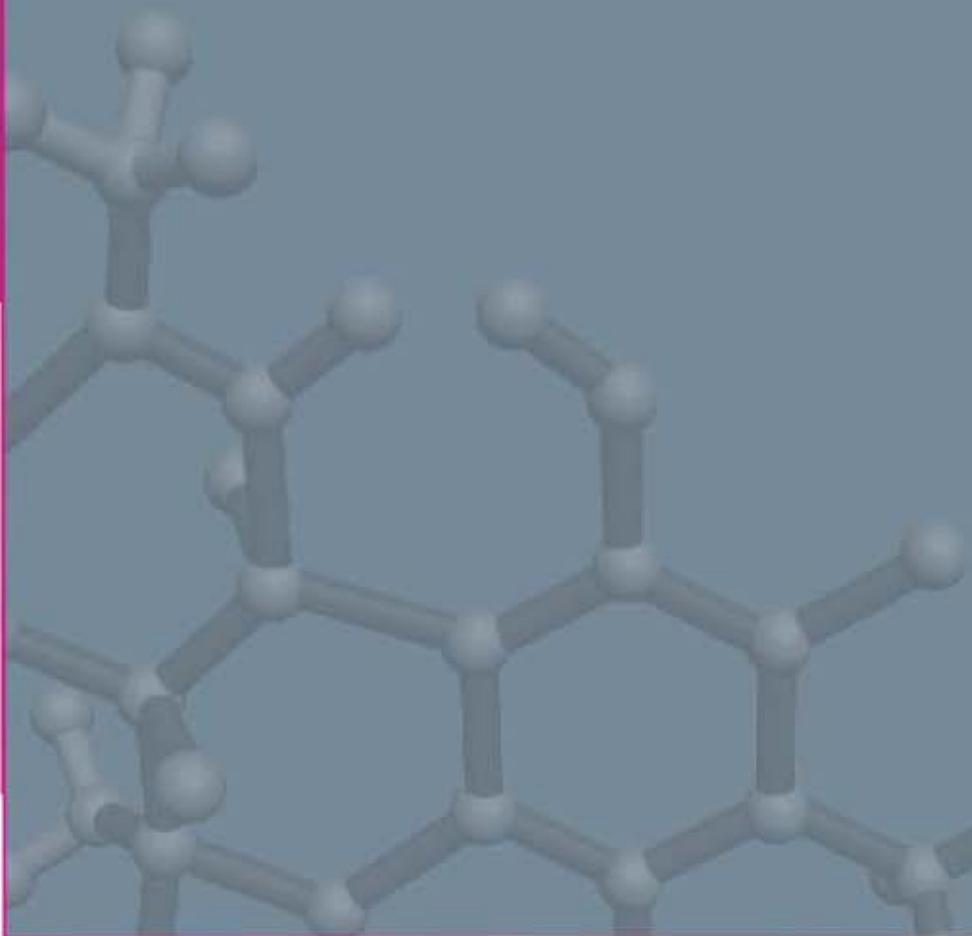
REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

reference **guide**



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SUBSTANCE ABUSE SCREENING DEVICES

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laboratory services

Redwood Toxicology Laboratory (RTL) performs drug and alcohol testing in accordance with strict forensic standards and scientifically accepted methods. Testing is performed by a highly educated, experienced staff using state-of-the-art equipment under the scrutiny of state and federal agencies. We'll find out.

Drugs of Abuse Urine Testing — RTL processes over 75,000 urine specimens each week for thousands of clients.

Drugs of Abuse Oral Fluid Testing — Oral fluid testing is gaining popularity with many programs that require easy, gender-neutral specimen collection combined with the accuracy of lab testing.

EtG/EtS Alcohol Testing — RTL offers ethyl glucuronide (EtG) and ethyl sulfate (EtS) testing, known as the EtG/EtS Alcohol Testing solution. This test allows for the detection of EtG/EtS in urine for up to 80 hours after ethanol ingestion.

Steroid/Sports Drug Testing — A comprehensive laboratory test that detects a full list of prescription androgenic anabolic steroids, prohormones, designer anabolic steroids, essential masking and anti-estrogen agents, diuretics and stimulants.

Synthetic Cannabinoid Drug Testing — RTL provides reliable urine metabolite and oral fluid parent drug detection for JWH-compounds; common ingredients in "K2", "Spice" and other brand names.

Comprehensive Drug Testing — Detects a wide-range of prescriptions, illicit drugs, and alcohol in urine. Includes expanded list of opiates/narcotics.

Esoteric Testing — RTL also offers a wide range of specialized tests including: gamma-hydroxybutyric acid (GHB) testing; fentanyl testing; hCG (pregnancy) testing, and more.

Drugs of Abuse Testing — *Urine*

laboratory service

OVERVIEW

The following is an explanation of RTL's urine screening and confirmation procedures/cut-off levels. The routine cut-off levels listed may periodically change. Note: some cut-off levels may differ for your agency. The analytical methods used by RTL are scientifically accepted and approved by the U.S. Department of Health and Human Services.

URINE SCREENING METHODOLOGY

In order to determine if a urine specimen is negative or positive for drugs of abuse, all specimens are initially screened by an enzyme immunoassay (EIA) procedure. Specimens that yield an EIA response below the specified cut-off are reported as negative. Specimen that show an EIA response at or above the specified cut-off is considered "presumptive positive" for a particular drug or drug class. Based on your agency's account, presumptive positive specimens may be confirmed by a second method prior to reporting positive results. (See "urine confirmation methodology").

Screening Cut-off Levels by EIA *Cut-off levels updated periodically*

DRUG	EIA
Alcohol *(ethanol)*	0.04gm/dL
Amphetamines *(amphetamines & methamphetamines)*	1000/500 ng/mL
Barbiturates	200 ng/mL
Benzodiazepines	200 ng/mL
Buprenorphine	5 ng/mL
Cocaine[1]	300/150 ng/mL
Methadone	150 ng/mL
Methadone Metabolite	150 ng/mL
Methaqualone	300 ng/mL
Opiates *(morphine and codeine)*	300 ng/mL
Oxycodone	300 ng/mL
Phencyclidine *(PCP)*	25 ng/mL
Propoxyphene	300 ng/mL
THC *(cannabinoids)*	20/50 ng/mL[2]

URINE CONFIRMATION METHODOLOGY

Analytical methods of confirmation include thin layer chromatography (TLC), radioimmunoassay (RIA), gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). The subsequent confirmatory procedures are performed on a second independent portion of the original urine specimen.

Confirmation Cut-off Levels by Procedure

DRUG	TLC	RIA	GC/MS	LC/MS/MS
Alcohol *(ethanol)*			.02 gm/dL *(GC-FID)*[3]	
Amphetamines				
- Amphetamine/Methamphetamine/MDMA & MDA	*<500 ng/mL*		*100 ng/mL*	
Barbiturates	<500 ng/mL		200 ng/mL	
Benzodiazepines		200 ng/mL		50 ng/mL
Buprenorphine			0.5 ng/mL	
Cocaine[1]		150 ng/mL	50 ng/mL	
EtG				100 ng/mL
EtS				25 ng/mL
Fentanyl			5 ng/mL	
GHB			10 mcg/mL	
Marijuana Metabolite *(THC-COOH)*		25 ng/mL	5 ng/mL	
Methadone	<500 ng/mL		100 ng/mL	
Methaqualone	<500 ng/mL			
Opiates				
- Total Morphine/Codeine	*<500 ng/mL*		*100 ng/mL*	
- 6-Monoacetylmorphine			*5 ng/mL*	
- Hydrocodone/ Hydromorphone/	*1000 ng/mL*		*100 ng/mL*	
- Oxycodone				*50 ng/mL*
Phencyclidine *(PCP)*			10 ng/mL	
Propoxyphene	<500 ng/mL		200 ng/mL	
Tricyclic Antidepressants				
- Amitriptyline/ Desipramine/ Imipramine/Nortriptyline/ Maprotiline			*50 ng/mL*	
- Doxepine			*100 ng/mL*	

1. Cocaine Metabolite Benzoylecgonine
2. Agency has the ability to choose cut-off levels indicated.
3. Test performed by Gas Chromatography Flame Ionization Detection (GC/FID)

Urine Drug Testing: Classification Table & Detection Time

Drug Class	Trade Name	Street Names	Detection Time	DEA†
ANALGESICS (Synthetic)				
Meperidine	Demerol	Demmies, Pain Killer	24-48 Hours	II
Methadone	Dolophine	Dollies, Meth	72 Hours	II
Pentazocine	Talwin	T's	No Data	III
Propoxypene	Darvon	Pain Killer	24-48 Hours	IV
CANNABINOIDS				
Cannabinoids	None	Mary Jane, Grass, Pot, Smoke, Weed	See below[1]	I
HALLUCINOGENS				
Lysergic acid diethylamide	None	LSD, Acid	1.5-5 Days	I
Methylenedioxyamphetamine	None	MDA, Love Drug	24-72 Hours	I
Methylenedioxymethamphetamine	None	MDMA, Adam, Ecstasy, X	24-72 Hours	I
Phencyclidine	None	PCP, Angel Dust	14-30 Days	II
DEPRESSANTS/SEDATIVES/HYPNOTICS				
Barbiturates				
Amobarbital	Amytal	Yellow Jackets		III
Butabarbital	Butisol	Bute, Stoppers	2-3 Weeks	III
Butalbital	Fiorinal	Schoolboy	3-10 Days	III
Pentobarbital	Nembutal	Nembies	4-6 Days	III
Phenobarbital	Luminal	Downers, Goofballs	Up to 30 Days	IV
Secobarbital	Seconal	Barbs, Reds	4-6 Days	III
Benzodiazepines *(See more on pg. 37)*				
Alprazolam	Xanax	Downs, Nerve Pills, Tranks	24-72 Hours	
Chlordiazepoxide	Librium	"	1-7 Days	IV
Clonazepam	Clonopin	"	24-72 Hours	IV
Clorazepate	Tranxene	"	1-7 Days	IV
Diazepam[2]	Valium	"	1-7 Days	IV
Flurazepam	Dalmane	"	24-72 Hours	IV
Lorazepam	Ativan	"	1-5 Days	IV
Midazolam	Versed	"	24-72 Hours	
Oxazepam[2]	Serax	"	1-7 Days	IV
Methaqualone	Quaalude	Ludes		IV
Tricyclic Antidepressants				
Amitriptyline	Elavil	None	No Data	
Desipramine	Norpramin			
Doxepin	Sinequan			
Imipramine	Tofranil			
Maprotiline	Ludiomil			
Nortriptyline	Aventyl			
Alcohol				
Ethanol	N/A	Booze	After absorption (~1 hour) blood alcohol decreases ~.02 gm%/hour	
OPITATES/ANALGESICS (Semi-Synthetic)				
Codeine	Empirin, Tylenol Codeine	Schoolboy	24-72 Hours	III
Diacetylmorphine	Heroin	Horse, Smack, "H", Speedball (w/ Cocaine)	24 Hours (as 6-MAM)	I
Hydrocodone	Hycodan, Vicodin	None	24-72 Hours	
Hydromorphone	Dilaudid	Juice, Dillies	24-72 Hours	
Morphine	Roxanol	"M", Morph	24-72 Hours	II
Oxycodone	Oxycontin, Percodan, Percocet	OC, OXY, Oxy-Coffins, Killers, Percs	24-72 Hours	II
Oxymorphone	Opana, Numorphan	Blues, Nu-Blues, Biscuits, Blue Heaven	24-72 Hours	II
STIMULANTS				
Amphetamine	Benzedrine, Obetrol	Ice, Speed, Crank	24-96 Hours	II
Cocaine	None	Coke, Rock, Crack, Snow, Blow, Toot	24-96 Hours	II
Methamphetamine	Desoxyn	Upper, Snot, Glue	24-96 Hours	II

1) Cannabinoids Detection Time

Light smoker or acute dosage	1-3 Days
Moderate Use (4 times/week)	3-5 Days
Heavy Smoker (daily)	10-21+ Days
Heavy, Chronic Use (5+ joints/day)	10-30+ Days
Oral Ingestion	1-5 Days

2) Chronic use over period of months or years; 4-6 weeks

† Explanation of Drug Enforcement Agency (DEA) Classification

- I — Illicit drugs with no medical use; high potential for abuse
- II — Prescription drugs with high potential for abuse and physical dependency
- II — Drugs with less abuse potential than schedule II; have moderate to low physical dependency, but may have high psychological dependence
- IV — Prolonged use of these drugs may lead to limited physical or psychological dependency; lower abuse potential than schedule III

FREQUENTLY ASKED QUESTIONS

Who should consider urine drug testing?
RTL Urine Drug Testing is recommended for a large variety of arenas, including the following: Federal & State Corrections, Clinics & Hospitals, Methadone Clinics, Federal, State & County Probation, Counseling Centers, Physician Offices, Federal Halfway Houses, Drug Courts, Pre-employment, Behavioral Health, Jails & Detention Centers, Rehabilitation & Treatment, Child & Family Services, Mental Health and Schools & Universities.

How do I collect the urine and send in a specimen?
Instructions for use are included with your first order of lab supplies. Please read these instructions carefully. RTL offers telephonic training and instructional materials.

How long can the urine specimen be stored before testing?
Specimens can be stored at room temperature up to 7 days. Urine specimens should be refrigerated if testing is delayed. However, it is strongly recommend that the sample be tested as soon as possible after collection.

What testing methodology does RTL use to perform initial drug screening?
RTL screens urine specimens by enzyme immunoassay (EIA). An immunoassay is a test that uses antibodies to detect the presence of drugs and other substances in urine. The initial screening process does not measure the specific amount of drug present in urine samples. It provides either a positive or negative result, indicating the presence or absence of detectable drug metabolites above a specific cut-off level.

What testing methodology does RTL use for confirmations?
Confirmations are available by thin layer chromatography (TLC), radioimmunoassay (RIA), gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). Based on your agency's account settings, specimens may be confirmed by one or more of the aforementioned methods. GC/MS and LC/MS/MS provides identification of the molecule(s) based on characteristic fragmentation patterns at specific retention times.

Why are screening and confirmation cut-off levels different?
Screening and confirmation testing are performed using different methodologies that necessitate different cut-off levels. The cut-off levels of an immunoassay screen are typically higher than those of a more sensitive GC/MS or LC/MS/MS confirm test, because they screen for a larger group of parent compounds, metabolites and other structurally similar compounds.

If an immunoassay test detects a drug (above the screening cut-off level) the presumptive positive specimen may be sent to GC/MS or LC/MS/MS confirmation testing. Many times, these individual compounds are present in concentrations much lower than the total immunoassay response, thus resulting for the cut-off levels being lower for the GC/MS or LC/MS/MS test.

What is the importance of checking the urine temperature strip on the collection cup?
Under normal situations fresh urine will display a temperature between 90 and 100 degrees Fahrenheit on the temperature strip, if read within 4 minutes of the collection. Should the temperature strip not register, the specimen should be immediately re-checked using a new cup (or strip) and the results recorded on the requisition. Specimens with a temperature out of range may indicate a substituted or adulterated sample.

How long does it take for results?
Urine screening results are typically available within 24 hours of receipt of the specimen, while oral fluid screen results take 24-48 hours. Presumptive positive specimens are usually confirmed (unless they are "Screen Only") within 24-72 hours depending on the method. Confirmation of specimens that are presumptive positive by instant/on-site devices take a minimum of 48 hours.

What does ng/mL mean?
Drug testing cut-off levels are usually expressed in the units of measure ng/mL (nanograms per milliliter). A quantitative positive GC/MS result is commonly expressed in ng/mL, or occasionally in mcg/mL.

Drugs of Abuse Testing — *Oral Fluid*

laboratory service

OVERVIEW

Oral fluid testing is gaining popularity with many programs that require convenient, gender-neutral specimen collection combined with the accuracy of lab testing. RTL provides an easy and affordable lab-based testing solution for the detection of drugs of abuse in oral fluid: RTL-Oral. RTL-Oral utilizes the only collection device that has a volume adequacy indicator. This indicator ensures that sufficient saliva (1 mL) is collected to prevent possible false negative results due to insufficient sample size, and to provide a meaningful quantitative result.

The RTL-Oral collection device also allows drug concentrations to be reported per mL of oral fluid (GC/MS confirmations only). One (1) mL of oral fluid combined with three (3) mL of buffering agent provides four (4) mL of specimen, allowing a sufficient amount of sample for screening and confirmation procedures.

The following is an explanation of RTL's saliva screening and confirmation procedures/cut-off levels. The routine cut-off levels listed below may periodically change. Note: some cut-off levels may differ for your agency.

SALIVA SCREENING METHODOLOGY

Specimens collected with the RTL-Oral collection device are sent to Redwood Toxicology Laboratory for screening by Enzyme-Linked Immunosorbent Assay (ELISA).

Screening Cut-off Levels by ELISA *Levels updated periodically*

DRUG	ELISA
Amphetamine	50 ng/mL
Barbiturates	50 ng/mL
Benzodiazepines	20 ng/mL
Benzoylecgonine (cocaine metabolite) & Cocaine	20 ng/mL
Methamphetamine	50 ng/mL
Opiates (codeine, hydrocodone, hydromorphone, morphine, oxycodone, 6-monoacetylmorphine)	40 ng/mL
Phencyclidine	10 ng/mL
THC (△-9-THC)	4 ng/mL
Methadone	50 ng/mL

These oral fluid cut-offs are based upon preliminary guidelines established by the Substance Abuse Mental Health Services Administration (SAMHSA) Drug Advisory Board for drug testing of alternative matrices.

SALIVA CONFIRMATION METHODOLOGY

Positive screens are confirmed by gas chromatography/mass spectrometry (GC/MS).

Confirmation Cut-off Levels by GC/MS *Levels updated periodically*

DRUG	GC/MS
Amphetamine	15 ng/mL
Barbiturates	20 ng/mL
Benzodiazepines	15 ng/mL
Benzoylecgonine (cocaine metabolite) & Cocaine	8 ng/mL
Methamphetamine	15 ng/mL
Opiates	
- Codeine	*20 ng/mL*
- Hydrocodone	*20 ng/mL*
- Hydromorphone	*20 ng/mL*
- Morphine	*20 ng/mL*
- Oxycodone	*20 ng/mL*
- 6-monoacetylmorphine)	*4 ng/mL*
Phencyclidine	5 ng/mL
THC (△-9-THC)	1 ng/mL
Methadone	10 ng/mL

Oral Fluid Detection Times

DRUG	Detection Time
Amphetamine	From minutes up to 48 hours
Barbiturates	From minutes up to 48 hours
Benzodiazepines	From minutes up to 48 hours
Cocaine	From minutes up to 48 hours
Methadone	From minutes up to 48 hours
Methamphetamine	From minutes up to 48 hours
Opiates	From minutes up to 48 hours
Phencyclidine	From minutes up to 48 hours
THC (△-9-THC)	From minutes up to 24 hours

FREQUENTLY ASKED QUESTIONS

How do I know the RTL-Oral Solution is right for my agency?

RTL-Oral is easily used in a variety of testing arenas: Federal & State Corrections, Clinics & Hospitals, Methadone Clinics, Federal, State & County Probation, Counseling Centers, Physician Offices, Federal Halfway Houses, Drug Courts, Pre-employment, Behavioral Health, Jails & Detention Centers, Rehabilitation & Treatment, Child & Family Services, Mental Health and Schools & Universities.

Why should I implement the RTL-Oral Solution at my facility?

Not only does oral fluid testing save your agency time and money in collection fees, it offers the convenience of testing for drugs of abuse anywhere, at any time.

What are the testing and confirmation methodologies?

Specimens collected with the RTL-Oral collection device are sent to RTL for screening by Enzyme-Linked Immunosorbent Assay (ELISA). Positive screens, other than methadone, are confirmed by gas chromatography/mass spectrometry (GC/MS).

The analytical methods used by RTL for the detection of drugs of abuse are scientifically accepted and approved by the U.S. Department of Health and Human Services.

What are the oral fluid drug detection times?

The drug detection times in oral fluid closely parallel those in blood. In general, Amphetamines, Barbiturates, Benzodiazepines, Opiates, Cocaine/Benzoylecgonine, Methadone, and PCP can be detected for up to 48 hours following use. Parent THC (marijuana) can be detected in oral fluid for up to 24 hours.

I suspect that my donor just used a substance of abuse, how long should I wait before collecting the specimen?

Depending on the drug and dosage, drugs may be detected in oral fluid in as little as a few minutes or up to approximately 2 hours from the time of use.

Why are the drug levels in oral fluids lower than those in urine?

Oral fluid drug levels largely correlate with the amount of drug in the blood (dependent on the saliva/plasma ratio for each drug). Higher drug and drug metabolite levels are found in urine because they are concentrated by the kidneys during the excretion process.

How do I collect the oral fluid specimen?

Instructions for use are included with your first order of RTL-Oral devices. Please read these instructions carefully. RTL offers telephonic training. If you have questions, please call 800-255-2159, ext. 4399.

Can I ship my oral fluid specimens with my urine specimens?

RTL will accept both oral fluid and urine specimens in the same lab pack when sending five or more specimens (e.g. three oral fluid specimens and two urine specimens). The specimens cannot, however, be mixed in the postage-paid mailer boxes due to U.S. Postal Service regulations.

***It is important that the test request form is included with the oral fluid specimen. The specimen cannot be processed without the information supplied on the test request form.*

How long does RTL store the oral fluid specimen?

RTL stores positive oral fluid specimens for six (6) months in frozen storage. Negative specimens are kept for 48 hours.

How will RTL report the RTL-Oral results?

RTL offers reporting for the RTL-Oral solution via internet, U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

What is the shelf life for the RTL-Oral collection device?

The RTL-Oral collection device has a shelf life of 12 months from the date of manufacture.

Does OSHA classify oral fluid as hazardous?

OSHA considers oral fluid collections non-hazardous as long as the specimen is not tinged with blood.

Who do I call to re-order the RTL-Oral devices?

To reorder supplies, please call us toll free at 800-255-2159.

EtG/EtS Alcohol Testing

laboratory service

OVERVIEW

EtG is a direct metabolite of alcohol (ethanol). Its presence in urine may be used to detect recent alcohol ingestion, even after ethanol is no longer measurable. The presence of EtG in urine is an indicator that alcohol was ingested and can be detected in urine for up to 80 hours after ingestion.

In addition to EtG, recent scientific studies have identified ethyl sulfate (EtS) as a second specific metabolite or biomarker of ethanol. For this reason, RTL tests and reports EtS, in conjunction with EtG, to confirm recent ethanol ingestion or exposure. EtG/EtS is only evident when alcohol is ingested and is not produced as a result of fermentation.

The detection of EtG and EtS offers greater sensitivity and accuracy for determination of recent alcohol ingestion, than by detection of either biomarker alone.

ETG TESTING METHODOLOGY

The RTL drug testing lab utilizes the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry), to screen, confirm and quantitate EtG/EtS. This methodology provides highly accurate alcohol biomarker test results.

FREQUENTLY ASKED QUESTIONS

What are Ethyl Glucuronide & Ethyl Sulfate?

Ethyl glucuronide (EtG) and ethyl sulfate (EtS) are direct metabolites of alcohol (ethanol). Their presence in urine may be used to detect recent alcohol ingestion, even after ethanol is no longer measurable. The presence of EtG/EtS in urine is an indicator that ethanol was ingested.

How long can EtG/EtS be detected in urine?

Traditional laboratory methods detect the actual ethanol in the body, which reflects current use within the past few hours (depending on how much is ingested). The presence of EtG/EtS in urine indicates that ethanol was ingested within the previous 3 to 4 days, or approximately 80 hours. Therefore, EtG/EtS is a more accurate indicator of the recent ingestion of ethanol than measuring for the presence of ethanol itself.

How accurate and reliable is the EtG/EtS test?

EtG/EtS are direct metabolites of alcohol (ethanol), and their detection in urine is highly specific, similar to testing for other drugs. Add to this, RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available, LC/MS/MS, to screen, confirm, and quantitate EtG/EtS. This methodology provides highly accurate results. As is the case with any laboratory test, it is also very important to obtain clinical correlation.

Can residual EtG/EtS be detected in the urine of long-term alcoholics who abstain?

Studies indicate that alcoholics in abstinence have no detectable levels of EtG/EtS in their urine after approximately 80 hours of detoxification.

What about urine alcohol produced by fermentation?

EtS is only detected in urine when ethanol is ingested. This is important since it is possible to have alcohol in urine without drinking. Alcohol in urine without drinking is due to the production of ethanol in vitro. Ethanol in vitro is spontaneously produced in the bladder or the specimen container itself, due to fermentation of urine samples containing sugars (diabetes) and yeast or bacteria. Since the ethanol produced is not metabolized by liver, EtS is not known to be produced and will therefore not be detected in a urine containing alcohol as a result of fermentation.

How stable is EtG/EtS in urine?

Studies show that EtG/EtS is stable in urine for more than 4 days at room temperature. Recent experiments indicate that heating urine to 100°C actually increased the stability of EtG/EtS. Therefore, heat does not cause the breakdown of EtG/EtS, it increases stability. In addition, no artificial formation of EtG/EtS was found to occur following the prolonged storage of urine at room temperature fortified with 1% ethanol. The presence of bacteria in urine can decompose EtG but EtS is not known to be susceptible to bacterial hydrolysis.

In general, what methods are used to detect EtG? What method does RTL use?

General methods to detect EtG/EtS include immunoassay (EIA or ELISA), gas chromatography/mass spectrometry (GC/MS),

liquid chromatography/mass spectrometry (LC/MS), and liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). Immunoassay methods are of limited specificity and sensitivity with a limit of detection of approximately 1000 ng/mL. GC/MS and LC/MS methods are much more specific than immunoassay, and offer detection limits of approximately 500 ng/mL.

LC/MS/MS methods utilize the most technologically advanced instrumentation currently available in forensic and clinical toxicology and provide the highest sensitivity. Redwood utilizes LC/MS/MS instruments for the confirmation of EtG/EtS, which has a limit of detection below 100 ng/mL for each compound.

Why do EtG cut-off values vary at different labs?

Various cut-off levels (100, 250, 500, or 1000 ng/mL) are suggested for use in EtG testing. Any EtG level over 100 ng/mL and EtS level over 25 ng/mL indicates exposure to ethanol. In order to provide alcohol abstinence programs with the most clinically relevant answer to whether or not recent alcohol ingestion has occurred, using a 100 ng/mL cut-off for EtG and a 25 ng/mL cut-off for EtS detection is the best and most definitive test available to answer this question. RTL uses a 100 ng/mL EtG cut-off level and a 25 ng/mL EtS cut-off level.

EtG Cut-off	Abuse Episodes Detected
1000 ng/mL	~60 – 90%
500 ng/mL	~80%
250 ng/mL	~ 98%
100 ng/mL	~ 99%

Will the use of incidental alcohol, such as mouthwash and over-the-counter (OTC) cough syrups trigger a positive result?

Tests show that "incidental exposure" to the chronic use of food products (vanilla extract), hygiene products, mouthwash, or OTC medications (cough syrups) containing ethanol can produce EtG concentrations in excess of 100 ng/mL. However, if measurable ethanol is detected (>.04 gm %) in the urine, and EtG is detected in excess of 100 ng/mL and EtS is also detected in excess of 25 ng/mL, then this is very strong evidence that beverage alcohol was ingested.

Most alcohol abstinence programs require an agreement to avoid all products containing alcohol, including; mouthwash, Nyquil®, OTC medications, etc. Consumption of these products could produce a positive test for ethanol and/or EtG/EtS and would thus violate the agreement.

What does a positive EtG test above 100 ng/mL and an EtS above 25 ng/mL mean?

A positive EtG test above 100 ng/mL and EtS above 25 ng/mL indicates recent ethanol ingestion. The only way EtG/EtS would show in urine is if ethanol was ingested & metabolized in the body. In addition, using a 100/25 ng/mL cut-off nearly doubles the time of detection of recent alcohol detection versus the use of a 250 ng/mL EtG cut-off. In summary, the 100/25 ng/mL EtG/EtS cut-off is superior for monitoring purposes, and provides the most sensitive and definitive indicator of recent ethanol ingestion.

How will RTL report my EtG/EtS results?

RTL offers reporting for EtG/EtS via internet (www.webtoxicology.com), U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

Steroid/Sports Drug Testing

laboratory service

OVERVIEW

Due to popular demand, RTL developed a comprehensive and affordable anabolic steroid panel that is comparable to WADA testing. In addition, RTL also offers a diuretics and stimulants panel. Our steroid/sports drug test is ideal for sports organizations, colleges and high schools, corrections and law enforcement, and occupational health agencies**. RTL offers the same high quality test results for steroids as we do for urine and oral fluid drug testing.*

TESTING METHODOLOGY

Anabolic steroid, stimulant and diuretic screening procedures utilize the most sophisticated, sensitive and specific equipment and technology available, GC/MS (gas chromatography/mass spectrometry). This methodology provides highly accurate results.

Specimens that screen positive are confirmed also by GC/MS using a separate aliquot of urine. The GC/MS confirmation procedure is specific to each individual steroid/sports drug. For specimens positive for multiple drugs, multiple individual confirmations are performed.

FREQUENTLY ASKED QUESTIONS

What are anabolic steroids?

Androgenic-anabolic steroids (AAS) are a class of steroid hormones with dual pharmacological actions: androgenic (promote development of male sexual characteristics) and anabolic (increase nitrogen retention, protein synthesis, muscle growth in the body).

Testosterone, the principal endogenous AAS, is produced in the testes by males and in the adrenal glands by both males and females.

Synthetic AAS are the chemical alterations of testosterone. They are designed to slow down metabolism in the body, enhance or reduce either anabolic or androgenic properties relative to testosterone, improve bioavailability and prolong the action of the drug.

AAS have limited medical use, but are abused as performance enhancing drugs in sports and more recently in some professional areas, where strong muscular appearance is important. In the general population, especially among adolescents and young adults, AAS are abused as a cosmetic tool helping to create attractive muscular bodies and to improve the physique.

AAS have been classified as Schedule III Controlled Substances in the United States since 1991. Side effects include suppression of endogenous hormone production, gynecomastia (female type breast growth in males), acne, liver toxicity, mood swings, aggression, infertility and masculinization in females: deepening of the voice, male type hair growth.

What are Prohormones and Designer Steroids?

The number of available prescription anabolic steroids has not changed since the late 1960's. However, since 1997 many new AAS have been released into circulation as nutritional supplements. They are commonly known as prohormones and designer steroids.

The term Prohormone has been used during the last decade to designate a substance (dietary supplement), which readily converts in the body into an illegal anabolic steroid. The most common prohormones are precursors of such anabolic steroids as testosterone, nandrolone (19-nortestosterone) and boldenone (1-dehydrotestosterone). These prohormones are now specifically banned and are included as an amendment to the Controlled Substances Act of January 2005.

More recent generations of anabolic dietary supplements feature synthetic designer anabolic steroids. Most of them were developed and studied more than 40 years ago, but have never been approved or marketed as legitimate drugs. Most of them are now listed as Controlled Substances.

What else is included in the RTL Steroid/Sports Drug Test?

RTL's Steroid/Sports Drug Test also includes a popular non-steroid anabolic agent, Clenbuterol; two masking agents, Prebenecid and Epitestosterone; and two anti-estrogens, Formestane and Testolactone. These drugs are also banned in sports.

Probenecid is a uricosuric drug. It restricts steroid excretion into urine, making detection difficult. Epiotestosterone may be used as a masking agent to balance excessive testosterone levels after testosterone ingestion, in order to keep the T/E levels below the cut-off limit of 6.

Anti-estrogens are often used to counteract so-called aromatization, conversion of excessive amounts of abused testosterone into female hormones, estrogens. Estrogens cause unpleasant effect in males such as female type breast growth.

What steroids on the test panel are popular?

Statistically, nandrolone, testosterone and stanozolol are found in routine testing more often than the others. However, consumer preferences vary depending on supply. Boldenone became very popular, when its precursor was released into the supplement market and was heavily advertised in the media. It was followed by the efficient anabolic steroid, 1-testosterone and methyl-1-testosterone. The newer designer steroids, desoxymethyltestosterone, methasterone and estra-4,9-diendione are now often seen in routine testing.

Why are steroids screened by GC/MS?
Most steroids convert in the body into multiple metabolites that are excreted in urine at low concentrations. These substances are similar to each other and to the endogenous steroids, normally present in urine in higher concentrations.
RTL performs GC/MS screening for the Steroid/Sports Drug Test because it provides an efficient separation and specific detection of individual compounds.

How accurate and reliable is the test panel?
The RTL Steroid/Sports Drug Test shows what steroids or metabolites are present in the urine at the time the sample was collected. In most cases, confirmation is based on positive identification of more than one metabolite (metabolic pattern), providing added confidence. Accurate quantification is performed for nandrolone and testosterone with cut-off levels of 2 ng/mL (nandrolone metabolite) and testosterone to epitestosteroine ratio above 6 (T/E > 6).

What is the T/E ratio?
Testosterone and its precursors may be endogenous (produced in the body naturally) or exogenous (ingested as drugs or supplements). The T/E ratio is used to distinguish between the two. This ratio is a urine concentration ratio of two steroids, testosterone (T) and its natural isomer, epitestosterone (E). The normal average ratio is approximately 1, with individual variation on both sides, either higher or lower. Ingestion of exogenous testosterone or its precursors suppresses internal steroid production in the body. Both endogenous T and E would be suppressed. However, total testosterone concentration in urine will rise above normal due to ingested drug. Low E and high T cause the T/E ratio to rise above 6 (cut-off), indicating testosterone abuse.

How long can steroids be detected in urine?
Detection time may vary from a few days (short-term pill) to as long as 12-18 months (oil-based injection), depending on the pharmacological form used, route of administration, length of usage and quantity. Individual differences may also contribute to the duration of the drug in the body. Test results cannot show when the drug was used, i.e. how long before the urine was collected.

What are diuretics?
Diuretics elevate the rate of bodily urine excretion (diuresis). All diuretics increase the excretion of water from the body, although each class of diuretics does so in a distinct way employing different mechanisms of action. Use of diuretics is prohibited in sports. Increased urine flow would reduce concentrations of banned performance enhancing substances in urine such as anabolic steroids, thus complicating their detection in doping control (masking). In sports where weight categories are involved, diuretics are abused as weight reducing agents. Diuretic abuse in sports is unethical and dangerous for athlete health (dehydration). Diuretic testing is a part of routine doping control in sports.

What are stimulants?
Stimulants are psychoactive drugs that induce temporary improvements in mental and/or physical function. The effects of stimulants include enhanced alertness, wakefulness, endurance, productivity and motivation; increased arousal, locomotion, heart rate/blood pressure; and a perception of a diminished requirement for food and sleep. Stimulants include the following: amphetamine, methamphetamine, cocaine and ecstasy (MDMA), which are classified as drugs of abuse in the US; ephedrine and its derivatives, which can be found in many cold medications; and many other prescription drugs and illicit substances used worldwide. Stimulant abuse can lead to addiction and is eventually destructive to human health.

How will RTL report results?
RTL offers steroid reporting by internet (www.webtoxicology.com), U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

** World Anti-Doping Agency*
*** Compliance with RTL non-pretesting policy is required*

See the complete list of steroids, diuretics, stimulants, and cut-off levels by procedure online at: ***www.redwoodtoxicology.com****. List updated periodically.*

Synthetic Cannabinoid Drug Testing

laboratory service

OVERVIEW

RTL offers lab-based testing for synthetic cannabinoid metabolites in urine or parent drug detection in oral fluid. Synthetic cannabinoids are compounds functionally similar to Δ9-tetrahydrocannabinol (THC), the principle active ingredient of cannabis, and are widely abused throughout the U.S. These chemicals are sprayed on herbal material and sold as "synthetic marijuana" under a variety of brand names.

TESTING METHODOLOGY

RTL's test will utilize the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018 and JWH-073 in urine metabolites. For oral fluid testing, the same technology will be utilized to confirm parent compounds of JWH-018, JWH-073 and JWH-250.

FREQUENTLY ASKED QUESTIONS

What are synthetic cannabinoids?

Synthetic cannabinoids are chemical compounds that mimic the effect of THC, the principle active ingredient of cannabis. Like THC, they bind to cannabinoid receptors in the brain and were initially developed as therapeutic agents for the treatment of pain. However, these psychoactive research chemicals are frequently being sprayed on herbal mixtures and sold as "fake weed" or "synthetic marijuana." JWH-018 and JWH-073 are the two most common synthetic cannabinoid chemicals found in a variety of herbal smoking blends. Others like JWH-250, JWH-081 and CP47, 497 have also started appearing in some products and preparations.

How are synthetic cannabinoids being used?

Legal in most states, JWH-018 and JWH-073 are the two most popular synthetic cannabinoids used today. Reportedly offering a high 4 times stronger than marijuana, JWH-018 and JWH-073 are commonly associated with herbal smoke and incense products sold under names like K2, Spice, Serenity and others.

Synthetic cannabinoid chemicals are often laced in the herbal smoking products that are readily available via the Internet and in many "head-shops" around the country. Users looking for a "legal high" often turn to these herbal smoking or incense products because they do not show up on a standard urine drug test.

Users smoke the product by wrapping joints, smoking it in pipes, or inhaling fumes via vaporizers. Users also report that herbal blends or pure chemical concoctions can be ingested with an infusion or solvent process; purportedly allowing them to manage the potency and dose of the active ingredient(s).

What are the effects of using synthetic cannabinoids like JWH-018, JWH-073, JWH-250 and others?

JWH-018, JWH-073, JWH-250 and other similar chemicals are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana and are among the numerous compounds found in herbal incense and smoke blends.

These synthetic cannabinoids do not contain cannabis but produce effects reported up to 4 times the strength of THC/marijuana. Users indicate the high comes on slow at first, then with surprising potency. There have been many reports about the adverse effects including agitation, rapid heart rate, confusion, dizziness and nausea. In fact, the American Association of Poison Control Centers issued a warning about the dangers of synthetic marijuana products in March 2010.

Long-term effects from these research chemicals are unknown.

What herbal incense brand names are being used?

Users looking for a "legal high" often turn to popular herbal smoking products marketed under brand names such as K2, K3, Spice, Genie, Smoke, Pot-pourri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Serenity and many others. RTL maintains a composition and concentration list for different products, brands and preparations. View the list on our website at: www.redwoodtoxicology.com (list updated periodically).

The Food and Drug Administration (FDA) does not regulate the products, but maintains they are not approved for human consumption. Without proper ingredient labeling or measured potency, users increase the risk of overdosing. To complicate labeling and dose concerns, some reports indicate many popular brands are now counterfeit or fake brands.

What is the legal status of these chemicals?

While legal under federal law, products containing JWH-018 and JWH-073 are banned in several states and by the U.S. armed forces. At present, JWH-250 is illegal in only one state. Legal restrictions on these compounds are likely to be imposed nationwide. Additionally, they are banned by a number of European countries, including Britain, France, Germany, Poland and Russia, as well as South Korea. The Drug Enforcement Administration (DEA) labeled them a "drug and chemical of concern" in 2009.

Why are JWH-018 and JWH-073 tested by RTL?

RTL laboratory analysis confirmed JWH-018 and JWH-073 as the primary active ingredients in 37 herbal smoking mixtures, and established test methods to identify the presence of their metabolites.

How long can JWH-018 and JWH-073 be detected in urine?

The presence of metabolites in urine confirms ingestion of JWH-018 and JWH-073. JWH-018 and JWH-073 metabolites can be detected in urine up to 72 hours (depending on usage/dosage).

How long can JWH-018, JWH-073 and JWH-250 be detected in oral fluid?

Drugs in oral fluid can be detected from minutes up to 24 hours after ingestion.

How is JWH-018 and JWH-073 metabolized in urine?

Both JWH-018 and JWH-073 metabolize extensively in humans via oxidation and glucuronide conjugation. Depending on dosage, the hydroxylated JWH-018 and JWH-073 and the carboxylated JWH-018 metabolites can be detected up to 72 hours in urine. Parent drug excreted in human urine has not been reported.

What are the cut-off levels?

There are no cut-off levels for RTL's Urine Synthetic Cannabinoid Test. Toxicology result reporting for JWH-018 and JWH-073 will indicate either "Detected" or "Not Detected." The cut-off level for the oral fluid test is 0.5 ng/mL for JWH-018, JWH-073 and JWH-250.

Will a standard drug test detect synthetic cannabinoids?

Conventional drug test panels will not detect the broad range of synthetic cannabinoids. They pass undetected in standard urine or oral fluid testing for such drugs as cocaine, marijuana, heroin and amphetamines. RTL's Urine or Oral Fluid Synthetic Cannabinoid Test can be ordered with your standard panel to ensure detection.

How accurate and reliable is the RTL Urine Synthetic Cannabinoid Test?

RTL's test will utilize the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018 and JWH-073 urine metabolites.

To reduce false-negative results, the detection method relies on monitoring multiple metabolites for each of the compounds. Other labs that only look for the parent drug in urine will report an increased number of false negatives. RTL's test methodology provides the most definitive synthetic cannabinoid biomarker test results.

How accurate and reliable is the RTL Oral Fluid Synthetic Cannabinoid Test?

RTL's test utilizes the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018, JWH-073 and JWH-250 in oral fluid.

Can I combine RTL Synthetic Cannabinoid Testing with other lab tests or on-site screening devices?

Yes. This test may be run in conjunction with your primary urine or oral fluid laboratory test panel. Likewise, a variety of solutions are available that combine rapid on-site devices with lab analysis.

See additional information online at:
www.redwoodtoxicology.com.

Comprehensive Drug Testing

laboratory service

OVERVIEW

Now your agency has the opportunity to choose a new testing option from RTL, America's premier drug testing lab. The solution is Comprehensive Drug Testing, detecting a wide-range of prescriptions, illicit drugs, and alcohol in urine.

TESTING METHODOLOGY

RTL screens urine specimens by enzyme assay (EA), enzyme immunoassay (EIA) and gas chromatography/ mass spectrometry (GC/MS). Presumptive positive specimens will be confirmed by a second method (GC/MS) prior to reporting positive results. RTL confirms urine specimens by gas chromatography/mass spectrometry (GC/MS) and gas chromatography-flame ionization detector (GC-FID). The analytical methods used by RTL are scientifically accepted.

FREQUENTLY ASKED QUESTIONS

Which prescription drugs are abused most often?

A few types of prescription drugs are misused/abused most often:

- ***Opiates/Narcotics***—alleviate pain, depress body functions and reactions, and when taken in large doses, cause strong euphoria.
- ***Barbiturates/Benzodiazepines***—slow down brain activity, treat anxiety, muscle tension, pain, insomnia, acute stress reactions, panic attacks, and seizure disorders. In higher doses, some CNS depressants may be used as general anesthetics.
- ***Antidepressants***—used to treat depression, anxiety and eating disorders. They are known as lifestyle drugs or "mood brighteners". Their side effects are the subject of many recent studies.
- ***Stimulants***—increase activity in certain areas of the brain. They are prescribed for attention-deficit hyperactivity disorder (ADHD), the sleep disorder narcolepsy, or obesity.

Each of these pharmacological classes may be divided into subgroups and includes a variety of drugs, which may or may not be structurally related and differ in their effect and potency.

The Drug Abuse Warning Network (DAWN), which monitors medications and illicit drugs reported in emergency departments across the nation, recently found that two of the most frequently reported prescription medications in drug abuse-related cases are benzodiazepines and opioid pain relievers.[1]

Where is prescription drug abuse most prevalent?

In 2003, approximately 15 million Americans reported using a prescription drug for non-medical reasons at least once during the year. This phenomenon is fairly common for some society groups in the U.S. Among them, medical worker abuse, drug seeking pain-patients, and teen abuse are the most alarming.

Comprehensive drug testing is well suited for a variety of environments including, healthcare settings—where easy access to prescription drugs is prevalent, medication adherence/ monitoring settings, and any other facility needing to detect an extensive range of controlled substances.

In a world where prescription drug abuse is increasing, Comprehensive Drug Testing from RTL is the perfect solution—the valuable, dependable, and verifiable choice.

Will a standard drug test detect prescription drugs?

Conventional drug test panels will not detect the broad variety of addictive prescription drugs. They pass undetected in standard testing for such drugs as cocaine, marijuana, heroin and amphetamines. RTL's Comprehensive Drug Test solves this problem.

What prescription drugs are tested?

This panel is designed to detect, in urine, a wide range of addictive prescription medications with high potential for abuse.

RTL's Comprehensive Drug Test detects prescription drugs within a variety of categories, including:

Antidepressants	Narcotics/Opiates
Anticonvulsants	Propoxyphene
Barbiturates	Sedatives/Hypnotic Agents
Benzodiazepines	Stimulants

RTL's Comprehensive Drug Test also tests for alcohol, illicit drugs and specimen validity.

Alcohol	Marijuana
Amphetamine	Methadone
Methamphetamine	PCP
Cocaine	Specimen validity *(Creatinine)*

1) *Trends in prescription drug abuse, "Prescription Drugs—Abuse and Addiction", NIDA Research Report, 2005.*

See the complete list of FAQ's, prescription drugs tested, brand names covered, and cut-off levels by procedure online at: ***www.redwoodtoxicology.com****. List updated periodically.*

Esoteric/Specialty Testing

laboratory service

OVERVIEW

Turn to RTL for a wide range of specialized tests including: gamma-hydroxybutyric acid (GHB) testing; fentanyl testing; hCG (pregnancy) testing, and more.

GHB TESTING

There are increasing reports of GHB being used recreationally as a euphoriant at "rave" type parties. GHB is typically associated with sexual assault or as a "date rape" drug due to its severe hypnotic and sedative effect at higher dosages.

RTL utilizes the most sophisticated, sensitive and specific equipment and technology available (GC/MS - gas chromatography/mass spectrometry), to confirm and quantitate GHB. This methodology provides highly accurate results.

Typical illicit use of GHB involves dissolving 2 - 3 grams of powder in water or other beverages. Onset of effects occur within 10 - 30 minutes of ingestion and include euphoria, increased libido, drowsiness, reduced inhibitions, dizziness, and nausea. Effects may persist for 2 - 5 hours. Toxic effects include hypotension, respiratory depression, seizure, unconsciousness, and coma. Deaths have been reported when GHB is used alone or in conjunction with ethanol, heroin, or ketamine.

Studies also indicate peak urine GHB concentrations of 100 mg/L following a 100 mg/kg oral dose, and no detectable drug in the urine by 12 hours. Less than 5% of an oral dose is eliminated unchanged in urine. To distinguish between endogenous and exogenous GHB, a reporting cutoff of 10 µg/mL is suggested.

FENTANYL TESTING

Fentanyl (Duragesic, Sublimaze) is an extremely fast-acting synthetic narcotic analgesic, of high potency (approximately 100 - 200 times that of morphine) and short duration of action. Fentanyl has similar dependency properties to that of morphine.

Fentanyl use, originally for chronic pain, has increased in illicit street-use and among healthcare workers due to the drug's euphoric effects and easy availability.

RTL utilizes the most sophisticated, sensitive and specific equipment and technology available (GC/MS - gas chromatography/mass spectrometry), to confirm and quantitate Fentanyl. This methodology provides highly accurate results.

HCG (PREGNANCY) TESTING

Quality hCG laboratory testing is a great alternative to over the counter devices and ideal for methadone clinics and corrections. Send urine specimens in for a qualitative human chorionic gonadotropin (hCG) test.

RTL utilizes a qualitative immunoassay screen to determine the presence of hCG. This screening methodology provides highly accurate results.

Home pregnancy testing is very similar to qualitative urine hCG testing in the laboratory, but there are factors surrounding its use that are important to note.

First, home tests come with very specific directions that must be followed explicitly. If you are using a home test, follow the directions extremely carefully.

Second, home tests are sometimes done too soon after the missed menstrual cycle to result in a positive test—it takes approximately 10 days after conception before the presence of hCG can be detected by the urine test. That is why a home test is sometimes negative when the test done by your doctor or laboratory is positive—the laboratory test is often done several days later when hCG levels have become detectable.

specimen collection // shipping

Redwood Toxicology Laboratory provides suggested specimen collection guidelines ONLY. It is the responsibility of individual collection agencies to adopt their own policies and procedures according to their needs in compliance with individual state and federal regulations.

Laboratory drug and alcohol test results are often used in legal proceedings. The manner in which specimens are collected and handled is very important. Specimens must be handled and controlled by collection site personnel throughout the collection process.

Directly observed urine collection is the best means to ensure specimen integrity. However, outside of probation and parole and some drug rehab environments, the question of civil rights arises. A uniform urine and oral fluid collection process, regardless of the testing environment, should be followed.

Collection: Site Preparation

suggested collection guidelines

PRINCIPLE

Requirements for specimen collection vary according to the purpose for which the results will be used. However, to meet evidentiary requirements the specimen collection site must be secure in order to eliminate the possibility of specimen tampering or adulteration and to ensure the security of the collected specimens.

COLLECTION AREA GUIDELINES

1. Storage area for collection supplies and related materials is secure.
2. Collection site facility is secure, well lit, and free of any areas where adulterants or substitute specimens can be hidden.
3. A suitable clean surface for the collector to use as a work area.
4. Eliminate or secure all sources of water in the area where urination occurs. Bluing agent should be placed in the toilet tanks and bowls to prevent sample dilution.
5. Eliminate or secure all soap or detergent dispensers or any other potential adulterants.
6. A secured storage area should be available to ensure specimen security prior to transport to the laboratory.
7. A general log book should be maintained to record collected specimens.

Redwood Toxicology Laboratory's Collection Area

Collection: Urine/Oral Fluid Collection Protocol

urine/oral fluid collection and shipping instructions

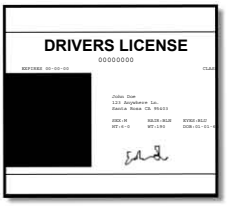
PRINCIPLE

The validity of urine drug screen results is dependent on specimen integrity. While direct-observation collections provide specimens of the greatest credibility, non-witnessed collections can be effective if safeguards are in place to ensure the donor does not have access to substances which may affect test results (water, chemicals, substitute urine, etc.).

SUGGESTED PROCEDURE PRIOR TO COLLECTION

Prior to any specimen collection procedure, secure the collection facility *(see Collection Site Preparation page 20)* and if necessary, perform a thorough search for hidden adulterants or substitute urine specimens. Place bluing agent in the toilet bowl or tank, remove or secure all chemicals (soaps, cleaning supplies, etc.) and secure or eliminate all water sources.

1. Check the identity of donor (e.g. social security number or driver's license number and photo I.D.). If using a drug screen test request form, note the identity on the form.



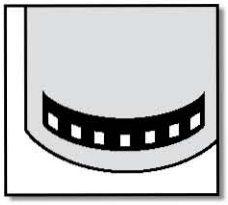
Verify the donors identity with a photo I.D.

2. Ask the donor to remove any unnecessary outer clothing. All personal belongings (the subject may retain a wallet) should be placed in a secure location outside the stall or partitioned area.
3. Do not ask the donor to empty his/her pockets or to remove articles of clothing such as shirts, pants, dresses, etc. If a collector notices any unusual behavior that indicates a donor may attempt to tamper with or adulterate a specimen (e.g., bulging pockets), the collector may request that the donor empty his/her pockets and explain the need for such items during collection.
4. Prior to collection, ask the donor to wash his/her hands to eliminate any possible adulterating or contaminating substances from under the donor's fingernails.

Donors should wash hands before donating specimens.

URINE COLLECTION PROCEDURE

1. Place the following information on the bottle label:
   - Date of collection
   - Donor's name and/or identification numbers
   - Collector's initials
2. Provide the donor with a clean, unused urine specimen collection container and instruct the donor to fill the container at least half full (a minimum of 30 mL's).
3. Unobserved Collection: Allow the donor to enter and maintain privacy within the stall or partitioned area. The collector will wait outside the collection area until the donor is finished urinating. Complete the remainder of the test request form while the donor is collecting the specimen. *(See page 27 for detailed labeling instructions).*
4. Observed Collection: Inform the donor that collection will occur under direct observation. Accompany the donor into the collection facility (the collector must be the same gender). Instruct the donor to urinate into the sample container with the witness observing urination. Complete the remainder of the test request form after the donor has completed collecting the specimen. *(See page 27 for detailed labeling instructions).*
5. Accept the specimen from the donor. The use of disposable gloves is recommended when handling specimens, so prior to accepting the specimen from the donor, be sure to wear gloves.
6. Upon receipt of the specimen from the donor, immediately apply the temperature strip (if applicable) to the outside of the bottle. If using a drug screen test request form, record the urine temperature on the form.



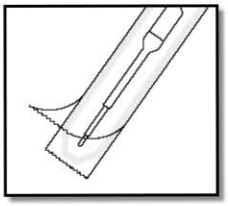
Apply temperature strip to sample bottle.

NOTE: Urine temperature should be measured within (4) four minutes of collection and should read between 90-100ºF.

ORAL FLUID COLLECTION PROCEDURE

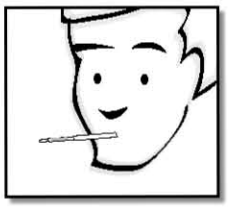
1. Remove the kit contents from the packaging. Save the outer packaging because the specimen must be placed in the re-closable outer packaging for shipment to the laboratory.

2. Peel open the collector pad package and remove the collection device. Do not touch the pad.



Peel open package and remove collector.

3. Place the collector pad under the donor's tongue and instruct the donor to close his/her mouth. The donor must not chew or suck on the pad. When the indicator window turns blue, remove the collection device from the donor's mouth. DO NOT remove the collection device until the indicator turns blue. If the indicator does not turn blue within 15 minutes, remove the collection device and discard. Re-collection with a new device may begin immediately after saliva has accumulated in the donor's mouth.



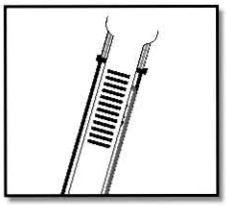
Place collector pad under the donors tongue.

4. Holding the transport tube in an upright position, remove the cap, and insert the collector device, pad first, into the tube. DO NOT set the transport tube on a table. If any of the buffer fluid is spilled, a new transport tube must be used. The amount of liquid in the transport tube is critical to the testing process.

Open transport tube and insert the collector.

5. Push the cap firmly onto the transport tube until you hear the SNAP. Gently shake the tube to mix the saturated collector pad with the buffer.

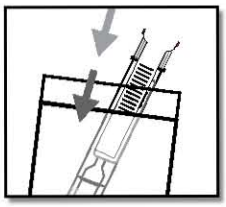
6. Write the collection date on the security seal, peel the seal off the test request form and place it across the cap (see diagram on test request form for instructions).



Snap cap firmly. Place tamper proof security seal over cap of collection device.

7. Have the donor initial the security seal to indicate the specimen was sealed in the donor's presence. Please do not use red ink or felt tip pens. Blue and black ballpoint pens are preferred.

8. Complete the information on the test request form. *(See page 27 for detailed labeling instructions).*



Place collector in provided resealable packaging.

9. Place the transport tube into the original outer packaging provided with the collector device. Place the collection device and top copy of the test request form in the supplied shipping pack or U.S. mailer box.

10. Send the specimen(s) to Redwood Toxicology Laboratory for testing. Keep the second copy of the test request form for your records. The specimen should be received by the laboratory within seven days of the date of collection.

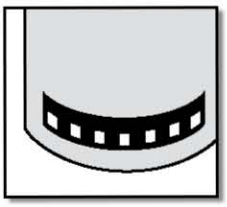
    (See page 29 for detailed shipping instructions).

Collection: *Specimen Validity*

specimen tampering/adulteration

PRINCIPLE

Methods to adulterate urine samples for substance abuse testing generally fall into three categories; 1) urine substitution; 2) ingestion of fluids or compounds for flushing out the system, diluting the sample, or interfering with the testing process; or 3) direct addition of adulterants to the urine specimen itself. The substitution of one's own urine sample with one which is clean is a common practice. The best means to combat this practice is to measure urine temperature, as urine specimens even held close to the body for extended periods of time will not produce a physiologically temperature-correct specimen. However, practices of reverse catheterization with clean urine and placement of urine filled balloons in the vaginal cavity can produce urines of correct temperature.



Human urine specimens should range between 90º and 100º F.

Drinking large volumes of liquid, especially cranberry juice or vinegar is common practice. However, studies demonstrate these practices have no effect on testing methodologies and may present unexpected results.

Many of the drugs being tested are pH dependent. When large volumes of cranberry juice or vinegar are consumed, the urine pH is lowered, and the excretion rate of these drugs may increase. If timed correctly, large amounts of a drug may appear sooner in the sample.

Be aware, drinking large volumes of vinegar can be toxic.

One potentially effective method which may negatively impact the testing process is to consume large volumes of water, as short term water loading can increase urine volume up to eight fold. Therefore, if the individual's drug concentration is near the cut-off of an assay, the urine may be diluted enough so that the sample will test below the cut-off level. Other attempted methods of adulteration include ingesting large amounts of vitamin C, vitamin B, niacin, Golden Seal, etc. All of these practices are ineffective.

Consuming too much fluid prior to collection can result in an invalid specimen.

Adulteration of a urine sample with various chemicals is shown (in the literature) to inactivate some of the laboratory testing methodologies, most notably, the enzyme immunoassay's. Addition of compounds such as sodium chloride, sodium bicarbonate, hydrogen peroxide, bleach, alcohols, blood, various soaps, etc. are shown to produce both false negatives and false positives.

The current list of urine adulterants is ever changing as the Internet provides an informational source, as well as a retail outlet for commercial products capable of affecting the outcome of some urine drug testing methodologies. Currently, nitrites (Klear and Whizzies) and chromates (Urine Luck) are two adulterating agents commonly found in the industry. RTL is capable of providing testing for these agents.

ADULTERATION & DILUTION DETECTION

Means to detect adulteration by the collector and/or the laboratory include the following:

1. *Specimen Temperature:* If specimen collection is not witnessed, the most effective means to detect specimen dilution, adulteration, or substitution is to measure the sample's temperature. The collector should measure the temperature utilizing the temperature strip affixed to the specimen container within four minutes of collection; it should read between 90 and 100 degrees Fahrenheit. The urine temperature should be noted on Urine Test Request form.

2. *Urine Appearance and Odor:* Adulterants such as isopropyl alcohol, soaps, bleach and perfumes are readily identified by their odor. Soaps are also identified by excessive bubbling. Use of solid adulterants is detected by the presence of residues in the container.

3. *Creatinine:* In general, creatinine is a metabolic byproduct of muscle metabolism which normally appears in urine in relatively constant quantities over each 24 hour period. Therefore, urine creatinine can be used both as a marker to specifically identify a specimen as urine, and as an indicator of urine water content (dilution). "Normal" random urine specimens will generally have urine creatinine levels of greater than 20 mg/dL, while specimens with creatinine levels between 10 and 20 mg/dL may be due to increased liquid consumption, dietary habits, or liquid ingestion preferences. Urine specimens with creatinine levels between 2 and 10 mg/dL are usually a result of ingestion of large volumes of water (or other liquid), termed short term water loading. This is a very common practice when attempting to dilute a urine so that any drugs in the urine will be diluted below analytical testing cutoff levels. Urine creatinine levels below 2.0 mg/dL are usually a result of "dipping", the direct addition of a liquid to the urine specimen. Creatinine levels of 0.0 mg/dL indicate the specimen is not consistent with human urine.

   Urine specimens become dilute as a result of the short term consumption of large amounts of a liquid due to an unknown stimulus such as a response to heat or exercise, herbal flushes, prescription diuretics, intentional dilution, or pathological situations such as diabetes insipidus. The dilution effect from consuming increased volumes of liquid can last from 2 – 5 hours. Therefore, the increased consumption of liquid would have to take place between 2 – 5 hours prior to the collection of the urine specimens.

   An important factor to consider when interpreting dilute urine samples is that drug use can never be assumed unless specifically detected, and confirmed in a urine sample. Certainly, a dilute sample can produce false negative results, as drugs in the urine at concentrations near the testing cutoff may be diluted below the testing cutoff level, however, due to the reasons stated above it can be difficult to establish the reason or intent for the sample(s) being dilute. For these reasons, urine creatinine is reported in conjunction with testing for drugs of abuse, as an indicator of specimen validity only, as urine specimens with a creatinine level below 20 mg/dL may have an increased likelihood of producing a false negative drug testing result.

   For more information about creatinine, refer to page 53.

4. *Specific Gravity:* Normally, a random urine specimen will have a specific gravity of between 1.005 and 1.035*. An extremely low specific gravity (<1.005) indicates a dilute specimen, while abnormally high specific gravity (>1.045) may indicate the presence of dissolved solids such as sodium chloride and sodium bicarbonate.

5. *pH:* Normal random urine pH is 4.8-7.8*. Low pH's indicate possible ingestion of acidic substances such as cranberry juice or vinegar; starvation; diarrhea; or direct adulteration of the specimen itself with acidic compounds. Elevated pH's may indicate the presence of basic compounds such as sodium bicarbonate, bleach, or Drano; vegetarian diet; or prolonged vomiting.

6. *Visible Blood:* Indicates the presence of blood in the urine specimen. The presence of blood in the urine sample may adversely impact the testing process and, in addition, constitutes a biohazard for laboratory employees. Collection of clean catch urine specimens during menstruation should be attempted.

Urine adulteration is a double edged sword as both false negative and false positive results can occur. However, most adulteration attempts can be detected by either trained collection site personnel or by collection procedures as outlined above. Coordination and cooperation between the collection site and the testing laboratory provide effective and reliable drugs of abuse testing.

***NOTE:** Normal ranges are indicated for freshly voided urines only.

Collection: *Problematic Situations*

donor situations

PRINCIPLE

While most donors will cooperate fully if treated with dignity and courtesy, there may be instances when unusual events may occur. For this reason, it is imperative for the collector to have a thorough understanding of the collection process and to have the ability to explain the process clearly to the donor so they will fully understand the directions. During collection of the specimen and completing the forms, it is vital that the collector devote his/her full attention to the procedure without interruptions. Any unusual appearance or behavior is to be noted on the urine chain of custody form.

PROCEDURE

While it is not possible to anticipate every type of unusual event, some of the more frequent are:

1. Specimen Temperature Outside Limits: If the specimen temperature is outside normal parameters, i.e., less than 90ºF or greater than 100ºF then:

   A. Inform the donor that the temperature of the specimen is outside normal limits (too low or too high) and that the specimen needs to be recollected. If the specimen cannot be recollected or the donor refuses, inform the donor that specimen temperature will be noted on the final report. NOTE: This is important because if the donor has drug in his/her system at the time of collection, collection at a later time may allow the drug to clear. Therefore, if at all possible, make every effort to resolve the situation at the time of the incident.

2. Specimen Contains Visible Blood: Urine specimens may not contain visible blood for drug testing because:

   - Blood may interfere with the testing process (which could result in false negative tests).
   - Urines containing visible blood are considered biohazardous and require special packing procedures in order to be shipped (Federal Bloodborne Pathogens standard).

   Instructions to client to obtain a clean catch urine specimen:

   A. Wipe area until free of blood.

   B. Start urinating into the toilet. After a few seconds, place the urine container under the stream of urine until the cup is at least half-full.

3. Uncooperative or Belligerent Donor: Presumably, the donor has agreed to the drug test prior to appearing at the collection site. However, attitudes may change just before, or during the collection process. Remain courteous and do not argue with a donor. It remains the right of the donor to refuse collection at any time, of course at his/her own risk. Remind the donor that you will call the requesting agency with a recount of the pertinent facts.

   If physical violence seems imminent, call for assistance and ask the donor to leave the premises. Use the same procedure you would use for any other circumstance in which you fear bodily harm or property damage, including calling 911.

4. Suspicion Donor is Adulterating Sample (Adding water or other substance): Remain courteous and do not argue with the donor. The following statement may be appropriate:

   "We are instructed to tell everyone that the lab tests for water and other materials that may have been added. It will show up on the test report."

Grounds for these type of suspicions may include out of range specimen temperature, abnormal urine smell or appearance, or unusual sediments.

5. Donor Cannot Urinate or Produces Insufficient Volume: Upon receipt of the specimen, the collector must first determine if there is sufficient urine for testing. Minimum sample volume is twenty (20) mL and is sufficient for retest and confirmatory procedures if required. If there is not sufficient urine volume, then follow the procedures below:

   A. Ask a supervisor to determine if there is adequate urine volume to perform the requested testing.

   B. If there is not a sufficient urine volume, the collector shall take possession of the partial specimen and instruct the donor to drink fluids (no more than 8 oz.) and try again in a reasonable amount of time. If possible, the donor should remain on the premises and preferably within visual contact of the collection site person until a complete specimen is provided.

   C. In the event a donor cannot provide a specimen of adequate volume, the requesting agency should be notified for further instruction. In some cases, it may be acceptable to reschedule the collection. However, it may be necessary to determine whether a valid medical reason exists for the donor's scarce urine output or if the donor is refusing to provide a specimen.

6. Donor Accuses Collector of Carelessness, Personal Misconduct, or Deliberate Mishandling of Specimen: This is unlikely; however it does occur.

   Remain calm and professional. Listen carefully. If there is another person at the site, ask that individual to join you and the participant. If you are alone, call your supervisor while in the presence of the participant. It is important to document what took place and what was said. The matter should be treated with the utmost seriousness. It could result in the loss of a client, a civil lawsuit, or even a criminal suit. State fully to the participant and, if possible, to a witness what you did or did not do. Make every reasonable effort to persuade the participant of your good intentions and lack of negligence; however, do not attempt to deny actual error on your part. If it is obvious that a participant is attacking you to perhaps cover the presence of drug use, treat it as a legal matter with documentation and immediate notification to your supervisor.

Labeling Protocol: *Urine Specimens*

labeling urine specimens for shipment to the laboratory

URINE SPECIMEN TEST REQUISITIONS

For each urine specimen, the forms should be completed with a water-resistant marker, such as a blue or black ball point pen (red color is not recommended since it tends to rub off).

NEW! OPTION A: WEBTOXICOLOGY TEST REQUISITION FORMS (ELECTRONIC COC – not shown)

Secure, easy-to-use, comprehensive drug test management solution. Order lab tests and print chain of custody (COC) forms from your laser printer—no special hardware required. COC forms are scanned by the lab and made available for viewing online. ***Please contact our IT Department for more information at: 800-255-2159, ext. 4311.***

OPTION B: URINE TEST REQUISITION FORMS (RF2 / RF3)

RF2 and RF3 labels are COC labels with either 2 or 3 part carbon copies. This is the most common label used with RTL.

1) ***Urine Drug Screen Type:*** Check the box corresponding to the reason donor is being tested and note specimen temperature.

2) ***Security Seal:*** After collecting the specimen, tighten the bottle cap. Place the security seal over the top of the cap and down the sides of the bottle. Have the donor initial the security seal.

3) ***Specimen Label:*** Indicate the following information in the appropriate area of the specimen label:

   - Please indicate which test(s) or panel is to be ordered by placing a check mark in the appropriate box or by writing the test on the "other" line. Specific tests by GC/MS should be written on the GC/MS request line.
   - Donor identification, collection date, and collector.

4) ***Donor Information & Collector Verification:*** The donor will enter his/her signature, printed name, date collected and donor ID (SSN or DL#). The collector will verify the information provided by the donor and validate that the specimen was collected correctly.

5) ***Receiving (lab only):*** This section is to be filled out by Redwood Toxicology Laboratory personnel only.

OPTION C: URINE TEST REQUISITION LABELS (LSL)

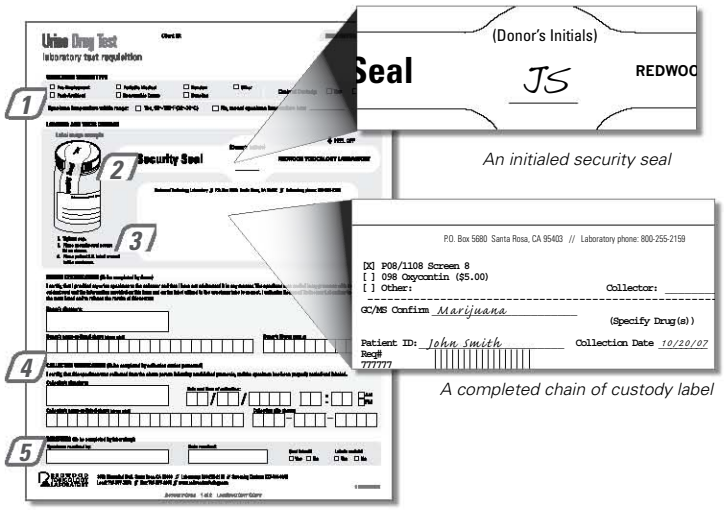
Another version of the Urine Test Requisition form is called the LSL Requisition Label. There are 6 labels per sheet.

1) ***Specimen Label:*** This section is to be filled out by the collector.

2) ***Tests Ordered:*** Please indicate which test(s) or panel is to be ordered by placing a check mark in the appropriate box, or by writing the test on the "other" line. Specific tests by GC/MS should be written on the GC/MS Request line.

For training or questions, please contact:
Client Services
Phone: 800-255-2159, ext. 4399
Fax: 707-577-0365
Email: clientservices@redwoodtoxicology.com
Web: www.redwoodtoxicology.com/resources/

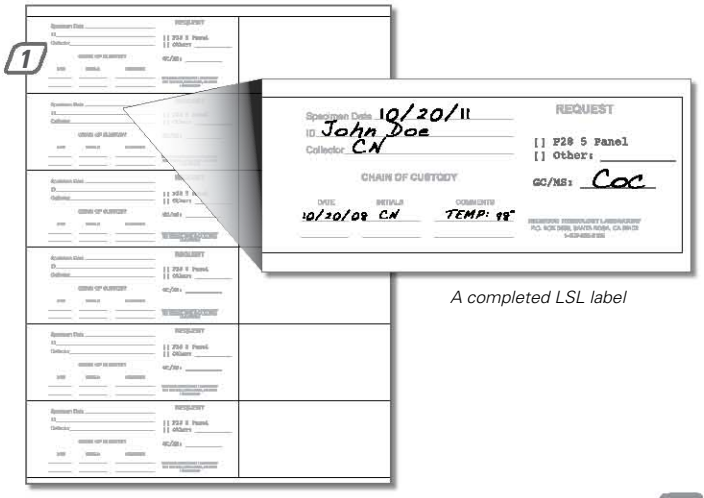
Fill out the appropriate test requisition form/label, indicating the drug(s) to be tested. Ensure that the security seal, dates and appropriate signatures are completed by the donor and the collector.



An initialed security seal

A completed chain of custody label

OPTION B: Urine Test Request Form



A completed LSL label

OPTION C: Urine Test Request Labels

Labeling Protocol: *Oral Fluid Specimens*

labeling oral fluid specimens for shipment to the laboratory

ORAL FLUID SPECIMEN TEST REQUISITIONS

For each oral fluid specimen, complete a test requisition form with a water-resistant marker, such as blue or black ball point pen (red color is not recommended since it tends to smear). Ensure that the security seal, dates and appropriate signatures are completed by the donor and the collector.

ORAL FLUID TEST REQUISITION FORM

Oral Fluid Test Requisition forms will be provided when ordering oral fluid tests through the lab. These forms are different from the Urine Test Requisition forms and are therefore, not interchangeable. Please send the appropriate form with the specimen. This form is a two-part carbon copy.*

1) ***Lab Test Request Information:*** Review agency specific test panel information. Test(s) to be performed will be printed on the top of the form. *(Diagram 1A)*

   On-site Device Test Request Information: Use the "GC/MS Confirm" line to list the presumptive positive drug(s) you want to confirm through the lab. *(Diagram 1B)*

   Check one of the boxes for why the donor is being tested in the green box below the test request information.

2) ***Security Seal with barcode:*** Ensure cap is tightly fastened. Place the center of the security seal over the top of the cap. Be sure that the barcode runs lengthwise/vertically on the collection tube.

3) ***Donor Information & Collector Verification:*** The donor will enter his/her signature, printed name, date collected and donor ID (SSN or DL#). The collector will verify the information provided by the donor and validate that the specimen was collected correctly.

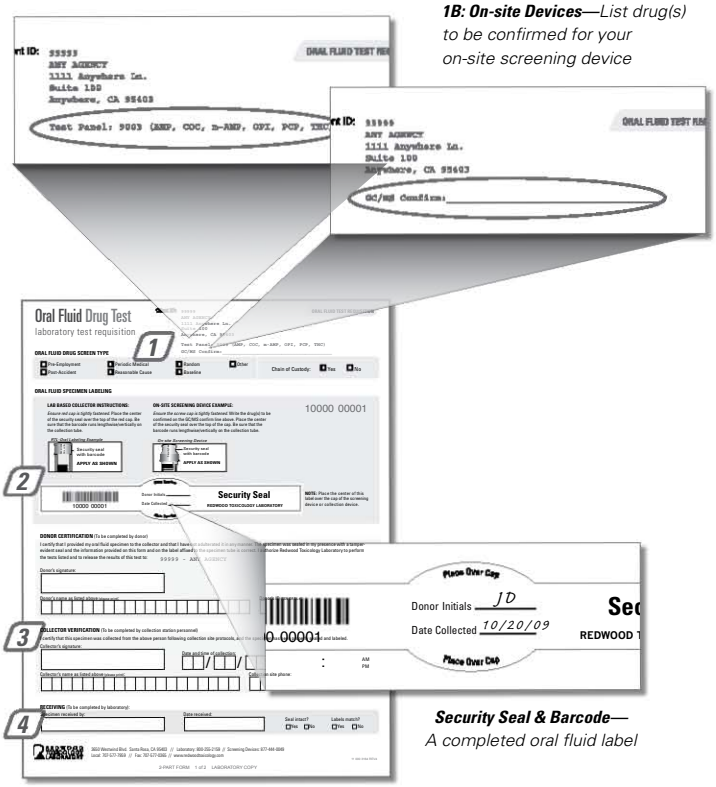
4) ***Receiving (lab only):*** This section is to be filled out by Redwood Toxicology Laboratory personnel only.

IMPORTANT LABELING INFORMATION

The oral fluid sample cannot be processed without the information supplied on the test request form. If the test request form does not accompany the specimen, testing will be delayed.

1A: Lab Tests*—Agency specific drug test panel listed*

1B: On-site Devices*—List drug(s) to be confirmed for your on-site screening device*



Security Seal & Barcode*—A completed oral fluid label*

Oral Fluid Test Request Form

For training or questions, please contact:
Client Services
Phone: 800-255-2159, ext. 4399
Fax: 707-577-0365
Email: clientservices@redwoodtoxicology.com
Web: www.redwoodtoxicology.com/resources/

** Specialty 5 part pre-employment forms are available for customer's requiring MRO, Employer, and Donor copies.*

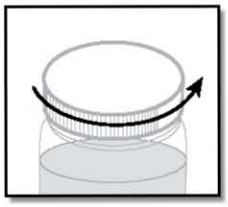
Packaging Protocol: *Shipping to Lab*

urine & oral fluid specimen shipping instructions

URINE & SALIVA SHIPPING PRINCIPLES

The following is a brief description of how to label and send your urine specimen in to the laboratory for testing:

1. With the donor watching, tightly seal the container lid/cap. If using tamper resistant tape (security seal), place the tape over the lid and down the sides of the container. Instruct the donor to sign his/her initials to the tamper resistant tape.



Ensure the lid/cap is tightly sealed prior to labeling.

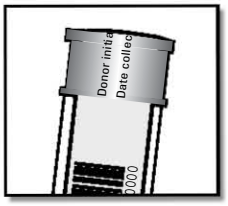
2. Place the patient I.D. label (prepared while or after the donor collected the specimen) around the specimen bottle/collector. The label should cover the ends of the tamper seal if used.

3. If using a drug screen test request form, have the donor read and sign the Donor Certification section, certifying the urine or oral fluid is the donor's and the specimen is sealed and labeled properly *(See page 27-28).*

Urine Collection Device

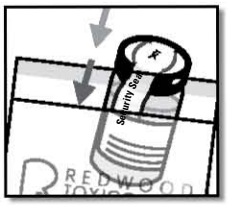
Place ID label around the security seal.

Saliva Collection Device



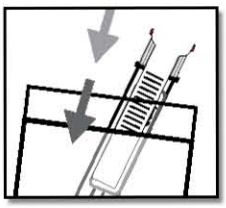
Place the security seal with barcode over the collection tube.

4. **All on-site device samples & lab urine samples:** After labeling and sealing the specimen tightly, place it into a RTL branded plastic baggie with absorbent material. Ensure baggie is sealed. Store in a secure area until the specimen is ready to be shipped to the laboratory.



Place urine specimen into the plastic baggie.

Lab RTL-Oral fluid samples: After labeling and sealing the specimen tightly, place the transport tube into the original outer packaging provided with the collector device. Ensure baggie is sealed. Store in a secure area until the specimen is ready to be shipped to the laboratory.



Place saliva specimen into the plastic baggie.

SPECIMEN SHIPPING

Your account has been set up with one of the following specimen shipping methods:

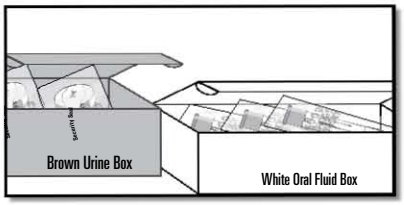
EXPRESS DELIVERY SERVICE—5 OR MORE SPECIMENS

Please use the packaging materials and labels that are included with your lab supplies. Instructions for packing and shipping specimens will be enclosed with your supply shipment.

5 or more specimens: Use express delivery package

U.S. POSTAL SERVICE—LESS THAN 5 SPECIMENS

Please use the pre-paid U.S. mailer boxes. Do not mix oral fluid and urine specimens in the same postage-paid mailer box! Per U.S. Postal Service regulations, use the box provided specifically for each type of test as indicated on the pre-paid label.



Fewer than 5 specimens: Use USPS Pre-paid Mailer Box

SHIPPING/PICKUP

If you need help with scheduling an express delivery pick-up, please call RTL Client Services at 800-255-2159, ext. 4410 or ext. 4382.

Supplies Re-ordering: *Lab supply re-ordering is available to existing clients with an account number. RTL offers two convenient methods for re-ordering drug testing supplies:*

Email: supplies@redwoodtoxicology.com
Web: www.redwoodtoxicology.com/supply_form/

Please order supplies through RTL ONLY. Do not ask drivers for labels or bags since RTL provides its clients with custom supplies. The supplies have specialized routing information that drivers do not have access to. This information is also important for billing purposes.

IMPORTANT PACKAGING NOTICE

FEDERAL LAW REQUIRES THAT SPECIMENS BE PACKAGED IN BAGS WITH ABSORBENT MATERIAL.

PLEASE BE SURE TO FASTEN THE LID OF THE BOTTLE TIGHTLY. LEAVE THE ABSORBENT MATERIAL IN THE BAG WITH THE SPECIMEN BOTTLE.

LEAKY SPECIMENS MAY BE RETURNED TO YOUR AGENCY BY YOUR SHIPPING PROVIDER.

IF YOU REQUIRE TRAINING ON SPECIMEN COLLECTION PROCEDURES, PLEASE CONTACT RTL'S CLIENT SERVICES DEPARTMENT:

Phone: 800-255-2159, ext. 4399
Fax: 707-577-0365
Email: clientservices@redwoodtoxicology.com

THANK YOU.

result reporting & collection management

Redwood Toxicology Laboratory's objective is to provide its clients with all the tools possible to help deter and prevent drug abuse. Reliable and useful toxicology reports are essential to this objective. Toxicology results are delivered in the following formats:

Web-Result Reporting & Collection Management—RTL's webtoxicology site provides a secure and complete solution for tracking, managing and printing your drug test reports and chain of custody forms.

- Fast collections—print chain of custody forms using a simple, step by step process on a single screen
- Accurate data—no more hand-written labels and laboratory data entry errors
- Real-time tracking—track specimens from collection to reporting; includes COC scans with donor, collector and lab receiving signatures
- Program management—schedule tests, generate collection rosters and view no-shows
- Powerful reporting—pending specimens, drug statistics, donor summaries and more

Mail/Fax Reports—RTL offers reporting solutions via U.S. mail or facsimile. Please indicate your preferred method at the time of account set-up.

Standard Result Reporting

toxicology results issued by fax or mail

FINAL TOXICOLOGY REPORT

Standard reporting from Redwood Toxicology Laboratory includes toxicology reports which are delivered via fax, mail or the internet. The combination of RTL's leading testing methods and chain of custody documentation guarantees legal defensibility.

For more information on specific drugs, including; classifications, metabolism, general abuse information and methods of analysis, please refer to the Drug Information Section, beginning on page 35.

For more information on how to read creatinine levels, please see page 53 within the "Drug Information" section.

REDWOOD TOXICOLOGY LABORATORY

3650 Westwind Blvd., Santa Rosa, CA 95403
Phone: 707-577-7959 // 800-255-2159
Fax: 707-577-0365
www.redwoodtoxicology.com

ACCOUNT NUMBER	ACCESSION NUMBER
0000	110130-00000

IDENTIFICATION: JOHN DOE

ORDERED BY: SAMPLE AGENCY T152

NOTES: (707) 555-5555

COLLECTED: 01/29/2011 by CN

RECEIVED	REPORTED
01/30/2011	01/31/2011

Sample Agency
300 Sample Road
Santa Rosa, CA 95403

POSITIVES	TEST NAME	RESULT
POS--------->	Amphetamines Confirmed as Methamphetamine by TLC. Confirmed as Methamphetamine by GC/MS. Confirmed as Amphetamine by GC/MS.	Positive
	Alcohol (Ethanol)	None Detected
	THC (Marijuana)	None Detected
	Cocaine (Benzoylecgonine)	None Detected
	Opiates	None Detected
	Barbiturates	None Detected
	Benzodiazepines	None Detected

NOTE: Amphetamine = 0.13 mcg/mL, Methamphetamine = 0.8 mcg/mL.

The results for this specimen have been tested in accordance to all Redwood Toxicology Laboratory standard operating procedures and have been reviewed by laboratory certifying scientists.

SAMPLE REPORT

110130-00000 01/31/2011 05:32:11

Specimen disposition: Specimens will be disposed of as follows: Negatives: destroyed within 2 days; Positives: destroyed after 6 months; all methadone maintenance urines after 2 months.

Standard Result Reporting Figure 1: Sample Final Toxicology Report

TOXICOLOGY SUMMARY REPORT

Summary reporting for your agency is also available via fax, mail and internet.

For more information on specific drugs, including; classifications, metabolism, general abuse information and methods of analysis, please refer to the Drug Information Section, beginning on page 35.

For more information on how to read creatinine levels, please see page 53 within the "Drug Information" section.

REDWOOD TOXICOLOGY LABORATORY
3650 Westwind Blvd., Satna Rosa, CA 95403 Phone: 707-577-7959 / 800-255-2159 / Fax: 707-577-0365
TOXICOLOGY SUMMARY REPORT

Client: 9999 Sample Agency

Print Date: 06/06/2011

Date Received: 03/24/2011

Accession # /Req #	Identification	Collected	Alc	Am	Barbs	Benzo	Coc	Mtd	Op	THC	Creat	Other / Comments
000000-11111	John Doe	03/20/2011 Jane Doe	-	-	-	-	-	-	-	-	18.4	[Creat] Specimen is dilute.
000000-11112	John Doe	03/20/2011 Jane Doe	-	POS GCM	-	-	-		-	-		[Amp] Confirmed as Methamphetamine by TLC. [Amp] Confirmed as Amphetamine by GC/MS. [Amp] Confirmed as Methamphetamine by GC/MS. Amphetamine = 0.13 mcg/mL, Methamphetamine = 0.8 mcg/mL. Updated 4/2/2008.
000000-11113	John Doe	03/19/2011 Jane Doe	-	-	-	-	-		-	591 RIA		[THC] Confirmed by RIA.
000000-11114	John Doe	03/19/2011 Jane Doe	-	-	-	-	-		-	599 RIA		[THC] Confirmed by RIA.

SAMPLE SUMMARY REPORT

Note: POS Indicates positive result; (-) indicates negative/none detected result; QNS indicates quantity of urine insufficient for testing.
GC/MS:Gas Chromatography/Mass Spectrometry
Creat: Creatinine Alc:Alcohol Op:Opiates Benzo:Benzodiazepines Barbs:Barbiturates Coc:Cocaine THC:Cannabinoids Amp:Amphetamines Mtd:Methadone

Fax No: (707) 577-0471

Standard Result Reporting Figure 2: Sample Toxicology Summary Report

Web Result Reporting & Collection Management

webtoxicology application

RTL's reporting website provides a secure and convenient solution for viewing, managing and printing your toxicology results. We have expanded the collection features of webtoxicology to create a more comprehensive drug test management solution for our clients. These productivity enhancements offer the following features, advantages and benefits:

FEATURES

FAST COLLECTIONS. Now your drug test collections can be performed quicker, easier and more efficiently because collections are performed on a single screen in just a few simple steps. All donor information is saved and stored in the website so you only have to enter it once. (With traditional chain of custody programs you have to fill out the donor information time and time again.)

CLEAR, ACCURATE DATA. The information you input is automatically transferred into RTL's laboratory information system, eliminating both the errors caused by hand-written labels and laboratory data entry errors.

COMPLETE, REAL-TIME TRACKING. Track specimens every step of the way—from collection to reporting—in real time, 24/7. These steps include:

- Scheduled for testing—the specimen has been scheduled for testing on a particular date (Optional)
- Collected—the specimen has been collected
- Shipped—the specimen has been shipped to the lab; you can even enter your FedEx tracking number to track the shipment (Optional)
- Received by lab—the specimen has been received by the lab and is being tested
- COC scans—track, view, print and manage signed COC's
- Reported—the specimen has been reported

CONVENIENT, IN-CONTROL PROGRAM MANAGEMENT. Get the big picture by organizing donors into specific groups and then schedule them for testing utilizing a monthly calendar. View groups scheduled for each day, the collection roster for the current date, and no-show lists.

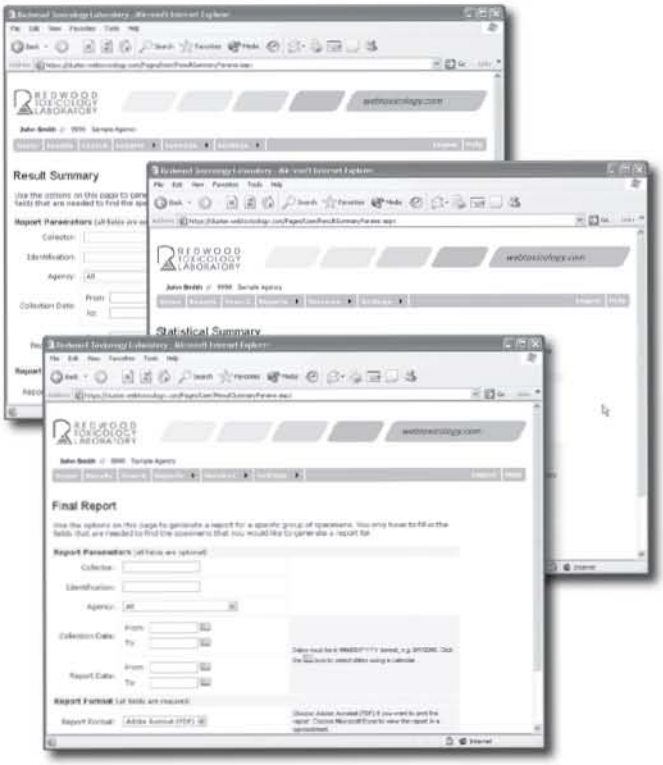


Figure 1: Result Summary, Statistical Summary, Final Report

POWERFUL, USABLE REPORTING. Generate, and within seconds, put at your fingertips a complete listing of a donor's test results, pending specimens, drug statistics, no shows and more.

TOTAL, DIGITAL DATA COLLECTION. webtoxicology.com is a complete donor data management solution that captures all the following information on each donor and stores it electronically:

- Name (First, M.I., Last)
- Sex
- Counselor/Probation Officer
- Default Test/Panel
- Status (Active/Inactive)
- Unique Identifier *(e.g. SSN, Employee ID)*
- Birth Date
- Intake Date
- Location/Agency
- Donor Group
- Special Instructions

View more information at: www.webtoxicology.com.
To request access, training or support please contact:
Information Technology Department (IT)
Phone: 800-255-2159, ext. 4311
Email: support@redwoodtoxicology.com

drug information

Included herein is specific drug information including classifications, metabolism, general abuse information and methods of analysis.

This section will assist you in understanding specific drugs of abuse and how Redwood Toxicology Laboratory's wide range of urine and oral fluid screening programs test for each drug.

Alcohol

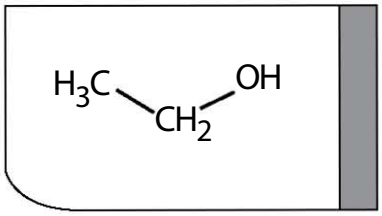
drug information

CLASSIFICATION

Common alcohols are a group of compounds whose structures include a hydroxyl group attached to a carbon chain of varying length. The number of carbons determine both the name and individual properties. The common alcohols are designated as primary, secondary, or tertiary depending on the number of carbons that are attached to the carbon bearing the hydroxyl group. Examples of primary alcohols include methanol and ethanol, which contain one and two carbons respectively. Secondary alcohols include isopropanol, a three carbon alcohol. Tertiary or four carbon alcohols include N-butanol. The information contained herein will deal primarily with ethanol, or beverage alcohol.

METABOLISM

Ethanol is a small molecule which is readily soluble in water and penetrates membranes throughout the GI tract, including the mouth, stomach and small intestine. Rate of absorption varies greatly due to factors such as type of beverage ingested, quantity of food in the stomach, frequency of gastric emptying, drinking pattern, etc. The average time to peak absorption is usually 30 to 60 minutes, but may range from 15 minutes to 3 hours. Approximately 95% of an ingested dose of ethanol is metabolized by liver enzymes, principally alcohol dehydrogenase, with the remainder eliminated unchanged in the urine, breath, sweat, and feces. Ethanol is metabolized to acetaldehyde and then to a final end product of acetic acid. Distribution of alcohol throughout the body occurs via the blood supply and since ethanol is hydrophilic (strong affinity for water), it will diffuse into body tissue or fluid compartments such as urine, saliva, plasma, etc. Since plasma or serum have a higher percentage of water by unit volume, it will have a higher ethanol concentration than whole blood. A wide range of elimination rates exists, however, ethanol is typically metabolized at approximately .015-.018 gm/dL per hour in healthy individuals. Therefore, the detection time of ethanol in body fluids is dose dependent.



ABUSE

Ethanol is the most widely consumed drug in society and is generally consumed socially. Ethanol is predominantly consumed as fermented or distilled beverages and is also a component of mouthwashes, medicinal, and industrial products. Fermented beverages such as beers and ales contain 3-6% ethanol by volume, wines contain 10-12%, and distilled spirits contain 20-60% ethanol. Acute ingestion of ethanol typically leads to progressive stages of effects depending upon the amount consumed. With low to moderate consumption, a person may initially experience mild euphoria, sociability, decreased inhibitions and the beginning of sensory-motor impairment. With increased consumption the effects can progress to emotional instability, loss of perception, memory and comprehension in addition to decreased response time and slurred speech, staggered gait and loss of muscular coordination. Finally, excessive acute ethanol consumption can lead to impaired consciousness, respiratory depression, coma and death. Chronic ethanol abuse can result in multi-organ pathological effects. These can include cirrhosis of the liver, acute and chronic gastritis, pancreatitis, cardiomyopathy and various neurological and metabolic disorders.

METHODS OF ANALYSIS

One of the most widely used techniques for detecting alcohols in urine include enzyme assay utilizing alcohol dehydrogenase. The method is very sensitive and specific in that methanol and acetone are not detected. However, longer chain alcohols such as isopropanol may be detected. This is appropriate for clinical settings, however, for forensic purposes, a secondary more definitive confirmation method is required. Gas chromatographic methods, either direct injection or headspace sampling, with the incorporation of an internal standard offer very accurate and precise quantitation of ethyl alcohol, in addition to identifying other volatile compounds such as methanol, acetone, isopropanol. Definitive identification of ethanol and accurate quantitation are required when relating a blood alcohol concentration to a particular level of impairment. This is especially critical when the blood alcohol concentration is to be used as evidence to determine whether grounds exist for presumption of impairment.

Amphetamines

drug information

CLASSIFICATION

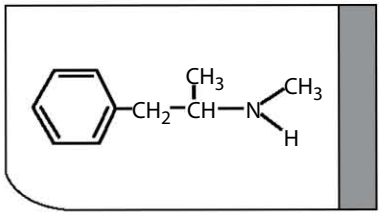
Amphetamine and methamphetamine are Schedule II drugs included in a group of chemicals called sympathomimetic amines, which contain a phenethylamine chemical nucleus. Sympathomimetic amines mimic the effects of the endogenous neurotransmitters such as epinephrine (adrenaline), norepinephrine (noradrenaline) and dopamine. Also included in this group are various over-the-counter drugs such as phenylpropanolamine, pseudoephedrine, ephedrine as well as the Schedule I drug methylenedioxymethamphetamine (MDMA or Ecstasy). The amphetamines are powerful central nervous system stimulants and can be taken orally, intravenously, snorted or smoked. Methamphetamine is one of the most commonly abused drugs in the Western United States. It is readily synthesized, with ephedrine being used as the primary precursor.

METABOLISM

Amphetamines are rapidly absorbed from the gastrointestinal tract and are either deactivated by the liver or excreted unchanged into the urine. Methamphetamine is excreted primarily unchanged (44%) and some of the drug (6%) is metabolized and excreted as amphetamine. Amphetamine is also excreted largely unchanged (30%) with 20-25% being metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. The elimination rate of amphetamines varies with the pH of the urine, as at low pH the excretion of unchanged drug increases, while at high pH the excretion of unchanged drug decreases. Within a few hours after any type of administration, amphetamines appear in the urine and can typically be detected for up to 72-96 hours.

ABUSE

Amphetamines, particularly methamphetamine, are among the most popular drugs of abuse. Common street names include speed, crank, crystal, meth, and ice. Ice and crystal meth are crystals of methamphetamine HCL. Snot and glue are oils formed from methamphetamine free base and baking soda. Methamphetamine is frequently smoked in a glass pipe as it is easily volatilized into a gas that is inhaled. Although the ice form is primarily found in Hawaii, it has gained the most notoriety mainly due to the fact that it is 98-100% pure methamphetamine HCL and its effects are rapid, intense, and of longer duration than other forms of methamphetamine.



The signs and symptoms associated with the abuse of methamphetamine depend upon the amount used and the duration of use. With infrequent or low dose use, a person may experience euphoria, lowered anxiety, talkativeness, decreased appetite, increased sexual arousal, increased alertness, and decreased fatigue. Physiologically there can be increased heart rate and blood pressure. With increased dose or prolonged abuse (either binge or chronic), an individual may experience a set of secondary effects that can include increased anxiety, irritability, aggressiveness, paranoia and hypersexuality. Physiological effects can include dilated pupils, dry mouth, hippus, increased body temperature and tachycardia. In overdose situations, a person may experience hallucinations, coma or death. Crash symptoms typically follow binge abuse of methamphetamine. This phase is marked by extreme fatigue, depression, mental exhaustion and prolonged periods of sleep.

METHODS OF ANALYSIS

Screening methods for detecting amphetamines in urine include enzyme immunoassay (EIA), radioimmunoassay (RIA), and fluorescent polarization immunoassay (FPIA) methods. All three assays detect both methamphetamine and amphetamine to varying degrees of sensitivity and specificity. However, all three assays will cross-react with several over-the-counter cold and diet preparations which indicates the importance of confirmatory testing for samples screened presumptively positive by immunoassay tests. Thin layer chromatography (TLC), gas-liquid chromatography (GLC) with nitrogen-phosphorous detection, and gas chromatography/mass spectrometry (GC/MS) all provide reliably sensitive and specific resolution as confirmatory methods.

Barbiturates

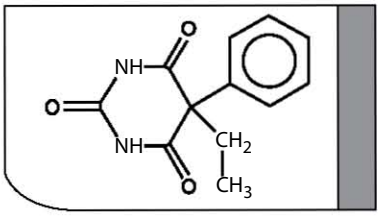
drug information

CLASSIFICATION

Barbiturates are a class of drugs capable of producing CNS depression, and depending upon the drug and dosage, may produce varying states of sedation or hypnosis and are thus classified as sedative/hypnotics. They are further categorized according to the duration of their effects, ranging from ultra-short acting, short acting, intermediate acting, and long acting. Duration of effects lasts anywhere from 15 minutes for the ultra-short acting barbiturates to a day or more for the long acting drugs. Short and intermediate acting barbiturates include amobarbital, butalbital, pentobarbital, and secobarbital, while the long acting barbiturates include phenobarbital. Other common therapeutic indications for use are as anticonvulsants and for migraine headaches.

METABOLISM

Barbiturates are distributed throughout the body with highest concentrations occurring in the brain, liver and kidneys. In general, duration of action is dependent upon lipid solubility and extent of protein binding with the short acting barbiturates showing the most lipid solubility and percentage of protein binding. The short and intermediate acting barbiturates are nearly entirely metabolized by the liver and excreted in the urine, while 25-50% of a dose of a long acting barbiturate is excreted as unchanged drug. The half-life is variable with short acting barbiturates being detectable in urine for 24 hours and the long acting drugs detectable for 2-3 weeks following ingestion.



ABUSE

The most common detected barbiturates are butalbital and phenobarbital. Butalbital is routinely prescribed for migraine and muscle relaxation while phenobarbital is primarily prescribed for seizure disorders. Trade and street names of some common barbiturates are as indicated below.

Chemical Name	Trade Name	Street Name
Amobarbital	Amytal	Yellow Jackets
Butalbital	Fiorinal	Blue Devils
Secobarbital	Seconal	Reds
Phenobarbital	Luminal	Downers, Goofballs

Chronic abuse leads to tolerance, and abrupt discontinuance of use can induce a life-threatening withdrawal syndrome that can result in seizures.

METHODS OF ANALYSIS

Immunoassays readily detect barbiturates as a class of drugs. Specific barbiturate identification can be accomplished by utilizing confirmatory methods such as thin layer chromatography (TLC), gas chromatography (GC), high pressure liquid chromatography (HPLC), and gas chromatography/mass spectrometry (GC/MS).

Benzodiazepines

drug information

CLASSIFICATION

The benzodiazepines are a class of drugs primarily classified as anti-anxiety, sedatives, or hypnotics. All contain a benzene ring fused to a 7-membered diazepine ring, hence the term benzodiazepine. Various modifications and substitutions of the ring structure yield compounds of similar activities. The clinical effects of these drugs result from actions on the central nervous system and these effects include sedation, hypnosis, muscle relaxation, and anticonvulsant activity.

METABOLISM

The benzodiazepines are well absorbed after oral administration and are rapidly distributed throughout the body. They are extensively metabolized by the liver, and in general, slowly excreted in the urine as pharmacologically inactive conjugated metabolites. Some metabolites may possess some pharmacological activity of their own, thus displaying the "next day" effects of some benzodiazepines. Oxazepam is a common urinary metabolite of several benzodiazepines such as diazepam and temazepam. Duration of detectability in urine is varied. Ingestion of therapeutic dosages may be detectable for 1-3 days while extended usage over a period of months or years can extend excretion times up to 4-6 weeks after cessation of use (depends on dosage & benzodiazepine).

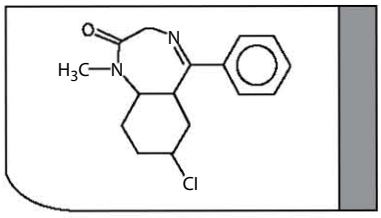
ABUSE

The benzodiazepines are considered one of the most widely prescribed drugs in the United States, thus leading to its widespread abuse. Diazepam (Valium®) and alprazolam (Xanax®) are two of the most widely abused of the benzodiazepines. Many abusers will attempt to accentuate the effects of benzodiazepines by the concomitant use of alcohol or other CNS depressant drugs. As a result, benzodiazepines are involved in approximately one third of all drug self induced poisonings. Other commonly abused benzodiazepines are chlordiazepoxide, flurazepam, clonazepam, and lorazepam. Prolonged high doses of benzodiazepines can cause dependency and a withdrawal syndrome may occur following abrupt cessation of use.

Chemical and trade names are as follows:

Chemical Name	Trade Name
Alprazolam	Xanax®
Chlordiazepoxide	Librium®
Clonazepam	Klonopin®
Clorazepate	Tranxene
Diazepam	Valium®
Flunitrazepam	Rohypnol®
Flurazepam	Dalmane®
Lorazepam	Ativan®
Midazolam	Versed®
Oxazepam	Serax®
Prazepam	Centrax®
Temazepam	Restoril®
Triazolam	Halcion®

METHODS OF ANALYSIS



There are many problems associated with a comprehensive approach to the analysis of the benzodiazepines. The benzodiazepines are a very diverse and complex group of compounds which are extensively metabolized in urine. For this reason, it is not always possible to determine the parent drug with urine testing. In addition, dosage levels and half-lifes vary substantially between the benzodiazepines which can affect the ability to detect therapeutic use of some benzodiazepines. Therefore, the analytical detection limits may preclude the detection of therapeutic use.

The most common analytical methods to screen for the presence of benzodiazepines in urine are the immunoassay methods (EIA, RIA, FPIA, etc.). The immunoassay methods are class specific in that they detect oxazepam, a common metabolite of many benzodiazepines. However, many other structurally similar benzodiazepines may also be detected.

While immunoassay cross-reactivity to non-benzodiazepine compounds is extremely rare, most immunoassay manufacturers recommend that positive results be confirmed by an alternate analytical method such as thin layer chromatography (TLC), high pressure liquid chromatography (HPLC), gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). Most routine confirmation methods are targeted to detect the group of benzodiazepines which share a common metabolic pathway and metabolize to nordiazepam and oxazepam thus making these methods class specific. However, common benzodiazepines such as alprazolam (Xanax®), lorazepam (Ativan®), and clonazepam (Klonopin®) do not share this metabolic pathway and must be confirmed by specific techniques, such as GC, GC/MS or LC/MS/MS. It is essential to understand the advantages and limitations of the various laboratory analytical methods to ensure proper detection of benzodiazepines. If a case history indicates the use of a particular benzodiazepine, then a method must be chosen which will have the necessary sensitivity and specificity to identify the drug of interest.

Buprenorphine

drug information

CLASSIFICATION

Buprenorphine (Suboxone, Subutex) is a semi-synthetic thebaine derivative that has both analgesic and opioid antagonist properties. As an analgesic, buprenorphine is approximately 25 to 40 times more potent than morphine and as an opioid antagonist it is roughly equivalent to naltrexone. Buprenorphine is prescribed in the hydrochloride form and therapeutic dosages range from 0.3 - 0.6 mg when given parenterally, or 0.2 - 0.4 mg sublingually, every 6 - 8 hours. The use of larger daily doses (2 - 16 mg daily) have been used successfully for the treatment of opiate withdrawal or maintenance. Overdose symptoms include confusion, dizziness, pinpoint pupils, hallucinations, hypotension, respiratory difficulty, seizures and coma. Fatalities due to buprenorphine overdosage alone and by poly-drug use have been reported.

METABOLISM

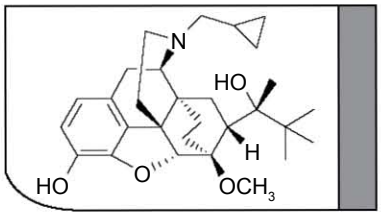
Buprenorphine is rapidly metabolized in the liver by the cytochrome P450 system to form a pharmacologically active N-dealkylated metabolite, norbuprenorphine and glucuronide conjugates. Buprenorphine and norbuprenorphine are excreted in urine almost exclusively as glucuronides with very little free drug being detected. Studies indicate that concentration of free buprenorphine and norbuprenorphine in urine can be less than 1 ng/mL following therapeutic administration, but can range up to 20 ng/mL in abuse situations. Total buprenorphine and norbuprenorphine concentrations in urine, ranging from 0.5 - 2936 ng/mL and 4.0 - 4462 ng/mL respectively, have been reported following daily doses between 0.2 - 24 mg. The corresponding median norbuprenorphine to buprenorphine ratio was 0.23. However, there is significant inter- and intra-individual variability in the ratio because the elimination kinetics of norbuprenorphine are slower; therefore, the ratio is greatly influenced by dosage and sample time. Approximately 95% of a labeled dose is excreted within 144 hours, 68% in the feces and 27% in the urine.

ABUSE

Like methadone when buprenorphine is taken by an individual who is addicted to heroin or other opioid, buprenorphine reduces craving and helps the person remain drug-free. Because of its opioid effects, buprenorphine can also be abused, particularly by individuals who are not physically dependent on opioids.

Compared with methadone, buprenorphine has a relatively lower risk of abuse, dependence, and side effects, and it has a longer duration of action. Because buprenorphine is a partial opioid agonist, its opioid effects, such as euphoria and respiratory depression, as well as its side effects, reach a ceiling of maximum effect, unlike with methadone or heroin. For this reason, buprenorphine may be safer than methadone, as long as it is not combined with sedatives such as tranquilizers or alcohol. The side effects of buprenorphine are similar to those of other opioids and may include nausea, vomiting, and constipation. Both buprenorphine and buprenorphine with naloxone can result in the opioid withdrawal syndrome if used by people on high doses of other opioids. Symptoms of opioid withdrawal can include: dysphoria, nausea and vomiting, muscle aches and cramps, sweating, tearing, diarrhea, mild fever, running nose, insomnia, and irritability.

METHODS OF ANALYSIS



Enzyme immunoassay is used as a screening method for the detection of buprenorphine. The method has a screening cutoff of 5 ng/mL and has equal cross reactivity to norbuprenorphine, the primary urinary metabolite of buprenorphine. Confirmation of screened positive urines is performed by GC/MS. A direct method for the detection and quantitation of buprenorphine and norbuprenorphine in urine using solid-phase extraction, deuterated internal standards and silyl-derivatization followed by GC/MS SIM analysis was developed and validated. Accuracy of the method is in excess of 99% at three different concentrations with an overall precision of less than 5% for both compounds. Linearity of the method is 0.5 to 20 ng/mL and 0.5 to 50 ng/mL for buprenorphine and norbuprenorphine respectively. Limits of detection for the method are 0.5 ng/mL for buprenorphine and 1.0 ng/mL for norbuprenorphine.

Cocaine

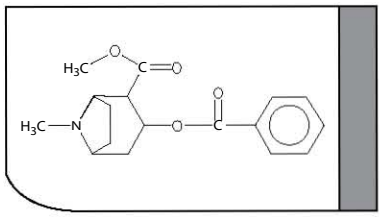
drug information

CLASSIFICATION

Cocaine (benzoylmethylecgonine) is a central nervous system stimulant derived from the leaves of the coca plant. Cocaine has two major pharmacological actions; one is a local anesthetic, and the other is an indirect acting sympathomimetic having many of the properties of an amphetamine. The drug is either in the salt/powder form (cocaine HCL) which can be administered by snorting or intravenous injection or in the free base "crack" form which is smoked.

METABOLISM

After smoking, cocaine is rapidly absorbed with peak plasma concentrations occurring at about 5 minutes, versus 30-40 minutes following intranasal ingestion. Cocaine is extensively metabolized by the liver and blood enzymes with approximately one percent of the dose excreted in the urine unchanged. The major metabolite found in the urine is benzoylecgonine (25-40% of the dose), followed by ecgonine methyl ester (18-22%). Depending upon the dosage ingested, frequency of use, and metabolic variation, benzoylecgonine can remain detectable in the urine for as long as 48-96 hours post ingestion.



ABUSE

Cocaine produces a short-lived, intense high which is extremely addictive. The signs and symptoms associated with the abuse of cocaine depend upon the amount used and the duration of use. With infrequent or low dose use a person may experience euphoria, lowered anxiety, talkativeness, decreased appetite, increased sexual arousal, increased alertness, and decreased fatigue. Physiologically there can be increased heart rate and blood pressure.

With increased dose or prolonged abuse (either binge or chronic) an individual may experience a set of secondary effects that can include increased anxiety, irritability, aggressiveness, paranoia and hypersexuality. Physiological effects can include dilated pupils, dry mouth, hippus, increased body temperature and tachycardia. In overdose situations, a person my experience hallucinations, coma or death. Crash symptoms typically follow binge abuse of cocaine. This phase is marked by extreme fatigue, depression, mental exhaustion and prolonged periods of sleep.

METHODS OF ANALYSIS

The immunoassay methods (EIA, RIA, FPIA) are widely used screening methods designed to specifically detect benzoylecgonine and to lesser extents, cocaine and ecgonine methyl ester (secondary cocaine metabolite). Commonly used confirmation methods include thin layer chromatography (TLC), high pressure liquid chromatography (HPLC), gas chromatography (GC), and gas chromatography/mass spectrometry (GC/MS). GC/MS methods offer excellent sensitivity and specificity and are the methods of choice for the confirmation of the immunoassay positive screens.

Diuretics

drug information

CLASSIFICATION

Diuretics elevate the rate of bodily urine excretion (diuresis). All diuretics increase the excretion of water from the body, although each class of diuretics does so in a distinct way employing different mechanisms of action. In medicine, diuretics are used to treat heart failure, liver cirrhosis, hypertension and certain kidney diseases. Side effects include dehydration, hypotension, disturbed electrolyte balance, muscle cramps and weakness.

Diuretics are prescription drugs with relatively low potential for abuse among the general population. They are not classified as Controlled Substances in the United States. There are several categories of diuretics:

- High ceiling loop diuretics such as furosemide, bumethanide and ethacrynic acid may cause substantial diuresis. They inhibit the body's ability to reabsorb sodium in the kidney which leads to retention of water in the urine as water normally follows sodium back into the extracellular fluid.
- Thiazides such as hydrochlorothiazide, cause moderate diuresis. They act as carbonic anhydrase inhibitors with the major site of action in the renal distal tube. They enhance excretion of sodium, potassium, calcium and chlorine ions.
- Potassium sparing diuretics such as amiloride, triamterene and spironolactone do not promote the secretion of potassium into the urine; thus potassium is spared and not lost as much as in other diuretics.
- Osmotic diuretics like mannitol, glucose and other sugars are filtered in the kidneys, but cannot be reabsorbed leading to elevated water elimination with urine.
- Low ceiling diuretics—the term is used to indicate a pharmacological profile with rapidly flattening dose effect curve (in contrast to "high ceiling", where the relationship is close to linear). The thiazides usually fall into this category.

METABOLISM

Most diuretics are excreted in urine with minimal metabolites. A few exceptions include spironolactone metabolizing into canrenone and canrenoic acid; and triamterene, which in the body undergoes conversion to hydroxytriamterene sulfate.

ABUSE

Diuretics are sometimes abused by people with eating disorders for weight loss. Use of diuretics in sports is prohibited. Increased urine flow would reduce concentrations of banned performance enhancing substances in urine such as anabolic steroids, thus complicating their detection in doping control (masking). In sports where weight categories are involved diuretics are abused as weight reducing agents. Diuretic abuse in sports is unethical and dangerous for athlete health (dehydration). Diuretic testing is a part of routine doping control in sports.

METHODS OF ANALYSIS

Methylation and gas chromatography/mass spectrometry have been traditionally used for diuretic screening and confirmation in athletic doping control. In recent years, liquid chromatography/mass spectrometry has been successfully applied for direct analysis of unextracted urine.

Fentanyl

drug information

CLASSIFICATION

Fentanyl (Duragesic, Sublimaze, "China White") is an extremely fast-acting synthetic narcotic analgesic, of high potency (approximately 100 – 200 times that of morphine) and short duration of action. There are several analogues and derivatives of fentanyl which are also abused, and may have higher potencies. Pharmaceutical fentanyl has been available since 1963 as an anaesthetic supplement, and is available as a citrate salt for I.V or I.M injection. Transdermal patches are also available for management of chronic pain or for breakthrough cancer pain. Fentanyl abuse among healthcare workers has become popular due to the drugs euphoric effects and easy availability. Due to the lipophilicity of the drug, fentanyl rapidly crosses the blood-brain barrier, producing fast and pronounced CNS effect, such as a heightened euphoria and respiratory depression, and possible toxic effects which include muscle rigidity, seizures, coma, and hypotension. Fentanyl also has similar tolerance and physical dependence properties to those of morphine.

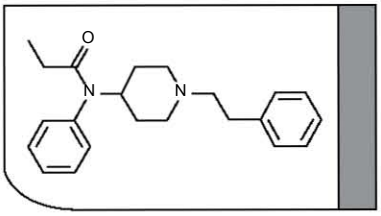
METABOLISM

Fentanyl is rapidly metabolized by the liver to the inactive metabolites, norfentanyl, hydroxyfentanyl, and hydroxynorfentanyl. Approximately 85% of an intravenous dose is excreted in urine over a 3 – 4 day period, with 0.4 – 6% of the drug excreted unchanged, 26 – 55% excreted as norfentanyl, and unknown amounts of hydroxyfentanyl, and hydroxynorfentanyl excreted.

Fentanyl is administered I.V. or I.M. at single dosage levels of 25 – 100 µg as needed, transdermally at dosages of 25 – 100 µg/hr for 72 hours for chronic pain management, or by oral transmucosal dosages of 200 – 1600 µg for breakthrough cancer pain. Following a single 50 – 100 µg fentanyl dose, fentanyl was detected in the urine of 3 of 7 patients for 24 hours. Urine fentanyl concentrations ranged from 89 – 449 ng/mL in 4 adults who died following the excessive use of transdermal fentanyl. In another series of 7 adult deaths, fentanyl concentrations ranging from 5.0 – 93 ng/mL were found following self-administered intravenous injections.

ABUSE

Illicit fentanyl which appears on the street in the U.S., is principally in the form of the transdermal patches, which can be cut up and eaten, or the gel can be extracted from the patches and smoked or injected by addicts. Illicitly synthesized fentanyl powder manufactured in Mexico has appeared in the U.S. recently, and may be abused by itself or mixed with heroin or cocaine, which have resulted in several deaths.



METHOD OF ANALYSIS

Redwood Toxicology Laboratory has developed and validated a direct method for the detection of fentanyl in urine using liquid-liquid extraction, deuterated internal standards, and GC/MS SIM detection. Accuracy of the method is in excess of 99.5% at 3 different concentrations with an overall precision of <5.0%. Linearity of the method is 5-10,000 ng/mL with a limit of detection of 5ng/mL.

Gamma-hydroxybutyric Acid (GHB)

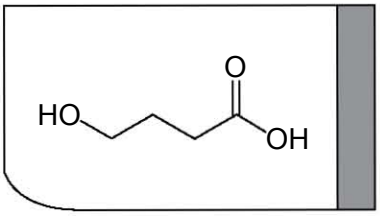
drug information

CLASSIFICATION

GHB was first developed as an anesthetic, but was discontinued for this use due to its adverse and unpredictable effects. However, GHB is readily available and used in Europe as a sedative. The salt form of GHB has been marketed in gymnasiums and health food stores for the past few years as a steroid alternative for body-building and as a tryptophan replacement for sedation. There have also been increasing reports of GHB being used recreationally as a euphoriant at "rave" type parties. As typically follows, there have also been reports of GHB being associated with sexual assault or as a "date rape" drug due to its severe hypnotic and sedative effect at higher dosages.

METABOLISM

GHB is thought to be extensively metabolized by alcohol dehydrogenase and/or succinic semialdehyde dehydrogenase. Metabolic precursors to GHB, gamma-butyrolactone (GBL) and 1,4 butanediol are also readily available as substances of abuse. Endogenous GHB is also a product of GABA metabolism, and concentrations of 0 – 6.6 mg/L have been reported. Oral doses of approximately 2.5 g (I teaspoon of GHB powder) dissolved in water, produced urine GHB concentrations of 29 mg/L in a 100 kg man. Studies also indicate peak urine GHB concentrations of 100 mg/L following a 100 mg/kg oral dose, and no detectable drug in the urine by 12 hours. Less than 5% of an oral dose is eliminated unchanged in urine. To distinguish between endogenous and exogenous GHB, a reporting cutoff of 10 µg/mL is suggested.



ABUSE

Typical illicit use of GHB involves dissolving 2 – 3 grams of powder in water or other beverages. Onset of effects occur within 10 – 30 minutes of ingestion and include euphoria, increased libido, drowsiness, reduced inhibitions, dizziness, nausea and may persist for 2 - 5 hours. Toxic effects include hypotension, respiratory depression, seizure, unconsciousness, and coma. Deaths have been reported when GHB is used alone or in conjunction with ethanol, heroin, or ketamine. The California Department of Health Services and the Food and Drug Administration (FDA) banned over-the-counter sales of GHB in 1990 and GHB is currently classified as Schedule I by the federal Controlled Substances Act.

METHOD OF ANALYSIS

A simple method for the direct analysis of gamma-hydroxybutyrate (GHB) uses liquid–liquid extraction, and silyl-derivatization, then gas chromatographic–mass spectrometric analysis using a GHB deuterated internal standard. The method is linear from 5 to 1000 ug/mL, and coefficients of variation are less than 5%. Compared with existing methods, the method described here is superior because it is specific to GHB without conversion to gamma-butyrolactone (GBL).

Marijuana (THC)

drug information

CLASSIFICATION

Marijuana is a preparation derived from the leaves and flowering tops of cannabis plants (Cannabis sativa) that is capable of producing psychoactive effects when ingested. One of the primary classes of compounds found in marijuana is called cannabinoids. There are up to 60 cannabinoids in marijuana with delta-9-tetrahydrocannabinol (THC) being the primary psychoactive constituent.

METABOLISM

When marijuana is smoked, THC is rapidly absorbed through the lungs and enters the bloodstream in minutes. Following oral ingestion, THC does not reach the bloodstream for approximately 1.5-3 hours. Once in the blood, THC is bound to blood proteins and carried throughout the body where it is either absorbed into body tissues (including the brain, heart, and fat) or transformed by the liver into the water soluble metabolites 11-hydroxy-THC and carboxy-THC. These water soluble metabolites, are readily excreted into the urine, with the inactive metabolite carboxy-THC being the predominant metabolite detected. Initially, THC is quickly absorbed into the body tissues and then is slowly released back into the blood stream where it is carried to the liver and metabolized. Because THC tends to be stored in fatty tissues, it accumulates faster than it can be eliminated in chronic repetitive smokers. This leads to extended retention of THC which is then eliminated from the body at a relatively constant rate with an average elimination half-life being estimated at 18-30 hours. Urinary concentrations of THC are very difficult to interpret due to variables such as dosage of THC ingested, frequency of use, timing of urine collection relative to last exposure to marijuana, rate of release of stored cannabinoids in adipose tissue, and an individual's hydration state. Therefore, the detection of THC metabolites in the urine is only an indication of past marijuana use and is not related to the degree of intoxication or impairment.

ABUSE

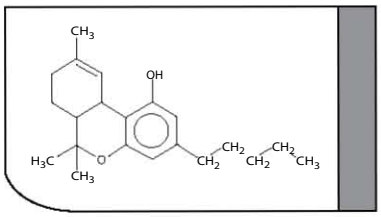
The psychological effects of THC include an increased sense of well being or euphoria, relaxation, slowed psycho-motor response, an altered sense of time, short term memory impairment and impairment of multi-tasking performance.

THC Retention Time

- Infrequent (less than twice/week) Smoking: When screening assays of 50 ng/mL or greater are used, urine samples will generally be positive for 1-3 days.
- Regular (several times per week) Smoking: May result in urine specimens testing positive for 7-21 days.
- Chronic (daily) Smoking: An individual who smokes marijuana daily for prolonged periods of time can test positive for 30 days or longer.
- Oral Ingestion: Metabolic profiles in urine samples cannot generally differentiate between marijuana ingested orally versus marijuana ingested by smoking. However, oral ingestion requires approximately three times more THC than smoking to produce similar effects or "highs"; therefore, visual detection of the marijuana in the ingested item would seem reasonable, thus ruling out unknown consumption. Retention time of orally ingested marijuana ranges from 1-5 days.
- Passive Inhalation: In general, routine passive exposure to marijuana smoke will not result in a positive result for cannabinoids in excess of a 50 ng/mL screening cut-off.

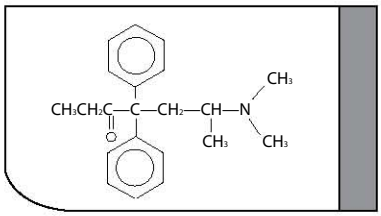
METHODS OF ANALYSIS

The most common analytical methods used to detect cannabinoids in urine include immunoassays (EIA, RIA, and FPIA), gas chromatography (GC), gas chromatography/mass spectrometry (GC/MS), high pressure liquid chromatography (HPLC), and thin layer chromatography (TLC). Urine cannabinoid immunoassays are usually optimized for the detection of carboxy-THC, but also react with other cannabinoids present in the urine. Because of this cross-reactivity, immunoassay results are expressed in terms of "total cannabinoids" and not specifically in terms of carboxy-THC concentration as is detected by GC/MS. Therefore, when interpreting THC concentrations, it is important to realize that GC/MS, which measures only carboxy-THC, generally yields quantitative results which may represent only 10-50% of the "total cannabinoid" value as detected by immunoassays. While immunoassay cross-reactivity to non-cannabinoid compounds is extremely rare, most immunoassay manufacturers recommend that positive results be confirmed by an alternate analytical method. The chromatographic methods meet this requirement, with GC/MS considered the most reliable method. Other methodologies such as TLC and HPLC also achieve good sensitivity and specificity.



Methadone

drug information



CLASSIFICATION

Methadone is a narcotic analgesic which is approximately equipotent to that of morphine. Methadone has been utilized to treat opioid dependency and prescribed as a heroin substitute in methadone maintenance programs since the 1960's Typically, daily oral dosing with doses up to 180 mg/day, is prescribed with efficacy measured by the absence of withdrawl symptoms. Dosing is then gradually decreased until opiate dependency is eliminated.

METABOLISM

Methadone is metabolized primarily to two pharmacologically inactive metabolites, EDDP and EMDP. Monitoring for the presence of EDDP (methadone metabolite) is a means to determine compliance to methadone treatment. The elimination half-life of methadone is approximately 15-55 hours with about 5-50% of a dose eliminated as methadone and 3-25% as EDDP. Large individual variations in elimination do occur due to urine pH, urine volume, dose, rate of metabolism, drug interation, etc.

METHODS OF ANALYSIS

Detection Limits

Chemical Name	Trade Name	Results Reported EIA	Results Reported TLC	Detection Limits (mcg/mL) EIA	TLC	GC/MS
Methadone	Dolophine	+	+	0.15	<0.5	0.1
Methadone Metabolite		+	+	0.15	0.5	0.1
Levomethadyl (LAAM)	ORLAAM	+ -	-	*	N/A	N/A

*The EIA method for methadone will detect LAAM at high concentrations. LAAM is quickly metabolized, therefore parent LAAM will not always be detected.

Interpretation of Results

Result Reported: *Methadone*	Result Reported: *Methadone Metabolism*	Interpretation
+	+	Methadone was ingested due to presence of metabolite.
-	+	Methadone ingested due to presence of metabolite; Parent methadone below testing detection limit.
+	-	Methadone ingested and metabolite below detection limit; or if creatinine is 0.0 (water) then methadone, was poured directly into urine; or if creatinine is present then methadone may have been poured into an alternate urine specimen.
-	-	Methadone was not ingested; or methadone and methadone metabolite were below the detection limit. GCMS can be utilized to increase sensitivity.

NOTE: Some individuals metabolize methadone at increased rates and may test negative for both methadone and methadone metabolite.

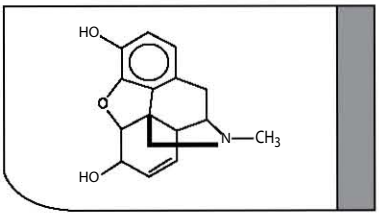
Opiates

drug information

CLASSIFICATION

The term "opioid" refers to all drugs, natural or synthetic, with morphine-like properties. Both morphine and codeine are naturally occurring alkaloids derived from the seed pod of the opium poppy. Semi-synthetic opiates include heroin, a diacetyl derivative of morphine; hydromorphone, hydrocodone, and oxycodone derived by a simple modification of the morphine molecule. Synthetic opiates such as methadone and meperidine, mimic opiate effects but are not prepared from the poppy. The drugs may be administered by snorting, subcutaneous or intravenous injection, or smoking. Opioid compounds have analgesic and antitussive properties.

METABOLISM



Morphine is rapidly absorbed. Plasma peak levels following an oral dose occur after 15-60 minutes, and following IV injection occur after 15 minutes. Extensively metabolized by the liver, only 2-12% is excreted as unchanged drug, while 60-80% is excreted as morphine-3-glucuronide. The half-life of morphine is 1.7-4.5 hours. Heroin is rapidly metabolized (plasma half-life is 3 minutes), first to 6-monoacetylmorphine (6-MAM) and further to morphine. The urinary excretion profile is similar to morphine, in that 7% is excreted as unchanged morphine and 50-60% as glucuronides. Trace amounts of 6-MAM, a specific metabolite of heroin, are also excreted for approximately 6-8 hours following heroin use. Following an oral dose, codeine is also rapidly absorbed and metabolized, principally to codeine-6-glucuronide, with 10-15% metabolized to morphine and norcodeine. Opiates may be detected in urine for 2-4 days following ingestion.

The interpretation of results for urines positive for opiates merit special consideration. Since codeine is metabolized to morphine, both substances may appear in the urine following codeine ingestion. However, the codeine concentration is generally greater than that of morphine. Street heroin also contains acetylcodeine, which metabolizes to codeine, therefore, both codeine and morphine may be present in the urine of some heroin users, although morphine generally predominates. In cases of low morphine and codeine concentrations in urine, it is not possible to determine whether codeine, morphine, or heroin were ingested. The presence of morphine alone would generally indicate either clinical morphine use or illicit morphine or heroin use. A specific metabolite of heroin, 6-monoacetylmorphine, is also at times detected and would definitely confirm illicit drug (heroin) use. Poppy seeds, which have not been effectively washed, contain trace amounts of codeine and morphine. When consumed in sufficient amounts, poppy seeds may produce urines which test positive for opiates.

ABUSE

Opioid compounds have effects on the CNS and usually on the bowel. They produce analgesia, respiratory depression, euphoria, mood changes, confusion, and constipation. Tolerance and dependence develop with repeated use, with overdose being characterized by coma, respiratory depression, and pinpoint pupils. Discontinuing the drug in a dependent individual will precipitate a withdrawal syndrome. Heroin and morphine are the most commonly abused opioid compounds; however codeine, propoxyphene, oxycodone, hydrocodone, etc. are also extensively abused, as they are more readily available. Most heroin and morphine abusers inject or "mainline" the drugs intravenously, as this produces the most immediate and intense effects. The heroin or morphine "rush" is the most desired sensation which is characterized by an intense orgasmic sensation centered in the abdomen.

METHODS OF ANALYSIS

The immunoassay methods (EIA, RIA, FPIA) detect codeine and morphine in free and conjugated forms at cut-off levels of approximately 300/2000ng/mL or less. Other opioids detected by immunoassay at higher cut-off levels are hydrocodone, hydromorphone, while the routine detection of oxycodone requires a more sensitive and specific immunoassay screen. Since the immunoassays do not distinguish between the various narcotics, a confirmation method is required that can specifically identify these compounds. Methods commonly used include thin layer chromatography (TLC), high-pressure liquid chromatography (HPLC), gas chromatography (GC) or gas chromatography/mass spectrometry (GC/MS). These methods determine the total form of morphine and codeine, and since 90% of these compounds are conjugated in the urine, acid or enzyme hydrolysis is required to convert the conjugated form into the free form. Individual immunoassays are also available for propoxyphene and methadone and can be confirmed by the same methodologies listed above.

Oxycodone

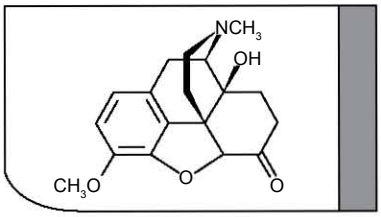
drug information

CLASSIFICATION

Oxycontin® is the trade name of one of numerous Schedule II prescription drugs that contain the opioid oxycodone as the active ingredient. Opioids refer to a class of drugs, natural and synthetic, with morphine-like actions. Oxycodone is reported to have equivalent potency to that of morphine. Other prescription drugs that contain oxycodone include Percodan® and Percocet®. Schedule II drugs are those which are approved for medical use and have a high potential for abuse and may lead to severe physical and psychological dependence. Oxycontin® was first introduced by Purdue Pharma in 1996 as a controlled sustained release formulation for pain relief. It was estimated that almost 6 million prescriptions for Oxycontin® were filled in the year 2000 and sales reached 1 billion dollars. It is legitimately prescribed for moderate to severe chronic or long-lasting pain. Oxycontin® is available in tablet forms containing 10, 20, 40, and 80 mg. A 160 mg oxycodone tablet was available which was discontinued in May 2001. By comparison, Percocet® typically contains 5 mg of oxycodone. Thus, one 160 mg tablet of Oxycontin® contained the equivalent amount of oxycodone as 32 Percocet® (5 mg) tablets.

One of the primary benefits of Oxycontin® is that because it is controlled release, it only needs to be taken orally every 12 hours. In contrast, short acting oxycodone tablets like Percocet® require the dosage be taken every 4-6 hours to maintain pain relief. Thus, the controlled release formulation allows for continuous pain relief for a substantial period of time when compared to traditional Percodan® or Percocet® tablets.

METABOLISM



A large portion of oxycodone is N-dealkylated to noroxycodone during first-pass metabolism. Oxymorphone, is formed by the O-demethylation of oxycodone. The metabolism of oxycodone to oxymorphone is catalyzed by CYP2D6. Free and conjugated noroxycodone, free and conjugated oxycodone, and oxymorphone are excreted in human urine following a single oral dose of oxycodone. Approximately 8% to 14% of the dose is excreted as free oxycodone over 24 hours after administration. Following a single, oral dose of oxycodone, the mean ± SD elimination half-life is 3.51 ± 1.43 hours.

ABUSE

The attraction of Oxycontin® as a preferred drug of abuse over other oxycodone containing products has several reasons. The large amounts of oxycodone per tablet versus Percodan® or Percocet® are one of the primary reasons, while a second factor is that Percodan® and Percocet® additionally contain 325 mg of aspirin or up to 650 mg of acetaminophen, respectively while Oxycontin® has neither. Thus, the oxycodone high will not be associated with any toxic side effects that may result from either excessive aspirin or acetaminophen. Oxycontin® tablets are to be taken whole to allow for the controlled release of oxycodone. Abusers will destroy the controlled release capabilities of Oxycontin® by either chewing the tablets prior to swallowing, crushing the tablets and snorting the powder or they may be crushed, dissolved in water and injected. This allows for a rapid and large absorption of oxycodone into the blood stream producing a powerful euphoric high. This rapid, bolus absorption is also thought to be responsible for an apparent increase in oxycodone related overdoses in the east. Several Oxycontin® street slang's include "OC", "OXY", "Oxy-Coffins", Hillbilly Heroin, Poor-Mans Heroin and Killers. Diversion of the prescription has also been a problem associated with Oxycontin®. It has been reported that while a single 160 mg tablet may retail for up to $14, it can fetch up to $1 per mg on the street. Thus, a 160 mg tablet, known as a "blue bomber", may sell for up to $160 with its illicit sale. Interestingly, Oxycontin® is sometimes referred to as poorman's heroin. We recently encountered a case in California in which a parolee who was being prescribed Oxycontin® was suspected of diverting his prescription to purchase heroin. Specific analysis of his urine determined no detectable level of oxycodone but the primary heroin metabolite, morphine, was present in his urine in excess of 2,000 ng/mL. Thus, offering scientific support to the diversion suspicion.

METHODS OF ANALYSIS

Typically oxycodone does not produce a positive response to routine immunoassay screens for opiates, which generally target morphine and/or codeine; therefore, Redwood Toxicology Laboratory utilizes an enzyme immunoassay screening method which specifically targets oxycodone at a cutoff of 300 ng/mL. Confirmation of presumptive positive urines is performed by LC/MS/MS. A direct method for detection and quantitation of oxycodone in urine using liquid-liquid extraction, deuterated internal standard and derivatization followed by LC/MS/MS analysis was developed and validated. Accuracy of the method is in excess of 99% at three different concentrations, with an overall precision of 1.2%. Linearity of the method is 100-4000 ng/mL, with a limit of detection of 50ng/mL.

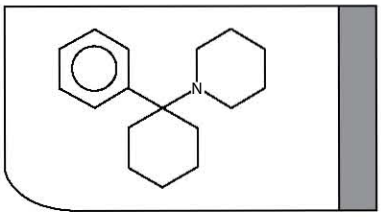
Phencyclidine (PCP)

drug information

CLASSIFICATION

Phencyclidine (l-phencyclohexylpiperidine, PCP) is prepared from l-piperidinocyclohexane-carbonitrile in a Grignard reaction, as first performed in 1956 for use as an intravenous anesthetic. Pharmacologically PCP is classified as a dissociative anesthetic. PCP is currently a popular drug of abuse and was once used as a veterinary tranquilizer. A structural analog, ketamine, is currently used as a veterinary tranquilizer. PCP is self-administered either by smoking (drug-laced tobacco, marijuana, or parsley), by nasal insufflation and intravenous injection, or by oral ingestion.

METABOLISM



PCP is a lipophilic drug with a large volume of distribution. It undergoes extensive hepatic oxidative metabolism with about 10-15% of a dose excreted unchanged in urine, and about 65% excreted as hydroxylated metabolites and other polar metabolites. Renal excretion of PCP (pKa 8.5) is enhanced when urine is acidic, and it is reduced when urine is alkaline. Frequent or chronic PCP users may excrete PCP for 2-10+ days following last use. Urine concentrations may range from <0.1 mcg/mL to 340 mcg/mL.

ABUSE

Phencyclidine's pharmacological actions are complex, since it interacts with several neurotransmitter systems (i.e., GABAergic, dopaminergic, cholinergic, and adrenergic). As a result, PCP has stimulant, depressant, hallucinogenic, and analgesic properties. Adverse effects are unpredictable and include agitation, delusions of grandeur, anxiety, hostility, stupor, paranoia, and coma. Death has been known to result following the ingestion of 120 mg of PCP (toxic dose 10-20 mg).

METHODS OF ANALYSIS

The immunoassay methods (EIA, RIA, FPIA) are widely used screening methods designed to specifically detect phencyclidine and its inactive metabolites. Commonly used confirmation methods include thin layer chromatography (TLC), gas chromatography with nitrogen phosphorous detection, and gas chromatography/mass spectrometry (GC/MS). GC/MS methods offer excellent sensitivity and specificity and is the method of choice for most forensic applications. False positive immunoassays have been reported following the use of thioridazine (Mellaril), chlorpromazine (Thorazine), dextromethorphan, or diphenhydramine (Benadryl), therefore indicating the necessity for specific secondary confirmation testing.

Steroids

drug information

CLASSIFICATION

A steroid is a terpenoid lipid characterized by a carbon skeleton with four fused rings, generally arranged in a 6-6-6-5 fashion.

Steroids vary by the functional groups attached to these rings and the oxidation state of the rings. Hundreds of distinct steroids are found in plants, animals, and fungi. Many more have been produced as synthetic drugs.

Three steroid classes found in human body belong to a subset of the sex hormones that produce sex differences and control reproduction. They include androgens, estrogens, and progestagens.

- Androgens (androgenic-anabolic steroids) are a class of steroids responsible for the development and maintenance of male sexual characteristics. Androgens interact with androgen receptors to increase muscle and bone synthesis exhibiting their anabolic performance enhancing effect. There are natural and synthetic anabolic steroids available. Testosterone is a principal androgenic-anabolic steroid in the body. In popular language the word "steroids" usually refers to anabolic steroids.
- Estrogens are involved in female reproductive function.
- Progestagens serve as protectors of pregnancy.
- Corticosteroids include glucocorticoids and mineralocorticoids. Glucocorticoids regulate many aspects of metabolism and immune function, whereas mineralocorticoids help maintain blood volume and control renal excretion of electrolytes.
- Cholesterol is a major source for the synthesis all other steroid hormones in the body.

METABOLISM

In the body testosterone and its synthetic analogs are bio-transformed into more polar compounds, metabolites. Enzymatically catalyzed reduction, oxidation, hydroxylation and isomerization are the major metabolic reactions. Consequent conjugation with glucuronic acid or sulfate facilitates ultimate elimination of steroid metabolites from the body with urine.

ABUSE

Androgenic-anabolic steroids (AAS) have limited medical use, but are abused as performance enhancing drugs in sports and more recently in some professional areas, where strong muscular appearance is important. In the general population, especially among adolescents and young adults, AAS are abused as a cosmetic tool helping to improve physique.

AAS have been classified as Schedule III Controlled Substances in the United States since 1991. Side effects include suppression of endogenous hormone production, gynecomastia (female type breast growth in males), acne, liver toxicity, mood swings, aggression, infertility and masculinization in females: deepening of the voice and male type hair growth.

T/E RATIO

Testosterone and its precursors may be endogenous (produced in the body naturally) or exogenous (ingested as drugs or supplements). The T/E ratio is used to distinguish between the two. This ratio is a urine concentration ratio of two steroids, testosterone (T) and its natural isomer, epitestosterone (E). The normal average ratio is approximately 1, with individual variation on both sides, either higher or lower.

Ingestion of exogenous testosterone or its precursors suppresses internal steroid production in the body. Both endogenous T and E would be suppressed. However, total testosterone concentration in urine will rise above normal due to ingested drug. Low E and high T cause the T/E ratio to rise above 6 (cut-off), indicating testosterone abuse.

METHODS OF ANALYSIS

RTL utilizes the most sophisticated, sensitive, and specific equipment and technology available. RTL performs a fast, efficient and sensitive GC/MS steroid screen, capable of detecting 85 endogenous and exogenous compounds providing information about naturally occurring and synthetic steroids and metabolites. The RTL Steroid/Sports Drug Test includes specific GC/MS confirmation methods for each individual drug.

Accurate quantification is performed for nandrolone and testosterone with cut-off levels of 2 ng/mL (nandrolone metabolite) and testosterone to epitestosteroine ratio above 6 (T/E > 6).

Stimulants

drug information

CLASSIFICATION

Stimulants are psychoactive drugs that induce temporary improvements in mental and/or physical function. The effects of stimulants include enhanced alertness, wakefulness, endurance, productivity and motivation; increased arousal, locomotion, heart rate/blood pressure; and a perception of a diminished requirement for sleep. Symptoms of excessive stimulation of the central nervous system (CNS) include restlessness, difficulty sleeping, tremor, headaches and even psychotic episodes. Loss of appetite (anorexia) and weight loss also occur with CNS.

Most stimulants are classified as Controlled Substances (CS) in the United States. Designer drugs like MDMA (ecstasy), which have no medical use, are classified as Schedule I CS; the others belong to Schedule II – IV substances. There are several categories of stimulants possessing different chemical structures and employing different pharmacological mechanisms:

- *Amphetamine, Methamphetamine,* their precursors and structurally related designer drugs represent a broad range of classic stimulant agents.
- *Cocaine* is the most potent of naturally-occurring stimulants. It is commonly abused and a highly addictive drug.
- *Piperazines,* such as benzylpiperazine and trifluoromethylpiperazine, possess stimulant and hallucinogenic activity. They became especially popular worldwide as party drugs in the recent years.
- *Eugeroics,* like adrtafinil and modafinil, are prescribed for the treatment of narcolepsy (excessive daytime sleepiness). They were abused as "wakefulness promoting agents" and as CNS stimulants in sports.
- *Methylxanthines,* such as caffeine, are found in tea, coffee and "energy" drinks. They are also potent stimulants. However, their use is widely accepted in the society.
- *Nicotine* in tobacco products is also a stimulant, which is not currently banned.
- *Other Stimulants*—this is a broad group of Controlled Substances with different chemical structures and common CNS pharmacological effects. Many of them, like fenfluramine and phentermine, were originally designed as weight loss drugs. They are no longer used due to severe side effects.

METABOLISM

Most stimulants are excreted in urine unchanged with only minor metabolites. Numerous precursor drugs metabolize extensively into active amphetamine and methamphetamine. Cocaine is rapidly inactivated in the body and excreted with urine fully metabolized.

ABUSE

Stimulants may cause extreme psychological dependence. As drugs of abuse, stimulants are frequently taken to produce a sense of exhilaration, enhance self esteem, improve mental performance, increase activity, produce prolonged wakefulness, and to "get high". Stimulants are also popular as appetite suppressants. Ability to improve short-term physical performance made stimulants one of the most abused drug classes in sports.

METHODS OF ANALYSIS

Immunoassay screens with gas chromatography/mass spectrometry (GC/MS) for confirmation is a classic approach for amphetamines and cocaine analysis in urine. A comprehensive stimulant test for athletic doping control employs gas chromatography/mass spectrometry (GC/MS).

Synthetic Cannabinoids

drug information

CLASSIFICATION

JWH-018 and JWH-073 are synthetic chemicals that act as cannabinoid receptor agonists. Chemically they are not similar to cannabinoids but the term "Synthetic Cannabinoids" or "Cannabinomimetics" is widely used to refer to them as they're cannabinoid-like in their activity.

The synthetic cannabinoid receptor agonists fall into seven major structural groups:

- Naphthoylindoles (e.g. JWH-018, JWH-073)
- Naphthylmethylindoles* (JWH-185, JWH-199)
- Naphthoylpyrroles* (JWH-369, JWH-370)
- Naphthylmethylindenes* (JWH-176)
- Phenylacetylindoles (JWH-250)
- Cyclohexylphenols (e.g. CP 47,497 and homologues of CP 47,497)
- Classical cannabinoids (e.g. HU-210)

**Compounds in these groups have not been detected in herbal blends so far.*

METABOLISM

Little is known about the detailed pharmacology and toxicology of the synthetic cannabinoids and few formal human studies have been published.

Both JWH-018 and JWH-073 metabolize extensively in humans via oxidation and glucuronide conjugation. Depending on dosage, the hydroxylated JWH-018 and JWH-073 and the carboxylated JWH-018 metabolites can be detected up to 72 hours in urine. Very little parent drug excreted in human urine has been reported.

It is possible that, apart from high potency, some other synthetic cannabinoids could have particularly long half-lives, potentially leading to a prolonged psychoactive effect. In addition, there is considerable inter-and intra-batch variability in smoking mixtures, both in terms of substances present and their quantity. Thus, there is a higher potential for overdose than with cannabis.

ABUSE

Legal in most states, JWH-018 and JWH-073 are the two most popular synthetic cannabinoids used today. Reportedly offering a high 4 times stronger than marijuana, JWH-018 and JWH-073 are commonly associated with herbal smoke and incense products sold under names like K2, Spice, Serenity and others.

Synthetic cannabinoid chemicals are often laced in the herbal smoking products that are readily available via the Internet and in many "head-shops" around the country.

Users looking for a "legal high" often turn to these herbal smoking or incense products because they do not show up on a standard urine drug test. Users smoke the product by wrapping joints, smoking it in pipes, or inhaling fumes via vaporizers. Users also report that herbal blends or pure chemical concoctions can be ingested with an infusion or solvent process; purportedly allowing them to manage the potency and dose of the active ingredient(s).

Users indicate the high comes on slow at first, then with surprising potency. There have been many reports about the adverse effects including agitation, rapid heart rate, confusion, dizziness and nausea.

In fact, the American Association of Poison Control Centers issued a warning about the dangers of synthetic marijuana products in March 2010.

Long-term effects from these research chemicals are unknown.

METHODS OF ANALYSIS

RTL's test will utilize the most sophisticated, sensitive and specific equipment and technology available, LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) to confirm JWH-018 and JWH-073 in urine metabolites. For oral fluid testing, the same technology will be utilized to confirm parent compounds of JWH-018, JWH-073 and JWH-250.

To reduce false-negative results, the detection method relies on monitoring multiple urine metabolites for each of the compounds. Other labs that only look for the parent drug in urine could have a higher incidence of false-negative results. RTL's test methodology provides the most definitive synthetic cannabinoid biomarker test results.

Urine Creatinine

drug information

CLASSIFICATION

Creatinine is a metabolic by-product of muscle metabolism, and normally appears in urine in relatively constant quantities over a 24 hour period with "normal" liquid intake. Therefore, urine creatinine can be used as an indicator of urine water content (dilution) or as a marker identifying a specimen as urine. Greater than normal intake of water will increase the urine water content (lowering the creatinine level) consequently diluting any drug which may be present in urine. Conversely, a limited intake of water can lead to an abnormally concentrated urine specimen (as occurs with dehydration) resulting in elevated creatinine levels.

INTERPRETATION OF RESULTS

Creatinine Conc.:	Interpretation:
<20 mg/dL	Dilute urine specimen: Most likely due to increased water or liquid intake. Can be a result of short-term water loading (flushing) in an attempt to dilute any drug below testing cut-off concentrations.
<2.0 mg/dL	Abnormally dilute: Specimen showing an excessively low creatinine value. May be an indication that the specimen is not consistent with normal human urine.

NOTE: The above values are based on the critical points that the Federal Department of Health and Human Services, Substance Abuse Mental Health Services Administration (SAMHSA) has set as decision points for interpreting dilute or substituted urine specimens.

The above interpretations are general guidelines only. Redwood Toxicology Laboratory recommends consulting with a certified toxicologist regarding proper interpretation prior to taking administrative action based solely on the creatinine concentrations. Other physiological conditions may account for low creatinine concentrations such as diabetes or use of prescription diuretics.

Get in touch with us.

To contact Redwood Toxicology Laboratory (RTL), please select from the departments listed below. All requests made during non-business hours will be responded to as early as possible the next business day.

SALES AND GENERAL INQUIRIES

RTL offers toll-free sales and customer support services during regular business hours. RTL hours are 7:30 AM to 4:00 PM PST.

Phone: Laboratory Services – 800-255-2159 or 707-577-7959
Screening Devices – 877-444-0049 or 707-571-1157
Fax: 707-577-8102
E-mail: sales@redwoodtoxicology.com
Address: P.O. Box 5680, Santa Rosa, CA 95402 or
3650 Westwind Blvd., Santa Rosa, CA 95403

CLIENT SERVICES

Trained customer support representatives are available to assist you in a prompt and courteous manner. We'll get you up and running on specimen collection, results interpretation and technical inquiries.

. Phone: 800-255-2159, ext. 4399 or 707-577-7959, ext. 4399
Fax: 707-577-0365
E-mail: clientservices@redwoodtoxicology.com

INFORMATION TECHNOLOGY

IT is available during regular business hours to answer client inquiries about internet (www.webtoxicology.com) and statistical reporting. Contact IT to request your Webtoxicology username and password for convenient results retrieval.

Phone: 800-255-2159, ext. 4311 or 707-577-7959, ext. 4311
Fax: 707-577-0471
E-mail: helpdesk@redwoodtoxicology.com

TESTING SUPPLIES

To request labels, bottles and shipping materials, contact our Supplies Department. Lab supply re-ordering is available to existing clients with an account number.

. Phone: 800-255-2159, ext. 4399 or 707-577-7959, ext. 4399
E-mail: supplies@redwoodtoxicology.com
Web: www.redwoodtoxicology.com/supply_form/

SCHEDULING A SPECIMEN PICKUP

If you need help with scheduling an express delivery pick-up for your urine or oral fluid specimen, please contact a Client Services representative. Note, this service is available to existing clients with an account number.

Phone: 800-255-2159, ext. 4410, or ext. 4382

11 000 3034 REV6

CONFIDENCE IN TESTING

Redwood Toxicology Laboratory, Inc. (RTL) is the preferred choice in drug testing providers. RTL provides accurate laboratory testing services for drugs of abuse in urine and oral fluid, EtG/EtS, steroids, GHB, fentanyl and more. We also sell instant, on-site drug and alcohol screening devices. Our reputation for experience, accuracy and excellence in customer service speaks for itself.

CONTACT US TODAY!

Address: 3650 Westwind Blvd.,
Santa Rosa, CA 95403

Laboratory Services: (800) 255-2159

Screening Devices: (877) 444-0049

Fax: (707) 577-0365

Email: sales@redwoodtoxicology.com

REDWOOD TOXICOLOGY LABORATORY

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Alcohol / saliva test strips

An **easy** and **rapid** preliminary **method** to **detect saliva alcohol** concentration (SAC)

Detects saliva alcohol content at:

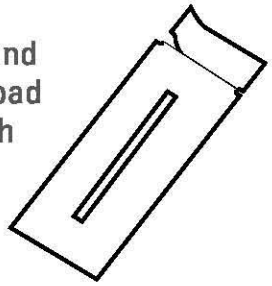
- *0.0%*
- *0.02%*
- *0.08%*
- *0.30%*

reditest®

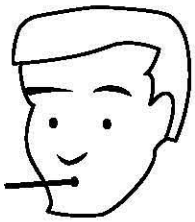
PRODUCT OVERVIEW

COLLECTION PROCEDURE

1. Tear open the pouch and saturate the reactive pad on the end of stick with saliva in mouth or cup for 10 seconds.



2. Remove stick from mouth or cup.



TESTING PROCEDURE

3. After exactly 2 minutes, match the color on the pad to color chart.

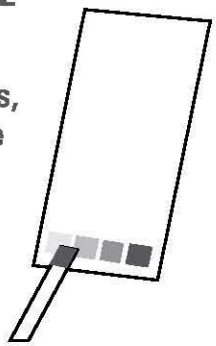


CHART INTERPRETATION

Negative: No color change on reactive pad
Positive: Reactive pad changes color in 2 minutes

0.0	20	80	300mg/100mL
0.0%	0.02%	0.08%	0.30% SAC

*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS ORAL FLUID TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For forensic use only.

Call today: **877-444-0049**

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11 000 0394 REV1

REDWOOD TOXICOLOGY LABORATORY™ | Confidence in testing.

Reditest® Alcohol–Saliva Test Strips / *frequently asked questions*

What does the Instant Alcohol test strip measure?

The Reditest® Instant Alcohol Saliva Test Strip is intended for use as a rapid method to detect the presence of alcohol in saliva at a concentration greater than 0.02%. An important point to remember is that the device is detecting and measuring the saliva alcohol concentration (SAC) and not the blood alcohol concentration (BAC).

What does a positive result indicate?

The concentration of alcohol in saliva is nearly equal to the corresponding blood alcohol concentration in blood. Therefore, if alcohol is detected in saliva at a concentration greater than 0.02%, then it is very likely that the corresponding blood alcohol at that point in time is also greater than 0.02%.

Does a positive saliva alcohol indicate the person has ingested alcohol?

Measuring the concentration of alcohol in saliva is equally as valid as measuring the blood alcohol concentration for the purpose of demonstrating that a person has been drinking and has alcohol in the body.

After consumption of alcohol, how long does it take before test strips show signs of alcohol use?

Rate of alcohol absorption varies greatly due to factors such as type of beverage consumed, quantity of food in the stomach, frequency of gastric emptying, drinking pattern, rate of metabolism, etc. The average time to peak absorption in the blood (saliva) is usually 30 to 60 minutes, but may range from 15 minutes to 3 hours.

Does the saliva alcohol concentration indicate intoxication?

The instant alcohol saliva test provides a semi-quantitative measurement only and does not indicate or measure intoxication.

How accurate is the Instant Alcohol Saliva Test Strip?

The alcohol saliva test is a screening test only (presumptive). To confirm the presence and concentration of alcohol in positive specimens, an alternate methodology such as gas chromatography should be used. However, it is advisable in situations where confirmation is required to perform the test on a simultaneously collected blood, urine, or breath specimen.

Will the strip indicate a false positive from mouth wash?

Nothing should be placed into the mouth of the subject for at least 10 – 15 minutes prior to performing the instant alcohol saliva test. This includes food, tobacco, alcoholic drinks, mouthwashes, etc. Saliva regenerates every 10 – 15 minutes. Therefore, the effects of residual mouth alcohol from recent drinking will not be a factor.

Will other types of alcohol be measured by the test strip?

The alcohol saliva test is an enzymatic reaction and is therefore capable of detecting other alcohols such as methyl and isopropyl alcohol. However, these other alcohols are rarely ingested and if detected by the alcohol screening test, they can be specifically identified by gas chromatography confirmation.

Is this test strip certified?

The instant saliva alcohol test is for forensic use only, and is not DOT or NHTSA certified. The device is not FDA 510(k) cleared. These certifications and clearances are in the preparation stages for submission.

Is it necessary to run controls?

This device is intended for use with saliva only. A positive control can be prepared by adding approximately 10 drops of at least 85 proof ethanol into an 8 oz. glass of water.

Alcohol–Saliva Test Strips: Key Points

This device screens for the presence of alcohol in saliva only, and provides a semi-quantitative measurement of the saliva alcohol concentration (SAC). The SAC does indicate an approximate corresponding blood alcohol concentration (BAC). All positive screens should be confirmed on blood, urine, or breath if the result is to be used punitively or administratively.

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reditest®

Alcohol / breath test device

Instructions

STEP 1

THIS IS NOT A SELF TEST.
YOU SHOULD NEVER TEST YOURSELF.
ALCOHOL IMPAIRS JUDGEMENT. Have someone who has not been drinking help you conduct the test and read the results. Wait 15 minutes after last alcoholic drink, if you cannot wait, rinse your mouth with water before taking the test. This removes the alcohol vapors in your mouth that could cause a false positive result.

STEP 2

Squeeze the middle of the Tester between thumb and forefinger to break inner glass tube.

SQUEEZE ONLY ONCE,
DO NOT CRUSH OR BEND TUBE.

Use the Tester immediately.

STEP 3

Subject should hold Tester vertically so arrows on "BLOW" end are pointing down. Subject should then **BLOW/EXHALE** very hard into tube, in one continuous breath, for 12 seconds. Shake the Tester side-to-side to distribute the crystals evenly in Tester window. Lay Tester on flat surface and **WAIT 2 MINUTES.**

STEP 4

Positive Results: Most of crystals are a light AQUA (GREEN/BLUE,BLUE/GREEN) cast. This shows that the breath alcohol is at or above the level printed on the Tester.

Negative Results: Most of the crystals, are light YELLOW. This shows that the breath alcohol is below the level printed on the Tester.

The YELLOW does not have to match the unused Tester. It may be much lighter or paler YELLOW than an unused Tester.

- The color change may be difficult to see under certain lighting. For best results, read under lighting such as incandescent, fluorescent, or indirect sunlight. A flashlight with an incandescent bulb can be used to help read the result. Hold the flashlight to the side so that the light does not fall directly on the Tester.
- Compare results to an unused Tester or to the YELLOW box. If most of the crystals are not GREEN or BLUE (under the suggested lighting), then the result is negative.
- Tester results may not be reliable if testing is not conducted according to these instructions.

Technical Assistance: If you have any questions or concerns please call 1-877-444-0049 or e-mail us at sales@redwoodtoxicology.com.
Visit our website for further information. www.redwoodtoxicology.com

FOR MORE INFORMATION SEE THE OTHER SIDE OF THIS PAMPHLET.

REDWOOD TOXICOLOGY LABORATORY
device division

Title: REDITEST ALCOHOL BREATH DEVICE PRODUCT INSERT

Redwood Toxicology Laboratory
3650 Westwind Boulevard
Santa Rosa, CA 95403
1(877) 444-0049

Item No:02 108 0006

REV: 9 (10/03/06)

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FORM 99 000 0019 REV 6

reditest®

Alcohol / breath test device

Read all instructions before beginning the test

Intended Use: Reditest Alcohol / breath test device (Tester) is a test for alcohol in human breath. It is a disposable screening device for one-time use.

Test System: The Tester is based on indicator chemistry that changes color in the presence of breath that contains alcohol. See our website for more information on the chemistry of the Tester. Testers are calibrated to turn positive at or above a specific level of alcohol in the breath. This level is called the cut-off. The cut-off is printed on the upper right corner of the Tester label. For example, the Tester labeled .02% will turn positive when the breath contains or exceeds .02 percent alcohol.

Preparation and Storage

The Tester is ready to use. Use the Tester immediately after breaking glass tube.

Store at room temperature **(59 to 81°F or 15 to 27°C).**

The lot number and "Use By" date is printed on the Tester or the package label.
Do not use the Tester after the "Use By" date.

Warnings, Precautions, and Limitations

- **Alcohol impairs judgment. Do not test yourself OR drive if you have been drinking. Someone who has not been drinking should conduct the test and read the results.**
- Tester results should not be interpreted by readers who are color-blind or visually impaired. Results are best viewed under white light. It may be hard to read Tester results under certain streetlights or under dim lighting. Under yellow street-lights (sodium vapor), green colors may look gray-green. Blue colors may look gray-white. Under blue-white streetlights (mercury vapor) yellow may look amber-green. A flashlight may be used to help read the results under these lighting conditions.
- Lighting studies were performed following NHTSA guidelines. Tester results were read under 5 lighting conditions. The results met the guidelines except for 1 reading. There was 1 false positive out of 1200 readings of the .04 Tester for a sample that did not contain alcohol.
- It is recommened that you have at least two unused Testers with the same lot number prior to beginning the test. One Tester will be used for testing your breath alcohol. The other unused Tester will be used for comparison to help you see if the Tester you are using turns light green or blue. Compare to the yellow box on this pamphlet if you do not have an extra unused Tester.
- Do not use the Tester if the glass tube containing crystals is broken before you begin the test. Do not use if the crystals are not yellow.
- Keep out of the reach of children. Do not immerse in liquid.
- DO NOT EAT the contents of the Tester. This Tester contains potassium dichromate, a hazardous chemical. If eaten, induce vomiting and contact your doctor.
- The Tester should be used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the user. Although breath alcohol levels have been shown to represent blood alcohol levels, the connection depends on many factors. The exact level of alcohol in the blood cannot be accurately determined by using the Tester.
- The Tester does not determine or detect the intoxication of the user. Decision's and/or actions based on the use of this device by any person shall be at person's own risk.
- A positive result should be taken as a warning that the user may have detectable alcohol in their system. A positive result should be confirmed by an evidentiary alcohol test before any legal or workplace actions are taken.
- There may be times that a person tests negative and later show that they are under the influence of alcohol or their judgement has been impaired by alcohol.

Manufactured in the U.S.A for:
REDWOOD TOXICOLOGY LABORATORY
3650 Westwind Blvd., Santa Rosa, CA 95403
On-site Devices: 877-444-0049
Laboratory: 800-255-2159
Fax: 707-577-9102
www.redwoodtoxicology.com

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1300068 R0

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FORM 99 000 0019 REV 6

OrAlert / substance abuse screening device

Equip your drug **screening** program with a **convenient** and **reliable** testing tool.

FEATURES/BENEFITS

- *Improved Sensitivity of Parent THC*
- *Results in under 10 minutes*
- *Detects up to Six Drugs*
- *Zero Exposure Collector*
- *Split Specimen Well*
- *Simple Procedure*

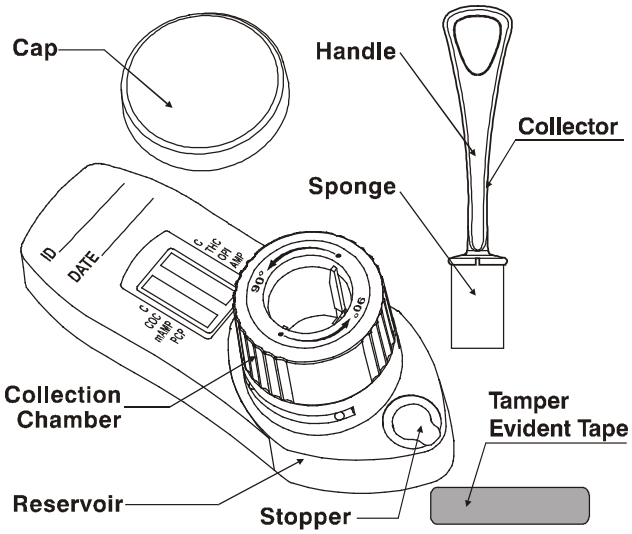
AVAILABLE TEST PANELS

6 Panel *— AMP, M-AMP, BZO, COC, THC, OPI (P/N: 2083)*
6 Panel *— AMP, M-AMP, COC, THC, OPI, PCP (P/N: 1960)*

REDWOOD TOXICOLOGY LABORATORY™

PRODUCT OVERVIEW

ORALERT COMPONENTS



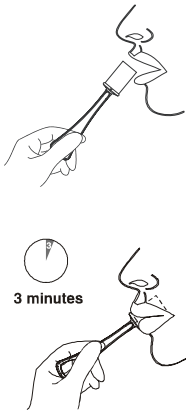
ORALERT TESTING PROCEDURE

1 Instruct the donor not to place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

2 Insert sponge end of collector into mouth.

Actively swab the inside of the mouth and tongue with sponge. As soon as the sponge softens slightly, gently press the sponge between the tongue and teeth to endure complete saturation.

The sponge is saturated when no hard spots can be detected. Collect for a total of 3 minutes before removing sponge.

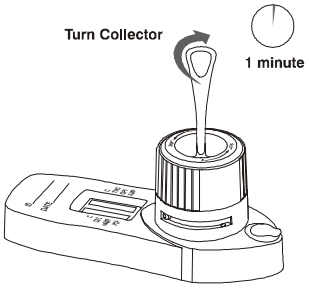


3 Insert collector into device as shown.

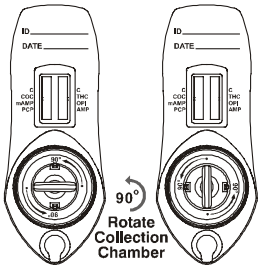
Push collector down into chamber.

Turn collector clockwise to lock into chamber.

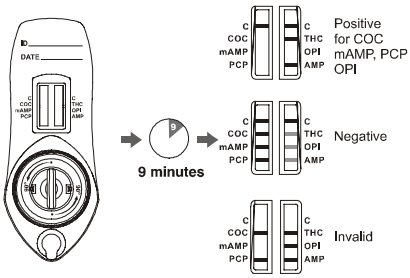
Wait 1 minute.



4 Rotate collection chamber 90° counterclockwise.



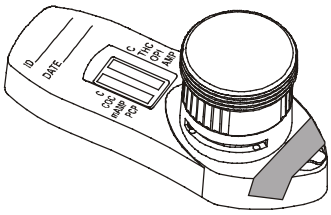
5 Wait 9 minutes and read results.



6 If results are positive, remove collector from device and secure reservoir with tamper evident tape.

Secure cap onto collection chamber.

Send device to laboratory for confirmation. Laboratory can access reservoir through stopper.



*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS SALIVA SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For forensic use only.

*Marijuana (THC), Benzodiazepines, Cocaine, Opiates (300), Phencyclidine, Methamphetamines, Amphetamines

Call today: **877-444-0049**

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11 000 0393 REV1

OrALert™

Oral Fluid Drug Screen Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana and phencyclidine and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	Δ^9- THC	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use.[1] Amphetamine can be detected in oral fluid for up to 72 hours after use.[1]

The Amphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the amphetamine concentration in oral fluid exceeds 50 ng/mL.

Methamphetamine (mAMP)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater central nervous system (CNS) stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use.[1] Methamphetamine can be detected in oral fluid for up to 72 hours after use.[1]

The Methamphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/mL.

Cocaine (COC)

Cocaine is a potent CNS stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and its metabolites, benzoylecgonine and ecgonine methylester, can be detected in oral fluid as early as 5-10 minutes following use.[1] Cocaine and benzoylecgonine can be detected in oral fluid for up to 24 hours after use.[1]

The Cocaine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

Opiates (OPI)

The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[2] 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.[3]

The THC assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the Δ^9-THC concentration in oral fluid exceeds 100 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in a hospital emergency department, PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[4]

The Phencyclidine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, Δ^9- THC and Phencyclidine.

PRECAUTIONS

- **For forensic use only**.
- Do not use after the expiration date.
- The Oral Fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

- Test devices
- Caps
- Collectors
- Procedure cards
- Tamper evident tape
- Package insert

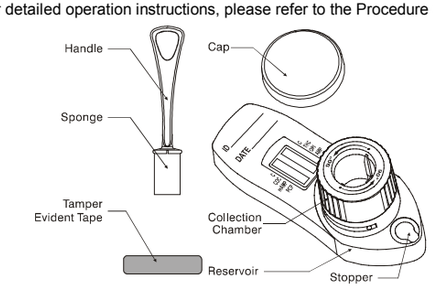
Materials Required but not Provided

- Timer

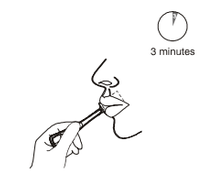
DIRECTIONS FOR USE

Allow the OrALert™ Oral Fluid Drug Screen Device to come to room temperature [15-30ºC (59-86ºF)] prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

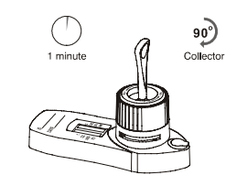
1. Bring the pouch to room temperature before opening it. Remove the test and cap from the sealed pouch and use the test as soon as possible.
2. Remove the collector from the sealed pouch and give it to the donor.
3. Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.
4. The sponge is saturated when no hard spots can be detected. Collect for a total of three (3) minutes before removing the sponge.
5. Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the test device by pushing it into the chamber and turning the collector clockwise until engaged. Wait 1 minute.
6. After 1 minute, rotate the collection chamber counterclockwise and set the timer for 9 minutes.
7. Read results at 9 minutes.
8. If positive results are observed, remove the collector by turning it counterclockwise and pulling. Secure the cap over the collection chamber, seal the reservoir with tamper evident tape and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the stopper.
9. For detailed operation instructions, please refer to the Procedure Card.



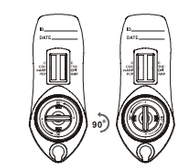
Step 1 and 2



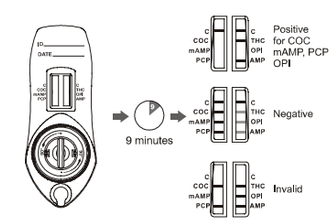
Step 3 and 4



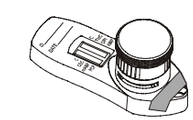
Step 5



Step 6



Step 7



Step 8

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE**: The shade of color in the test region (Drug/T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The OrALert™ Oral Fluid Drug Screen Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the Oral Fluid Drug Screen Device. The results are summarized below.

Drug conc. (Cut-off range)	n	COC		mAMP		PCP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0
Cut-off	30	20	10	23	7	22	8
+25% Cut-off	30	6	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	THC		OPI		AMP	
		-	+	-	+	-	+
0% Cut-off	120	120	0	120	0	120	0
-50% Cut-off	120	120	0	120	0	120	0
-25% Cut-off	120	108	12	108	12	109	11
Cut-off	120	60	60	60	60	60	60
+25% Cut-off	120	12	108	10	110	10	110
+50% Cut-off	120	3	117	0	120	0	120

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP identified positive results at a read time of 10 minutes.

COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
METHAMPHETAMINE (mAMP)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
MARIJUANA (THC)	
Δ^9-THC	100
11-nor-Δ^9- THC -9 COOH	12
Cannabinol	3,000
Δ^8-THC	100
OPIATES (OPI)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-D-Glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the OrALert™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 μg/mL.

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloralhydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
β-Estradiol
Ethyl-p-aminobenzoate
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
o-Hydroxyhippuric acid
Ibuprofen
d,l-Isoproterenol
Ketamine
Labetalol
Meperidine
Methylphenidate
Naloxone
Acetophenetidin
Acetylsalicylic acid
Amoxicillin
l-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine
d,l-Brompheniramine
Cannabidol
Chloramphenicol
d,l-Chlorophenirameine
Chloroquine
Clonidine
l-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
l-Ψ-Ephedrine
Estrone-3-sulfate
l-(-)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Nalidixic acid
Naltrexone
Naproxen
Nifedipine
d-Norpropoxyphene
d,l-Octopamine
Oxolinic acid
Papaverine
Pentazocine
Phenelzine
Phenylpropanolamine
Prednisone
d-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Thiamine
d,l-Tyrosine
Triamterene
Trimethoprim
Tyramine
Verapamil
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclopropylamine
Prednisolone
d,l-Propranolol
d-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-Acetate
Thioridazine
Tolbutamide
Trifluoperazine
d,l-Tryptophan
Uric acid
Zomepirac

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3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," *J Anal Tox*, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," *J Anal Tox*. 1984 Sep-Oct.; 8 (5), pp 197-201.

DN: 1150164101
Eff. Date: 2005-10-20

Printed in China

On-Site Oral / substance abuse screening device

A **reliable** and cost **effective** **oral** fluid **screening** solution.

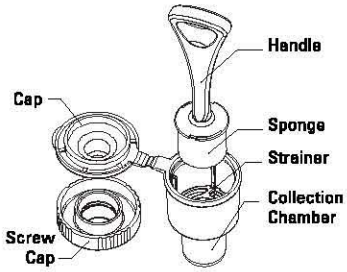
Drugs tested in oral fluid:

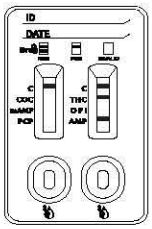
- *Amphetamine*
- *Cocaine*
- *Marijuana*
- *Methamphetamine*
- *Opiates*
- *Phencyclidine*

reditest®

PRODUCT OVERVIEW

ON-SITE ORAL COMPONENTS

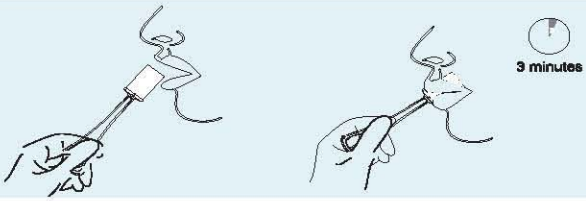




Test Cassette

COLLECTION PROCEDURE

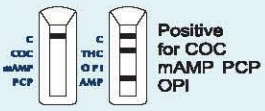
1. Remove the collector from sealed pouch and insert the sponge end of the collector into mouth.
2. Actively swab the inside of the mouth and tongue to collect oral fluid for a total of 3 minutes until the sponge becomes fully saturated.
3. Gently pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
4. Remove collector from mouth.



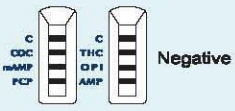
TESTING PROCEDURE

1. Flip open the cap of the oral fluid collection chamber (do not twist open cap of collection chamber at this time). Place saturated oral fluid collector into chamber and press sponge fully against strainer to collect oral fluid. Discard collector. Snap the cap shut on the collection chamber.
2. To run test, twist open screw cap of the dropper tip assembly to expose dropper tip. Invert the collection chamber and transfer 3 drops of oral fluid into each sample well of the test device. Place screw cap back onto collection chamber with remaining oral fluid. Apply security seal over screw cap.
3. Wait for colored lines to appear. Read results at 10 minutes. Do not interpret results after 1 hour.
4. Send in sealed collection chamber with remaining oral fluid to laboratory for confirmation.*

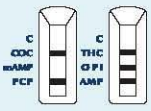
RESULT KEY



Positive for COC mAMP PCP OPI



Negative



Invalid (No control line)

*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS ORAL FLUID TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For forensic use only.

Call today: **877-444-0049**

REDWOOD TOXICOLOGY LABORATORY
Screening Devices: 877-444-0049 // Laboratory: 800-255-2159
Fax: 707-577-8102 // www.redwoodtoxicology.com
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Reditest® On-Site Oral Screening Device / *frequently asked questions*

What is the Reditest® On-Site Oral screening device?

The Reditest® On-Site Oral screening device offers an easy-to-use, non-invasive method for the detection of multiple drugs in oral fluids. This cutting-edge technology offers a unique, gender-neutral design that eliminates urine collection. With the Reditest On-Site Oral screening device, your agency can reduce collection-site fees, the need for special equipment, same sex collectors and complicated training. This test can be performed on-site anytime, anywhere and offers quick results.

How does the Reditest On-Site Oral screening device work?

The Reditest On-Site Oral screening device is a lateral flow, chromatographic immunoassay for the qualitative detection of multiple drugs and their metabolites in oral fluids based on the principle of competitive binding. Simply drop the collected oral fluid specimen into the device sample well and read in 10 minutes. It's that easy!

As with all of Redwood Toxicology Laboratory, Inc.'s (RTL), Reditest products, a detailed product insert is included with every order. Telephonic training is provided to all clients via our toll-free hotline at (877) 444-0049.

What is the principle of the On-Site Oral screening device?

The oral fluids test is based on competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a portion of the oral fluid sample migrates across the membrane. If no drug is present above the cut-off, the sample will not saturate the binding sites of its specific antibody. The antibody will then react with the drug -protein conjugate and a visible colored line will show up in the test line region. The presence of a drug above the cut-off concentration will saturate all the binding sites of the antibody and a line will not form in the test region. The lateral flow is the migration and competition across the membrane.

To serve as a procedural control, a colored line will appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

What are the benefits of Reditest On-Site Oral screening vs. other drug testing methods?

There are numerous benefits to using the Reditest On-Site Oral screening device.

- Eliminate urine collections and collector fees
- Observable, gender-neutral collections without privacy issues
- Non-invasive
- Easy to read test results
- Testing integrity (difficult to adulterate)
- Results available in 10 minutes—allows for immediate decision or treatment

Complete testing kit includes all components for testing including an easy-to-follow product insert. Telephonic training and support is available via RTL's toll-free hotline.

What is the detection window compared to other drug testing methods?

Saliva and blood have similar detection windows. Testing saliva/blood will detect drug use faster than testing urine. Saliva/blood may detect drug ingestion within minutes while drug detection in urine may take 6-8 hours post ingestion.

What are the cut-off levels for the Reditest On-Site Oral screening device?

The Reditest On-Site Oral screening device cut-off concentrations for amphetamine, methamphetamine, THC, PCP, cocaine, and opiates are as follows:

TEST	CALIBRATOR	CUT-OFF
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (MAMP)	d-Methamphetamine	50 ng/mL
Marijuana (THC)	THC-COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL

What is the analytical sensitivity of the Reditest On-Site Oral screening device?

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the Reditest On-Site Oral screening device. The results are summarized below.

DRUG CONCENTRATION (cut-off range)	n	COC		mAMP		PCP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0
Cut-off	30	20	10	23	7	22	8
+25% Cut-off	30	6	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

DRUG CONCENTRATION (Cut-off range)	n	THC		MOP		AMP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	24	0	28	2	30	0
Cut-off	30	15	10	23	7	22	8
+25% Cut-off	30	11	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Does the test quantify the concentration of drugs present in the oral fluids sample?

A positive test result does not indicate the concentration of drug in the sample. All positive results are presumptive and should be confirmed by an alternate method (e.g. GC/MS or GC/MS/MS). Negative results may not necessarily indicate a drug-free sample. Drug may be present in the sample below the cut-off level of the assay.

What type of agencies can use the Reditest On-Site Oral screening device?

Everyone can benefit from using the Reditest On-Site Oral screening device, particularly agencies in the pre-employment, workplace and corrections arena.

How is the oral fluids specimen collected?

The donor actively swabs the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, gently press the sponge between the tongue and teeth to ensure complete saturation (about 3 minutes).

If the donor has a dry mouth, can they have a drink of water?

A drink of water may be given to the donor. It is best to wait for about 10 minutes after the drink before attempting another collection.

How do I know the test device is working properly?

A control line will be present if the test is working properly. If a control line does not appear, repeat the test. Insufficient specimen volume or incorrect procedural techniques are most likely the reasons for control line failure. Review the procedure and repeat the test using a new device. If further assistance is required, please contact RTL via our toll-free hotline.

Can the test be adulterated?

The test is virtually impossible to adulterate. Make sure the donor has not eaten or had anything to drink for a minimum of 10 minutes prior to testing.

How do I know if the test is negative?

If the test is negative, red lines appear in the control region (C) and next to each particular drug name in the test region. The negative result indicates that the drug concentration is below the detectable level. The shade of red in the test region will vary, but it should be considered negative, even if there is a faint pink line.

How do I know if the test is positive?

If the test is presumptive positive, red lines appear in the control region (C), and no line appears in the test region next to a particular drug name. This positive result indicates that the drug concentration is above the detectable level. All positive results are presumptive and should be confirmed by an alternate method (e.g. GC/MS or GC/MS/MS).

What if the test line is very faint?

The shade of red in the test region will vary, but it should be considered negative whenever there is even a faint pink line.

Is it possible to confirm positive results?

To confirm a positive result, send the original leftover oral fluid specimen to RTL for confirmation via gas chromatography/mass spectrometry (GC/MS). Place the security seal over the screw cap, put the collection chamber in a plastic baggie and mail to RTL. Results are available by email, fax and U.S. mail. For laboratory support, contact RTL's Client Services Department at (800) 255-2159.

What is the shelf life of the On-Site Oral screening device?

The test has a shelf life of 18 months.

What is the recommended storage temperature for the Reditest On-Site Oral screening device?

Store as packaged in the sealed pouch at 2-30°C (36-86°F).

How can I order the Reditest On-Site Oral screening devices?

To order the Reditest On-Site Oral screening devices, call RTL toll-free at (877) 444-0049. A sales associate will assist you in placing your order.

Oral Fluid THC Explanation

Due to limitation of current testing technologies the detection of cannabinoids (THC) in oral fluids is problematic. There is very little evidence that THC in blood returns to oral fluids once it is absorbed into the bloodstream. However, the active component of marijuana, delta-9-THC, can be detected in oral fluid. During marijuana use (smoke or oral use) THC is deposited in the oral cavity and can be detected for approximately 12 - 24 hours after use. To optimize the detection of marijuana, RTL suggests, if marijuana use is suspected, to either submit the oral fluid to RTL for delta-9-THC GC/MS testing or to simultaneously collect and screen a urine specimen for THC-COOH (primary metabolite in urine).

REDWOOD TOXICOLOGY LABORATORY

Screening Devices: 877-444-0049 // Laboratory: 800-255-2159 // Fax: 707-577-8102
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Oral Fluid Drug Screen / *on-site device preliminary test results*

To be used for collector verification, donor certification and on-site screening device results. Preliminary result should not be interpreted as a laboratory result.*

DONOR INFORMATION — STEP 1: Collector completes donor information.

Requesting agency: _____ Account #: _____

Donor's last name: _____ Donor's first name: _____

Donor's social security: _____ – _____ – _____ Specimen ID: _____

COLLECTOR VERIFICATION — STEP 2: Collector completes and validates that the specimen was collected properly.

I certify that I collected the specimen provided by the Donor named above and that it was not substituted or adulterated to the best of my knowledge.

Collector name: _____ Collector signature: _____

Time of collection: _____ Date of collection: _____ Date shipped: _____

Comments: _____

DONOR CERTIFICATION — STEP 3: Donor completes and validates that the specimen was collected properly.

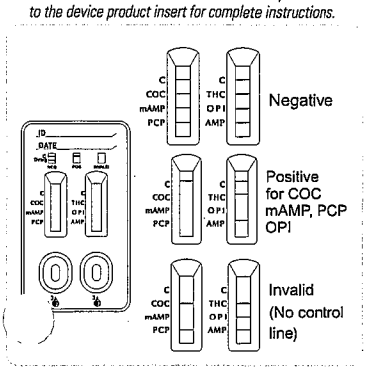
I certify that the specimen provided is my own and was not substituted or adulterated. I freely consent to the testing of my saliva specimen for drugs/metabolites.

Donor name (please print): _____ Donor signature: _____

Time of collection: _____ Date of collection: _____

PRELIMINARY TEST RESULTS — STEP 4: Perform test and log results. Use separate chain of custody label/form to submit presumptive positive specimens to a lab.

RESULTS KEY — *For reference only. Refer to the device product insert for complete instructions.*



Drug Name	Drug Code	Negative	Invalid	Presumptive Positive*	GC/MS Confirmation
Amphetamine	AMP	[ ]	[ ]	[ ]	[ ]
Cocaine	COC	[ ]	[ ]	[ ]	[ ]
Marijuana	THC	[ ]	[ ]	[ ]	[ ]
Methamphetamine	M-AMP	[ ]	[ ]	[ ]	[ ]
Opiates	OPI	[ ]	[ ]	[ ]	[ ]
Phencyclidine	PCP	[ ]	[ ]	[ ]	[ ]

Test performed by: _____ Date: _____

Positive specimen sent to lab for GC/MS confirmation: [ ] Yes [ ] No Date: _____

For professional in vitro diagnostic use only.

*Any positive result obtained with this saliva screening test is presumptive and should be confirmed by an alternate method such as GC/MS.

Oral Fluid Drug Screen Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP Test for Oral Fluids

rapid, screening test for the simultaneous, qualitative detection of amphetamine, methamphetamine, caine, opiates, marijuana and phencyclidine and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

e Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP is a lateral flow chromatographic munoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, encyclidine and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	THC-COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

is assay provides only a preliminary analytical test result. A more specific alternate chemical ethod must be used in order to obtain a confirmed analytical result. Gas chromatography/mass ectrometry (GC/MS) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are the eferred confirmatory methods. Professional judgment should be applied to any drug of abuse test sult, particularly when preliminary positive results are indicated.

SUMMARY

e Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP and their metabolites is a rapid, oral id screening test that can be performed without the use of an instrument. The test utilizes monoclonal tibodies to selectively detect elevated levels of specific drugs in human oral fluid.

mphetamine (AMP)

nphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected oral fluid as early as 5-10 minutes following use.[1] Amphetamine can be detected in oral fluid for up to 72 urs after use.[1]

e Amphetamine assay contained within the Oral Fluid Drug Screen Device yields a positive result when the nphetamine concentration in oral fluid exceeds 50 ng/mL.

ethamphetamine (mAMP)

ethamphetamine is a potent stimulant chemically related to amphetamine but with greater central nervous stem (CNS) stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral estion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early 5-10 minutes following use.[1] Methamphetamine can be detected in oral fluid for up to 72 hours after use.[1]

e Methamphetamine assay contained within the Oral Fluid Drug Screen Device yields a positive result when methamphetamine concentration in oral fluid exceeds 50 ng/mL.

ocaine (COC)

caine is a potent CNS stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). e drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. pending on the route of administration, cocaine and its metabolites, benzoylecgonine and ecgonine thylester, can be detected in oral fluid as early as 5-10 minutes following use.[1] Cocaine and nzoylecgonine can be detected in oral fluid for up to 24 hours after use.[1]

e Cocaine assay contained within the Oral Fluid Drug Screen Device yields a positive result when the caine metabolite concentration in oral fluid exceeds 20 ng/mL.

piates (OPI)

e drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring mpounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control in by depressing the central nervous system. The drugs demonstrate addictive properties when used for stained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. piates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; gal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[2] 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the Oral Fluid Drug Screen Device yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.[3]

The THC assay contained within the Oral Fluid Drug Screen Device yields a positive result when the THC-COOH concentration in oral fluid exceeds 12 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in a hospital emergency department, PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[4]

The Phencyclidine assay contained within the Oral Fluid Drug Screen Device yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, THC-COOH and Phencyclidine.

PRECAUTIONS

- **For forensic use only.**
- Do not use after the expiration date.
- The Oral Fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

- Test devices
- Collectors
- Collection chambers
- Procedure cards
- Security Seals
- Package insert

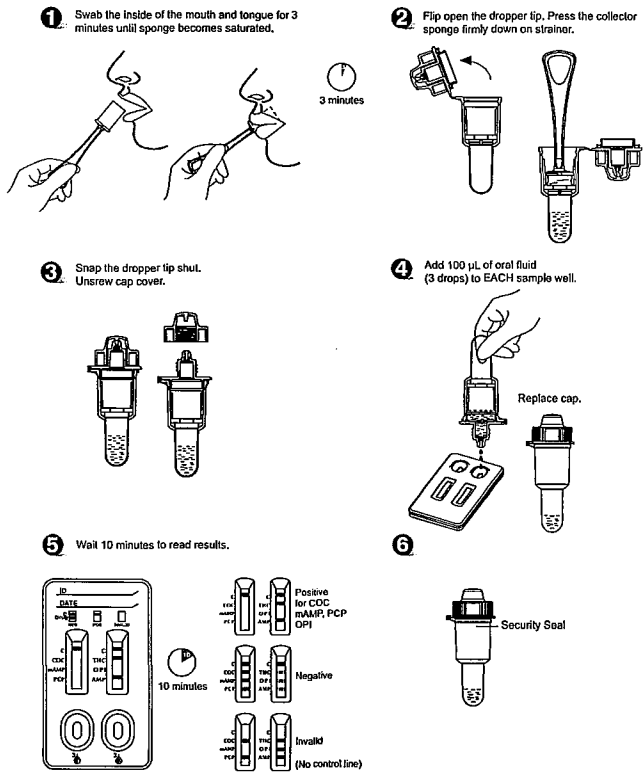
Materials Required but not Provided

- Timer

DIRECTIONS FOR USE

Allow the Oral Fluid Drug Screen Device to come to room temperature [15-30°C (59-86°F)] prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test and collector from the sealed pouch and use the test as soon as possible.
2. Remove the collector from the sealed pouch and give it to the donor.
3. Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.
4. The sponge is saturated when no hard spots can be detected. Collect for a total of three (3) minutes before removing the sponge from the mouth. **[See image (1).]**
5. Flip open the dropper tip of the oral fluid collection tube (do not twist open the screw cap at this time). Place the saturated oral fluid collector into the collection chamber and press the sponge firmly down on the plastic strainer to release as much liquid as possible. **[See image (2).]**
6. Snap the dropper tip shut on the collection tube and discard the collector. Place the test device on a clean and level surface. Unscrew the cap to expose the dropper tip. **[See image (3).]** Invert the collection tube and transfer 3 drops of oral fluid (approximately 100 µL) into each sample well of the test device and start the timer. Avoid trapping air bubbles in the specimen well. Twist the screw cap back onto the collection tube. **[See image (4).]**
7. Read results at 10 minutes. Do not read results after 1 hour. **[See image (5).]**
8. If positive results are observed, apply the security seal over the screw cap and send the device to a laboratory for confirmation. **[See image (6).]** The laboratory can access leftover oral fluid from the collection chamber.
9. For detailed operating instructions, please refer to the Procedure Card.



INTERPRETATION OF RESULTS

[See image (5) above.]

IEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent olored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug oncentration is below the detectable level.

NOTE: The shade of color in the test region (Drug/T) will vary, but it should be considered negative /henever there is even a faint colored line.

OSITIVE: One colored line appears in the control region (C). No line appears in the test region Drug/T). This positive result indicates that the drug concentration is above the detectable level.

IVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques re the most likely reasons for control line failure. Review the procedure and repeat the test using a new est panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

, procedural control is included in the test. A colored line appearing in the control region (C) is considered n internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and orrect procedural technique.

LIMITATIONS

- The Oral Fluid Drug Screen Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) are preferred confirmatory methods.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

, PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested /ith the Oral Fluid Drug Screen Device. The results are summarized below.

Drug conc. (Cut-off range)	n	COC		mAMP		PCP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0
Cut-off	30	20	10	23	7	22	8
+25% Cut-off	30	6	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	THC		OPI		AMP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	24	6	26	4	26	4
Cut-off	30	15	15	20	10	19	11
+25% Cut-off	30	11	19	5	25	7	23
+50% Cut-off	30	0	30	0	30	0	30

Analytical Specificity

he following table lists the concentration of compounds (ng/mL) above which the Oral Fluid Drug Screen levice for AMP/mAMP/COC/OPI/THC/PCP identified positive results at a read time of 10 minutes.

Compound	ng/mL
COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
METHAMPHETAMINE (mAMP)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	12
Cannabinol	12,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	10,000
OPIATES (OPI)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-D-Glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloralhydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
β-Estradiol
Ethyl-p-aminobenzoate
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
o-Hydroxyhippuric acid
Ibuprofen
d,l-Isoproterenol
Ketamine
Labetalol
Meperidine
Methylphenidate
Naloxone
Naproxen
Nifedipine
d-Norpropoxyphene
d,l-Octopamine
Oxolinic acid
Papaverine
Pentazocine
Phenelzine
Phenylpropanolamine
Prednisone
d-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Thiamine
d,l-Tyrosine
Triamterene
Trimethoprim
Tyramine
Verapamil

Acetophenetidin
Acetylsalicylic acid
Amoxicillin
l-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine
d,l-Brompheniramine
Cannabidol
Chloramphenicol
d,l-Chlorpheniramine
Chloroquine
Clonidine
l-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
l-Ψ-Ephedrine
Estrone-3-sulfate
l-(-)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Nalidixic acid
Naltrexone
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclopropylamine
Prednisolone
d,l-Propranolol
d-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-Acetate
Thioridazine
Tolbutamide
Trifluoperazine
d,l-Tryptophan
Uric acid
Zomepirac

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2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", *Clin Chem*, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," *J Anal Tox*, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," *J Anal Tox*. 1984 Sep-Oct.; 8 (5), pp 197-201.

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Eff. Date: 2007-09-11

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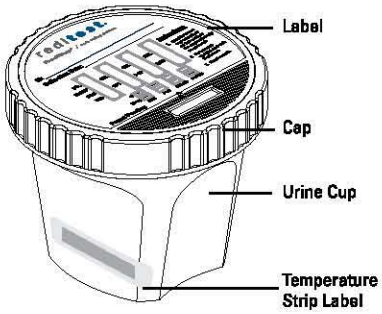
PRODUCT OVERVIEW

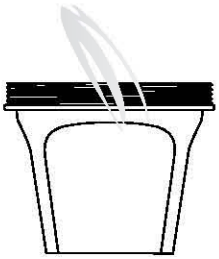
REDICUP COMPONENTS



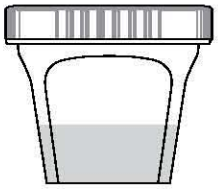
Security Seal Label

TESTING PROCEDURE

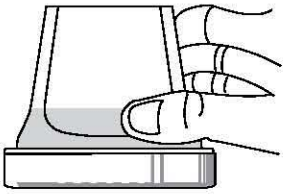
1 Collect specimen.



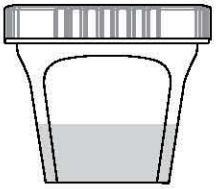
2 Secure cap. ***NOTE:*** Screw cap tightly to ensure adequate seal.



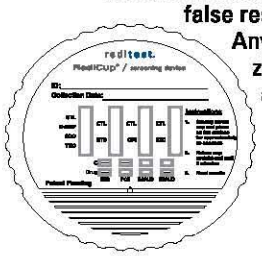
3 Quickly invert cup and place on a flat surface for approximately 30 seconds.



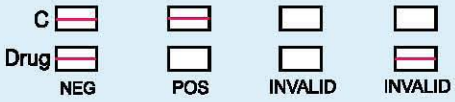
4 Stand upright on a flat surface. If no sample wicking is seen at 1 minute, repeat steps 3 and 4.



5 Read results at 5 minutes. Do not interpret results after 60 minutes as false results may occur. Note: Any line at all in the test zone is to be interpreted as negative.



RESULT KEY



*NOTE: ANY POSITIVE RESULT OBTAINED WITH THIS URINE SCREENING TEST IS PRESUMPTIVE AND SHOULD BE CONFIRMED BY AN ALTERNATE METHOD SUCH AS GC/MS. CONTACT OUR LAB FOR ADDITIONAL GC/MS CONFIRMATION SERVICES.

For professional in vitro diagnostic use only.

*Amphetamine, Barbiturates, Benzodiazepines, Cocaine Metabolites, Marijuana (THC), MDMA (Ecstasy), Methadone, Opiates (300 or 2,000 ng/mL cut-off), Oxycodone, Phencyclidine, and Tricyclic Antidepressants (TCA).

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Reditest® RediCup®
substance abuse screening device

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BUP/BZO/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The **Reditest® RediCup® substance abuse screening device** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the Reditest® RediCup® substance abuse screening device come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **Reditest® RediCup® substance abuse screening device** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

AMPHETAMINE (AMP 300)

The **Reditest® RediCup® substance abuse screening device** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.[3] The plasma half life of Buprenorphine is 2-4 hours.[3] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.[4,5] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[5]

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

COCAINE (COC 150)

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[2]

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

OPIATE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[7] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[8]

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **Reditest® RediCup® substance abuse screening device** yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

PRINCIPLE

The **Reditest® RediCup® substance abuse screening device** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

For best results, test specimens immediately following collection. Storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to testing.

MATERIALS

Materials Provided

- **Reditest® RediCup® substance abuse screening device** [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Caps
- Security seals
- Package insert
- Procedure cards

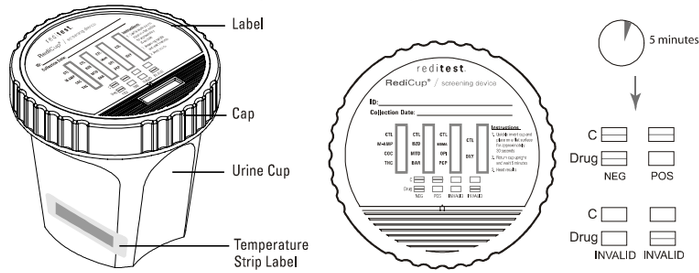
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test cap, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cap from the sealed pouch and use it as soon as possible.
2. Collect specimen.
3. Replace and secure cap.
4. Technician checks cap for tight seal.
5. Quickly invert cup and place on flat surface for approximately 30 seconds.
6. Return cup upright and wait 5 minutes.
7. Start the timer and wait for the red lines to appear. If no sample wicking is seen at 1 minute, repeat steps 5 and 6.
8. The results should be read at 5 minutes. Results remain stable for up to sixty minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **Reditest® RediCup® substance abuse screening device** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,4,3]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **Reditest® RediCup® substance abuse screening device** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BUP	Buprenorphine
BZO	Oxazepam, Nordiazepam, α-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
Reditest® RediCup® substance abuse screening device	AMP 1,000	Positive	129	0	>99%
		Negative	0	172	>99%
	AMP 300	Positive	127	0	>99%
		Negative	0	173	>99%
	BAR	Positive	126	1	>99%
		Negative	0	166	>99%
	BUP	Positive	*	*	*
		Negative	*	*	*
	BZO	Positive	131	0	>99%
		Negative	1	162	>99%
	COC 300	Positive	112	1	>99%
		Negative	0	186	99%
	COC 150	Positive	141	0	>99%
		Negative	0	159	>99%
	mAMP 1,000	Positive	121	0	99%
		Negative	1	174	>99%
	mAMP 500	Positive	108	39**	>99%
		Negative	0	153	80%
	MDMA	Positive	86	0	>95%
		Negative	4	152	>99%
	MOP	Positive	125	0	95%
		Negative	7	150	>99%
	MTD	Positive	120	0	89%
		Negative	18	168	>99%
	OPI	Positive	131	0	98%
		Negative	2	164	>99%
	OXY	Positive	142	0	97%
		Negative	4	154	>99%
	PCP	Positive	71	0	99%
		Negative	1	160	>99%
	PPX	Positive	157	0	>99%
		Negative	0	157	>99%
	TCA	Positive	45	0	92%
		Negative	4	177	>99%
	THC	Positive	124	1	>99%
		Negative	0	175	99%

* Commercial kit unavailable for BUP

** 32 specimens showed >500 ng/mL concentration by GC/MS

Method		GC/MS					
Reditest® RediCup® substance abuse screening device		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP 1,000	Positive	0	1	8	18	114	97%
	Negative	149	1	5	4	0	95%
BAR	Positive	0	0	4	5	117	92%
	Negative	150	1	5	1	9	98%
BZO	Positive	0	7	1	5	26	97%
	Negative	149	7	1	3	1	95%
COC 300	Positive	0	2	15	16	103	96%
	Negative	150	5	7	1	1	90%
THC	Positive	0	13	9	12	109	96%
	Negative	150	6	0	0	1	97%
MTD	Positive	0	0	10	10	112	99%
	Negative	150	17	0	0	1	94%
mAMP 1,000	Positive	0	0	10	9	126	99%
	Negative	150	0	4	1	0	94%
MDMA	Positive	0	0	3	6	82	98%
	Negative	147	0	2	0	0	>99%
MOP	Positive	0	2	7	10	131	>99%
	Negative	150	0	0	0	0	94%
OPI	Positive	0	0	16	18	116	>99%
	Negative	150	0	0	0	0	90%
PCP	Positive	0	0	6	10	40	>99%
	Negative	150	6	0	0	0	97%
*TCA	Positive	0	12	8	15	20	>99%
	Negative	150	17	0	0	0	89%

* Negative samples were confirmed negative using LC/MS by pooling these samples into groups of 15.

Method		GC/MS					
Reditest® RediCup® substance abuse screening device		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
BUP	Positive	0	0	0	5	50	98%
	Negative	150	15	5	1	0	>99%
PPX	Positive	0	0	2	7	158	94%
	Negative	152	5	18	10	0	99%
AMP 300	Positive	0	1	1	2	123	99%
	Negative	150	18	5	0	0	99%

Method		GC/MS				
Reditest® RediCup® substance abuse screening device		Neg.	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
COC 150	Positive	0	0	10	131	>99%
	Negative	150	7	0	2	98%
OXY	Positive	0	5	2	135	98%
	Negative	147	8	2	1	97%

Method		GC/MS		
Reditest® RediCup® substance abuse screening device		Neg.	Pos.	% agreement with GC/MS
mAMP 500	Positive	7	140	>99%
	Negative	153	0	96%

Forty (40) clinical samples for each drug were run using each of the **Reditest® RediCup® substance abuse screening device** by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

Precision

A study was conducted at three physician offices for Amphetamine (1,000 ng/mL), Cocaine (300 ng/mL), Marijuana, Methamphetamine (1,000 ng/mL), Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	90	0	88	2	89	1
-25% Cut-off	90	80	10	70	20	70	20
+25% Cut-off	90	34	56	13	77	12	78
+50% Cut-off	90	5	85	5	85	3	87

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	83	7	87	3	90	0
-25% Cut-off	90	67	23	75	15	80	10
+25% Cut-off	90	28	62	30	60	22	68
+50% Cut-off	90	1	89	0	90	2	88

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	15	0	1	14	0	15
15	15	15	0	0	15	0	15

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	25	5	25	5
Cut-off	30	17	13	13	17	13	17	14	16
+25% Cut-off	30	5	25	4	26	7	23	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	24	6	27	3	20	10
Cut-off	30	19	11	14	16	14	16	19	11
+25% Cut-off	30	3	27	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		MOP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	23	7	20	10	27	3
Cut-off	30	18	12	13	17	18	12	17	13
+25% Cut-off	30	5	25	8	22	10	20	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4	24	6	25	5
Cut-off	30	17	13	18	12	14	16	17	13	18	12
+25% Cut-off	30	4	26	6	24	6	24	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **Reditest® RediCup® substance abuse screening device** at 5 minutes.

Compound	**ng/mL**
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100

Compound	ng/mL
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8–THC	15,000
Δ^9–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000

Compound	ng/mL
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Reditest® RediCup® substance abuse screening device** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Reditest® RediCup® substance abuse screening device**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **Reditest® RediCup® substance abuse screening device** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine
Acetophenetidin	Deoxycorticosterone	Labetalol	Quinacrine
N-Acetylprocainamide	Dextromethorphan	Loperamide	Quinine
Acetylsalicylic acid	Diclofenac	Meperidine	Quindine
Aminopyrine	Diflunisal	Meprobamate	Rantidine*
Amoxicillin	Digoxin	Methoxyphenamine	Salicylic acid
Ampicillin	Diphenhydramine	Methylphenidate	Serotonin
l-Ascorbic acid	l -Ψ-Ephedrine	Nalidixic acid	Sulfamethazine
Apomorphine	β-Estradiol	Naproxen	Sulindac
Aspartame	Estrone-3-sulfate	Niacinamide	Tetracycline
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Tetrahydrocortisone
Benzilic acid	l (-)-Epinephrine	Norethindrone	3-acetate
Benzoic acid	Erythromycin	Noscapine	Tetrahydrocortisone
Benzphetamine*	Fenoprofen	d,l-Octopamine	3-(β-D-glucuronide)
Bilirubin	Furosemide	Oxalic acid	Tetrahydrozoline
d,l-Brompheniramine	Gentisic acid	Oxolinic acid	Thiamine
Caffeine	Hemoglobin	Oxymetazoline	Thioridazine
Cannabidol	Hydralazine	Papaverine	d,l-Tyrosine
Chloralhydrate	Hydrochlorothiazide	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrocortisone	Pentazocine	Triamterene
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	Trifluoperazine
d,l-Chlorophenirmine	p-Hydroxytyramine	Phenelzine	Trimethoprim
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo	Tryptamine
Cholesterol	Iproniazid	propylamine	d,l-Tryptophan
Clonidine	d,l-Isoproterenol	Prednisolone	Uric acid
Cortisone	Isoxsuprine	Prednisone	Verapamil
l-Cotinine	Ketamine	d,l-Propranolol	Zomepirac

*Parent compound only.

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REDWOOD TOXICOLOGY LABORATORY

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