



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 or
PO Box 104480
Jefferson City Mo 65110 - 4480

(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 2-9-11
PRINTED NAME Melissa A. Waterhouse		TITLE VP & Chief Compliance Officer, Corporate Secretary
COMPANY NAME American Bio Medica Corporation		
MAILING ADDRESS 122 Smith Road		
CITY, STATE, ZIP Kinderhook, NY 12106		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 14-1702188
PHONE NO. (518)758-8158.	FAX NO. (518)758-8171	E-MAIL ADDRESS info@abmc.com

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS: AS SUBMITTED IN ITS ENTIRETY		
CONTRACT NO. OSCA 11-029-01	CONTRACT PERIOD July 1, 2011 through JUNE 30, 2012	
CONTACTS COORDINATOR 	DATE 2-23-2011	STATE COURTS ADMINISTRATOR



February 9, 2011

Office of State Courts Administrator
Contracts Unit
2112 Industrial Drive
Jefferson City, MO 65109
Attn: Mr. Russell Rottmann

Re: RFP No. OSCA 11-029-00, Drug/Alcohol Testing Equipment & Services

Dear Mr. Rottmann

American Bio Medica Corporation (ABMC) welcomes the opportunity to provide cost-effective and reliable drug testing products in response to Solicitation No RFP OSCA 11-029-00, Drug/Alcohol Testing Equipment & Services (the "Solicitation") for the Office of State Courts Administration (OSCA). ABMC will be responding to the On-Site Drug Testing Kits Non-Instrument Based Immunoassay portion of the RFP only.

ABMC is a leading provider of rapid-result tests to government entities, including criminal justice systems. We offer testing products that are easy to perform and interpret, providing accurate results within minutes. We offer a large array of assays from which to select your panel¹.

ABMC offers comprehensive training and support services. We consider ourselves a partner in the drug testing process and we fully support our customers to ensure that the products are being used in the most effective manner. Our goal is to provide a drug testing system that works to meet your goals.

ABMC is ISO 13485, 2003 and ISO 9001, 2008 certified, ensuring that high quality standards are maintained. ABMC's world headquarters, located in Kinderhook, NY, is a 30,000 square foot medical device facility and is compliant with FDA's Quality System Regulations (QSR's). Our research and development facility, located in Logan Township, NJ, is also QSR compliant.

In addition to the product being offered to The OSCA in response to the Solicitation, ABMC offers oral fluid tests for those instances in which gender may be an issue with an observed collection, and the Rapid Reader®, a device that can be connected to your computer via a USB port. The Rapid Reader is a FDA cleared all inclusive result interpretation and data management system; and it virtually eliminates subjectivity from result interpretation.

If the OSCA is in need of clarification or additional information regarding this proposal, please feel free to contact either person below:

Sheila Powers
Sale Representative
Email: spowers@abmc.com
800-227-1243 ext 126
Fax: 518-758-8169

Melissa A Waterhouse
VP & Chief Compliance Officer, Corporate Secretary
Email: mdwaterhouse@abmc.com
800-227-1243 ext 107
Fax: 518-758-8171

Regards,

Melissa Waterhouse
VP & Chief Compliance Officer,
Corporate Secretary

¹ Although the OSCA has requested an onsite drug testing kit that tests for synthetic cannabinoids, ABMC is unaware of any onsite drug test that currently tests for this compound, including any ABMC onsite drug test.



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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

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PRINTED NAME Melissa A. Waterhouse		TITLE VP & Chief Compliance Officer, Corporate Secretary
COMPANY NAME American Bio Medica corporation		
MAILING ADDRESS 122 Smith Road,		
CITY, STATE, ZIP Kinderhook, NY 12106		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 14-1702188
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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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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.

OSCA 11-029-00 Drug/Alcohol Testing Equipment & Services

- 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.

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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

OSCA 11-029-00 Drug/Alcohol Testing Equipment & Services

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 systems – 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.

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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 not 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 X 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.

<u>Rapid TOX® Single Panels</u>	Product name	\$ <u>1.14-2.00</u>	firm, fixed price per each unit
<u>Rapid TOX® 2 Panel</u>	Product name	\$ <u>1.75</u>	firm, fixed price per each unit
<u>Rapid TOX® 3 Panel</u>	Product name	\$ <u>1.80</u>	firm, fixed price per each unit
<u>Rapid TOX® 4 Panel</u>	Product name	\$ <u>2.00</u>	firm, fixed price per each unit
<u>Rapid TOX® 5 Panel</u>	Product name	\$ <u>2.25</u>	firm, fixed price per each unit
<u>Rapid TOX® 6 Panel</u>	Product name	\$ <u>2.75</u>	firm, fixed price per each unit
<u>Rapid TOX® 7Panel</u>	Product name	\$ <u>3.00</u>	firm, fixed price per each unit
<u>Rapid TOX® 8 Panel</u>	Product name	\$ <u>3.25</u>	firm, fixed price per each unit
<u>Rapid TOX® 9 Panel</u>	Product name	\$ <u>3.45</u>	firm, fixed price per each unit
<u>Rapid TOX® 10 Panel</u>	Product name	\$ <u>3.75</u>	firm, fixed price per each unit
<u>RDS(kit) 2 Panel</u>	Product name	\$ <u>2.79</u>	firm, fixed price per each unit
<u>RDS(Card Only) 2 Panel</u>	Product name	\$ <u>1.95</u>	firm, fixed price per each unit
<u>RDS(kit) 3 Panel</u>	Product name	\$ <u>3.44</u>	firm, fixed price per each unit
<u>RDS(Card Only) 3 Panel</u>	Product name	\$ <u>2.45</u>	firm, fixed price per each unit
<u>RDS(kit) 4 Panel</u>	Product name	\$ <u>4.34</u>	firm, fixed price per each unit
<u>RDS(Card Only) 4 Panel</u>	Product name	\$ <u>2.95</u>	firm, fixed price per each unit
<u>RDS(kit) 5 Panel</u>	Product name	\$ <u>5.48-6.00</u>	firm, fixed price per each unit
<u>RDS(Card Only) 5 Panel</u>	Product name	\$ <u>3.50</u>	firm, fixed price per each unit
<u>RDS(kit) 8 Panel</u>	Product name	\$ <u>9.23</u>	firm, fixed price per each unit
<u>RDS(Card Only) 8 Panel</u>	Product name	\$ <u>6.75</u>	firm, fixed price per each unit
<u>RDS(kit) 9 Panel</u>	Product name	\$ <u>10.97</u>	firm, fixed price per each unit

OSCA 11-029-00 Drug/Alcohol Testing Equipment & Services

RDS(kit) 10 Panel Product name \$ 11.75 firm, fixed price per each unit
OralStat: Oral Fluid (Saliva) Drug Screen (6) Product name \$ 8.95 firm, fixed price per each unit
OralStat: Oral Fluid (Saliva) Drug Screen (10) Product name \$ 9.95 firm, fixed price per each unit

(*An additional charge of \$0.75 will be added to the price per unit if the cup, tamp seal, & bag are needed)**

Electronic Alcohol Monitoring

Pricing per participant

per day: N/A

per week: n/a

per month: N/a

Is there a minimum number of days? Yes _____ No _____ N/A

If yes, please indicate number of days: _____

Deposit or Start Up fee required? Yes _____ How much? _____ No _____ N/A

Please list system requirements, such as single land phone line, water resistance, range of coverage etc:

_____ N/a

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.

American Bio Medica Corporation (ABMC) is a publicly traded biotechnology company, incorporated in 1986, and has been providing workplace, government, corrections, clinical, and educational markets accurate, cost effective, immunoassay diagnostic point of collection test kits for drugs of abuse since 1996. ABMC's headquarters located in Kinderhook, New York is a 30,000 square foot medical device facility, compliant with FDA's Quality System Regulations (QSR). ABMC's research and development facility is located in Logan Township, New Jersey and is also QSR compliant.

- b. Describe the nature of the vendor's business, type of services performed, etc.

ABMC develops, manufactures and markets high quality point of collection, rapid immunoassay test kits for the detection of drugs of abuse in urine and oral fluids. ABMC offers one of the most comprehensive portfolios of self-contained, easy to use drug screening devices with the widest menu selection available. This allows the user to customize their drug-testing program to be more in-line with local trafficking and drug use trends as well as individual testing needs. We work with many county, state and federal agencies and consider ourselves a partner in the drug testing process by providing each customer with the necessary support to ensure that the products are being used in the most effective manner. Because of our extensive experience and knowledge in matters of drug testing, we can assist the customer in determining the best product configuration to make their drug-testing program extremely effective both in process and cost. Our goal is to provide a drug testing system that works to meet your goals.

- 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. ABMC has thousands of customers, some of which order through a contractual relationship, while others order via binding purchase orders. In addition to the references provided, ABMC also provides products to a number of local, county and state agencies. ABMC typically gains business as a result of our product quality, the ease of use of our products and customer and technical support. ABMC typically loses business due to cost when competing against foreign manufacturers. 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.

ABMC is a publicly traded corporation. Our corporate structure consists of a Board of Directors, which serves in an oversight capacity. The day-to-day operations of the company are handled by its officers (i.e. Chief Executive Officer, Chief Financial Officer, ad Chief Compliance Officer, EVP Operations and Vice President, Sales & Marketing). ABMC does not have any subsidiaries.

- 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.

ABMC does not have any pending litigation, any civil or criminal judgments, any bankruptcy proceeding, or any other issues that could affect our ability to perform.

- 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.

As previously noted, ABMC is a public company and therefore, our financials, both audited and unaudited, are a matter of public record. ABMC has a strong balance sheet and is financially solvent. A copy of our annual report for the year ended December 31, 2009 is included as a part of our submission to this RFP. As previously noted, ABMC is not a subsidiary, nor do we have any subsidiaries.

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: <u>American Bio Medica Corporation</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Joan Sakaba Hawaii Adult Probation
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	777 Punchbowl Street, 1st Floor Honolulu HI, 96813
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Joan Sakaba 808-539-4510 Joan.L.Sakaba@courts.state.hi.us
Dates of Prior Services:	ABMC customer since May 2001
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Provide Drug testing kits

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

EXHIBIT B

CONFIDENTIAL

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: <u>American Bio Medica Corporation</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Mary Stoddard 30 th Circuit Youth Services
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	211 W Walnut Bolivar MO 65613
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Mary Stoddard 417-777-8530
Dates of Prior Services:	ABMC customer since April 2000
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Provide Drug testing kits

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

CONFIDENTIAL

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: <u>American Bio Medica Corporation</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Linda Cape County Juvenile Office
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	44 N. Lorimier St., Suite E CAPE GIRARDEAU, MO 63701-7314
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Linda (573) 334-6001
Dates of Prior Services:	ABMC customer since October 2009
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Provide Drug testing kits

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
Signature

Date of

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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. <u>Sheila Powers</u> (Name) <u>Sales Representative</u> (Title) <u>Sales Rep./management of daily account activities.</u> (Proposed Role/Function)	If awarded, Sheila Powers will be the state of Missouri OSCA point of contact. Her role as the OSCA representative will include all necessary training and correspondence to ensure efficient and direct contract management. Ms. Powers has approximately 5 years of sales experience and also has a background in customer service.
2. <u>Whitney Cipkowski</u> (Name) <u>Customer Service Representative</u> (Title) <u>Customer Service/ assists Sales Rep.</u> (Proposed Role/Function)	Ms Cipkowski will work directly with Ms. Powers to ensure effective and efficient management of your account. Ms. Cipkowski has over 3 years experience in customer service and has extensive knowledge of ABMC products which enables her to answer any questions customers may have about our products and services.
3. <u>Melissa Waterhouse</u> (Name) <u>VP & CCO, Corp. Secretary</u> (Title) <u>Contract Contact</u> (Proposed Role/Function)	Ms. Waterhouse will be the contract administrator for account. As contract administrator, Ms. Waterhouse will manage all contractual requirements and issues between Missouri OSCA and ABMC. Ms. Waterhouse has over 10 years experience implementing and managing contracts, both private and public in nature.
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.

******NA (indicates not applicable as ABMC is only responding to the On-Site Drug Testing Kits Non-Instrument Based Immunoassay (both urine and saliva) portion of this RFP).**

1. Describe what is provided with which to collect the each sample (cups, chain of custody forms, mailing packets).
 - a. **Each product proposed by ABMC would include a collection cup with an integrated temperature strip, and tamper evident seal.**
2. Describe the instruction or training provided to treatment court staff pertaining to properly collecting a sample and completing necessary documentation.
 - a. **ABMC offers each customer a variety of different training methods, including web based product training with certification, webcast/teleconference training, and on site product training.**
3. Describe how the sample is transported to the testing laboratory (U S Postal, Fed Ex, UPS, etc.).
N/A*
4. Describe the methods of testing which are employed (LC/MS/MS, GS/MS, LC/MS, and/or Immunoassay methods).
N/A *
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

Compound	Test Abbreviation	Level (ng/mL)
Amphetamines (d-amphetamine sulfate)	AMP	500 1000 *
Barbiturates (butalbital)	BAR	300
Benzodiazepines (oxazepam)	BZO	300
Buprenorphine	BUP	12.5
Cocaine (benzoylecgonine)	COC	150 300 *
MDMA ((+/-) 3,4-methylenedioxy-methamphetamine) (Ecstasy)	MDMA	500 1000
Methadone	MTD	300
Methamphetamines ((+)-methamphetamine HCl)	MET	500 1000
Opiates (morphine-3-b-D-glucuronide)	OPi	300 2000 *
Oxycodone	OXY	100
Phencyclidine (phencyclidine HCl)	PCP	25 *
Propoxyphene	PPX	300
THC/ Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid)	THC	50 *
Tricyclic Antidepressants (nortriptyline)	TCA	1000
Specimen Validity Tests: pH, Specific Gravity, Oxidants	SVT	3 Panel

ABMC offers fourteen different drugs of abuse assays at various cutoff levels. Where applicable the cutoff levels are in accordance with the current Substance Abuse and Mental Health Services Administration's (SAMHSA) guidelines. ABMC offers Opiates for both 2000 ng/mL and 300 ng/mL cut-off levels and Benzodiazapines and Barbiturates at a cut- off level of 300 ng/mL. A complete listing of our cut-off levels can be found in the chart on the left.

6. Describe the turnaround time for results.
 - a. **The ABMC products offered provide results in three to five (3-5) minutes.**
7. Describe how test results will be reported (telephone, fax, or e-mail).
 - a. **The products offered in this RFP are rapid result, lateral flow immunoassay Point of Collection products that test for the presence or absence of drugs in a urine or oral fluid specimen. Once the specimen is collected and the test is administered, the test channel should reveal results within three to five minutes. The test results may be interpreted once the control lines have formed and the background on the test strips have cleared. The presence of a reddish-purple line adjacent to any of the drug abbreviations listed on the test indicates the absence of a drug in the specimen. If after five minutes no line forms adjacent to a particular drug, then this indicates a "non-negative", or positive, result for that drug. The test results are stable for up to four hours. Apart from the procedure noted above, there is no further reporting (telephone, fax, or email) as ABMC is not providing testing services.**
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.

A copy of our organizational chart can be found attached to this Exhibit D.
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.

ABMC customers are managed through a network that begins with the Vice President of Sales and Marketing. If awarded to ABMC, this contract would be handled by ABMC's Sales Representative for the state of Missouri, Sheila Powers, along with the assistance of dedicated Customer Service Representative, Whitney Cipkowski. Ms Cipkowski would supervise all aspects of the customer relationship, including but not limited to order processing, product shipment, and potential questions related to products.
 - 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.

As the enclosed organizational chart depicts, ABMC has a strong sales and marketing department. Although specific personnel would be directly responsible for performance under this contract, any and all resources within the sales and marketing department and throughout ABMC's organization would be available to the State of Missouri if necessary to ensure the completion of all requirements under the contract on time and on target. While ABMC has many other ongoing contracts that also require personnel resources, ABMC has more than sufficient personnel resources so these additional requirements will not affect ABMC's ability to perform under the contract with 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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 applicable.
- 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.

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- 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.

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- 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.

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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.

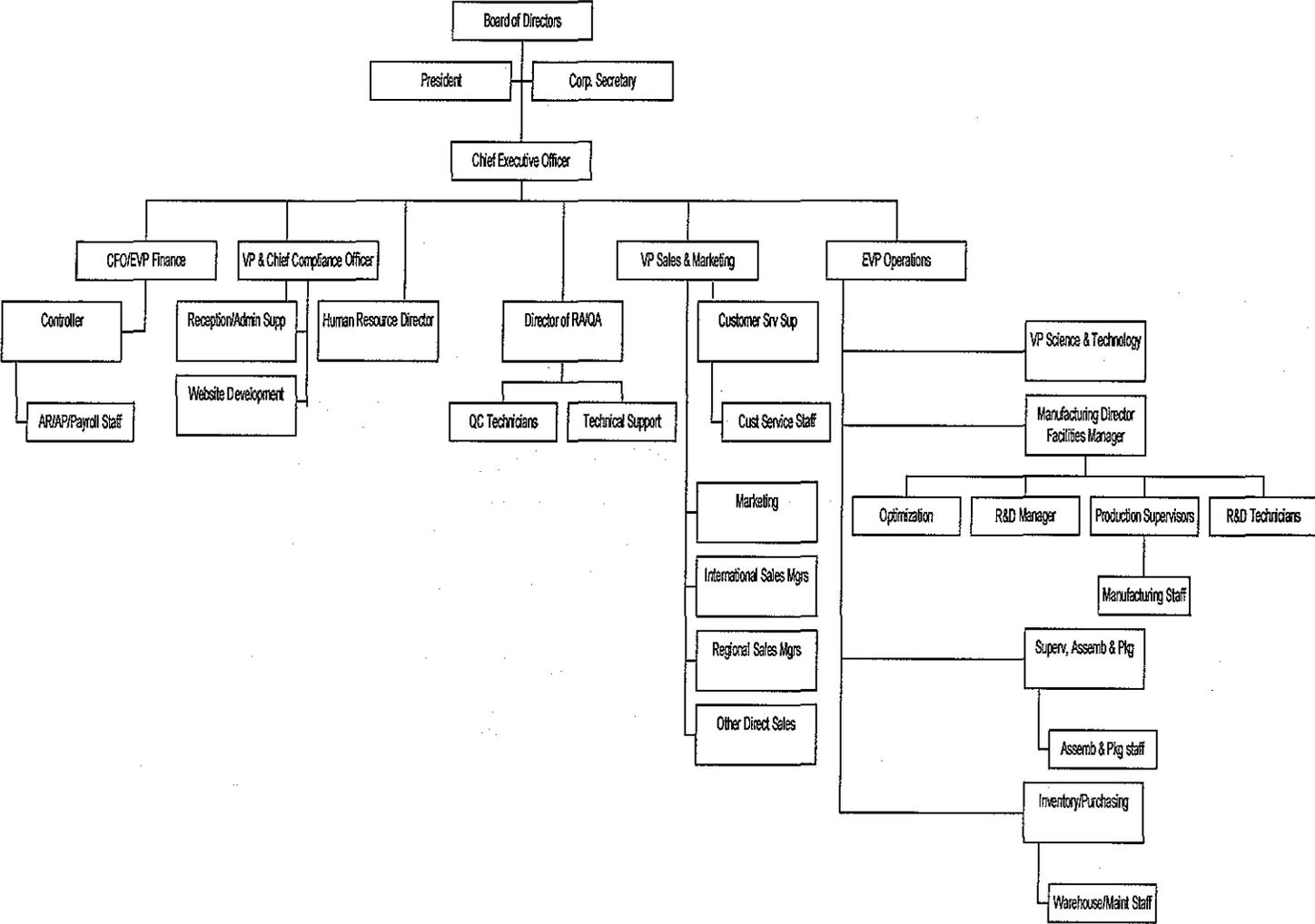
21. AMERICANS WITH DISABILITIES ACT

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.

American Bio Medica Corporation
Organizational Chart-February 2011



14992033

JUN 30 1999

Attachment D

510(k) Summary

Submitter's Name/Address:

American BioMedica Corporation
300 Fairview Avenue
Hudson, NY 12534

Contact Person:

Henry J. Wells, Ph.D.
Vice President of
Product Development
Phone: (410) 992-9357
Fax: (410) 992-0328

Date of Preparation of this Summary:

June 1999

Device Trade or Proprietary Name:

'Rapid Drug Screen' 9-Panel

Device Common/Usual Name or Classification Name: Rapid Drug Screen 9-Panel

Classification Number/Class:

[no classification number]/Class II

This 510(k) Summary is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

The assigned 510(k) is: _____

Predicate Devices: American BioMedica 'Rapid Drug Screen' 9-Panel test kit (510(k) No. K983770) and Biosite Diagnostics' Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants (510(k) No. K955935).

Test Description:

All of the assays employed in the Rapid Drug Screen 9-Panel are based on the same principle of the highly specific reaction between antigens and antibodies.

Each assay is a one-step, immunoassay in which a specially-labeled drug (drug conjugate) competes with drug which may be present in the sample for the limited number of binding sites on an antibody. The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of a visible line in the test area occurs when the test is negative.

When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the test area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine, and therefore, should be present in all reactions.

A negative urine will produce two colored bands, and a positive sample will produce only one band.

Intended Use:

The Rapid Drug Screen 9-Panel test is used for the qualitative detection of d-amphetamine; barbiturates; benzodiazepines; benzoyl ecognine; cannabinoids; d-methamphetamine; opiates; phencyclidine (PCP); and tricyclic antidepressants in human urine. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas-chromatography/mass spectrometry (GC/MS).

Performance Characteristics:

'Rapid Drug Screen' 9-Panel will detect 9 drugs in human urine at the following levels:

d-Amphetamine	750 ng/ml
Barbiturates	300 ng/ml
Benzodiazepines	300 ng/ml
Benzoyl ecognine	225 ng/ml
Cannabinoids	
(11-nor-9-carboxy-delta-9-THC)	50 ng/ml
Methamphetamine	1000 ng/ml
Opiates (codeine)	225 ng/ml
(morphine-3-glucuronide)	225 ng/ml
Phencyclidine (PCP)	19 ng/ml
Tricyclic antidepressants	1000 ng/ml

'Rapid Drug Screen' 9-Panel was compared to the previously 510(k) cleared 'Drug Screen' 9-Panel (510(k) No. K983770) and Biosite Triage Plus TCA tests. Ninety (90) samples were selected for evaluation, fifty (50) of which were found to be drug-free and forty (40) tested as positive by Syva EMIT-II. The forty positive specimens were identified but not quantified by HPLC. Both immunoassays correctly identified all of the

specimens which contained no drug as negative and determined the 40 drug-containing specimens to be positive.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. The results confirmed the reproducibility of the Rapid Drug Screen 9-Panel performance.

Conclusion:

The Rapid Drug Screen 9-Panel test is substantially equivalent to the previously-cleared 'Rapid Drug Screen' 9-Panel test (510(k) No. K983770) and the Triage® Panel for Drugs of Abuse plus Tricyclic Antidepressants (510(k) No. K955935), as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 30 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

American Bio Medica
c/o Mr. John B. Dubeck, Esq.
Keller and Heckman LLP
1001 G Street NW, Suite 500W
Washington, DC 20001

Re: K992033
Trade Name: 'Rapid Drug Screen' 9-Panel
Regulatory Class: II
Product Code: DKZ, DIS, JXM, DJG, DIO, LDJ, LAF, LCL, LFG
Dated: June 16, 1999
Received: June 16, 1999

Dear Mr. Dubeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

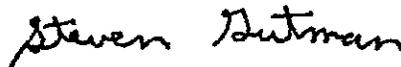
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 992033

Device Name: "Rapid Drug Screen" 9-Panel

Indications For Use:

'Rapid Drug Screen' 9-Panel is a one-step, lateral flow immunoassay for the simultaneous detection of 8 abused substances and tricyclic antidepressants in urine. The "Rapid Drug Screen" 9-Panel test is intended for use in the qualitative detection of the following 9 drugs in human urine at the following levels:

d-Amphetamine	750 ng/ml
Barbiturates	300 ng/ml
Benzodiazepines	300 ng/ml
Benzoyl ecognine	225 ng/ml
Cannabinoids	
(11-nor-9-carboxy-delta-9-THC)	50 ng/ml
Methamphetamine	1000 ng/ml
Opiates (codeine)	225 ng/ml
(morphine-3-glucuronide)	225 ng/ml
Phencyclidine (PCP)	19 ng/ml
Tricyclic Antidepressants	1000 ng/ml

'Rapid Drug Screen' 9-Panel is intended for use by professional laboratories. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas-chromatography/mass spectrometry (GC/MS).

'Rapid Drug Screen' 9-Panel provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a more confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 992033

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 2006

American BIO Medica Corp.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k053359
Trade/Device Name: RapidTox™
Regulation Number: 21 CFR§ 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, DIO, DJC, DJR, DJG, JXN, LDJ, LFG, LCM
Dated: May 9, 2006
Received: May 11, 2006

Dear Ms. White:

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.

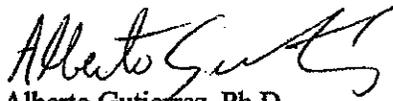
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 -

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

Indications for Use

510(k) Number (if known): K053359

Device Name: RapidTox™

Indications For Use:

The RapidTox™ is a one-step, lateral flow immunoassay for the simultaneous detection of up to ten abused drug analytes in urine (each analyte is represented by a line in the test window of the cassette).

Rapid Tox is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Compound	Test Abbreviation	Level (ng/ml)
Amphetamine (d-amphetamine sulfate)	AMP	1000
Barbiturates (secobarbital)	BAR	300
Benzodiazepine (oxazepam)	BZO	300
Cocaine (benzoylecgonine)	COC	300
MDMA ((+/-)3,4-methylenedioxy-methamphetamine) (Ecstasy)	MDMA	1000
Methadone	MTD	300
Methamphetamine ((+/-)methamphetamine HCl)	MET	1000
Opiates (morphine-3-b-D-glucuronide)	OPI	300 2000
Oxycodone	OXY	100
Phencyclidine (phencyclidine HCl)	PCP	25*
Propoxyphene/Norpropoxyphene	PPX	300
THC/Cannabinoids (11-nor- Δ^9 -THC-9-carboxylic-acid)	THC	50*
Tricyclic Antidepressants (nortriptyline)	TCA	1000

Rapid Tox provides only a preliminary analytic test result. More specific alternative chemical methods must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.

The Test is recommended for professional use. It is not intended for over-the-counter sales to nonprofessionals.

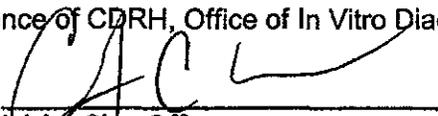
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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)

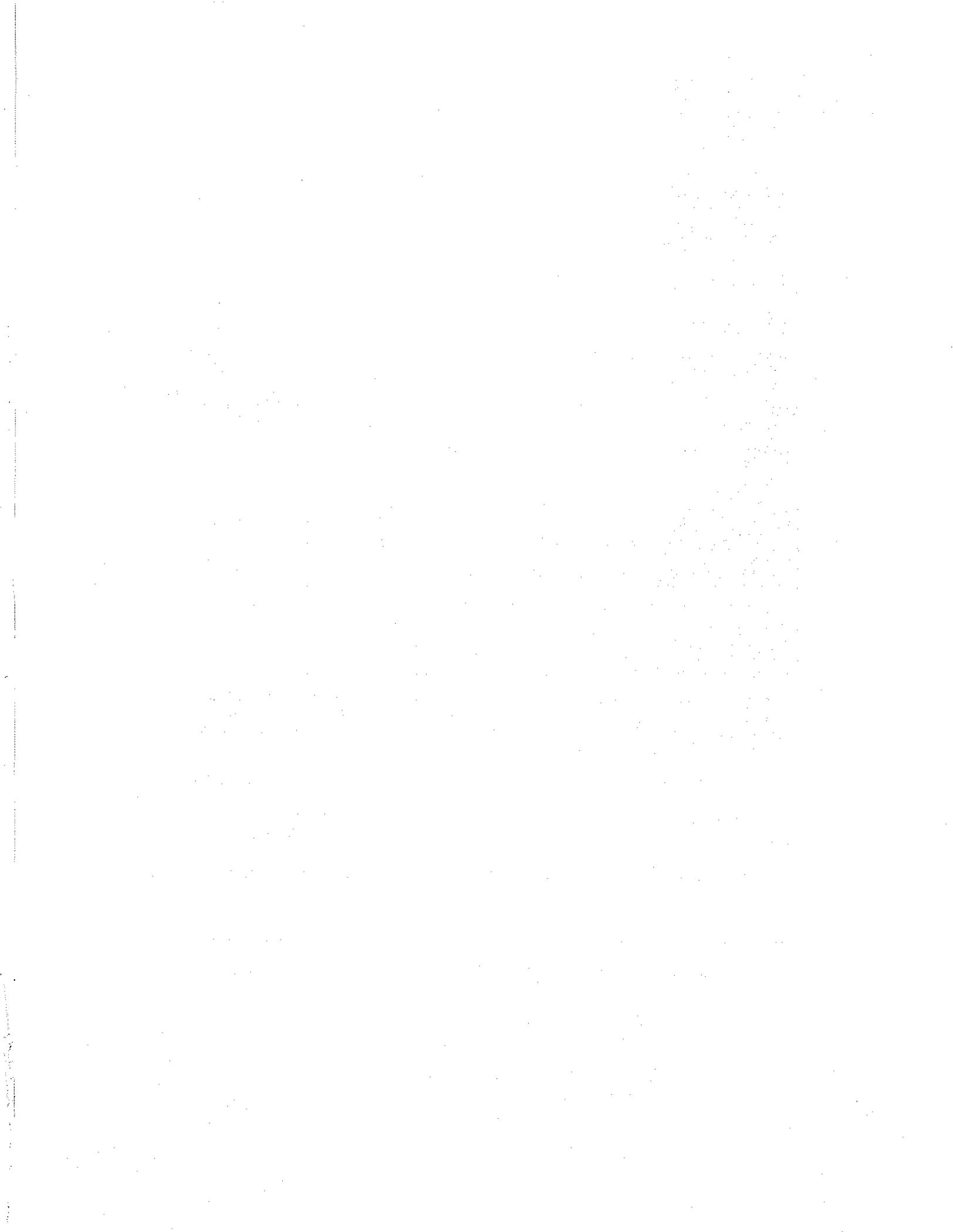

Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)

K053359



MAY 22 2003

K030835

510 (k) Summary

Submitter's Name/Address:

American Bio Medica Corportion
122 Smith Road
Kinderhook, NY 12106

Contact Person:

Henry Wells
VP Product Development
Phone: 410 992-4734
Fax: 410 992-0328

Date of Preparation of this Summary:

March 12, 2003

Device Trade or Proprietary Name:

'Rapid One'-Propoxyphene Test

**Device Common/Usual Name or
Classification Name:**

Propoxyphene Test System

Classification Number/Class:

[no classification regulation]/Class II

This 510(k) Summary is being submitted in accordance with the requirement of 21 CFR 807.92.

The assigned 510(k) number is: K030835

Predicate Device: MedTox Diagnostics, Inc. 2-Panel Propoxyphene/MAMP-MDMA Test. (510 (k) No. K002141).

Test Description:

The assay employed in the 'Rapid One'-Propoxyphene Test is based on the same principle of highly specific reactions between antigens and antibodies.

This assay is a one-step, competitive, immunoassay for the detection of propoxyphene and its metabolite norpropoxyphene in human urine. The test device consists of a membrane strip onto which a drug conjugate has been immobilized and a colloidal gold-multi-antibody complex is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody complex moves with the urine by capillary action to contact the immobilized drug conjugates. Antibody-antigen reactions occur forming visible lines in the 'test' area.

When drug is present in the urine sample, the drug or metabolite will compete with its corresponding drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex. If sufficient amount of drug is present, it will fill all of the available antibody binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the 'test' area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine, and therefore, should be present on all reactions.

A negative urine will produce two colored bands, and a positive sample will produce only one band.

Intended use:

'Rapid One'-Propoxyphene Test is used for the qualitative detection of propoxyphene and norpropoxyphene in human urine. This immunoassay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas chromatography/mass spectrometry (GC/MS.)

Performance Characteristics:

'Rapid One'-Propoxyphene Test will detect propoxyphene or norpropoxyphene at 300 ng/ml.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. All concentrations were verified by GC/MS. Each sample was tested four times, twice daily, for five days. The results confirmed the reproducibility of the 'Rapid One'-Propoxyphene Test performance.

Conclusion:

'Rapid One'-Propoxyphene Test is substantially equivalent to the previously cleared propoxyphene section of MedTox 2 Panel PPX/MAMP-MDMA Test (510(k) No. K002141).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Henry Wells
Vice President Product Development
American Bio Medica Corporation
9110 Red Branch Road
Suite B
Columbia, Maryland 21045

MAY 22 2003

Re: k030835
Trade/Device Name: Rapid One – Propoxyphene Test
Regulation Number: 21 CFR § 862.3700
Regulation Name: Propoxyphene Test System
Regulatory Class: II
Product Code: JXN
Dated: March 14, 2003
Received: March 17, 2003

Dear Dr. Wells:

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.

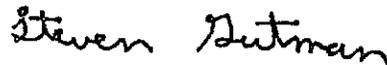
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

Page 2 –

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

Enclosure

510(k) Number (if known): K030835

Device Name: _____

Indications For Use:

'Rapid One'-Propoxyphene Test

'Rapid One'-Propoxyphene Test is a one-step lateral flow immunoassay for the qualitative detection of 300 ng/ml of propoxyphene and norpropoxyphene in human urine.

'Rapid One'-Propoxyphene Test is intended for professional use. It is not intended for over-the-counter sales to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified, qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas chromatography/mass spectrometry (GC/MS.)

'Rapid One'-Propoxyphene Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result. Particularly when preliminary results are used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use 510(k)
(Per 21 CFR 801.109)

K030835
OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

MAY 27 2004

6

SECTION II

510(k) SUMMARY

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

510(k) Number: K040411

Submitter:

Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Contact Person:

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Preparation Date:

February 17, 2004

Device Information:

Device Classification Name:	Radioimmunoassay, Oxycodone
Common/Usual Name:	Oxycodone Immunoassay Test System
Proprietary Name:	DRI [®] Oxycodone Assay
Regulation Number:	21 CFR§862.3650
Regulatory Name:	Oxycodone test system
Product Code:	DJG
Regulatory Class:	Class II

Predicate Devices:

The DRI[®] Oxycodone Assay is substantially equivalent to the Rapidone-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use.

Device Description:

The DRI[®] Oxycodone Assay is supplied as liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect oxycodone and oxymorphone without significant cross-reactivity to other opiate compounds. The assay is based on competition between oxycodone labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free oxycodone present in the urine sample for a fixed amount of specific antibody binding sites. In the absence of free oxycodone in the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use:

The DRI[®] Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative detection of oxycodone in human urine.

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

Comparison to Predicate Device(s):

The information provided in this pre-market notification demonstrates that the DRI[®] Oxycodone Assay is substantially equivalent to the RapidOne-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use.

Device Characteristics	Subject Device	Predicate Device (K014101)
Intended Use	<p>The DRI[®]Oxycodone Enzyme Immunoassay is intended for the qualitative and semi-quantitative detection of oxycodone in human urine.</p> <p>The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.</p>	<p>RapidOne-OXY Test is a one-step, lateral flow immunoassay for detection of oxycodone in urine.</p> <p>RapidOne-OXY Test is intended for the qualitative detection of oxycodone in human urine at 100 ng/mL.</p> <p>RapidOne-OXY Test is intended for professional use. It is not intended for over the counter sales to non-professionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional confirmatory testing, i.e., gas chromatography/mass spectrometry (GC/MS).</p> <p>The RapidOne-OXY Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a more confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.</p>
Analyte	Oxycodone	Oxycodone
Matrix	Urine	Urine
Calibrator Form	Liquid	None
Calibrator Levels	Five (5) Levels (0, 100, 300, 500 and 1000 ng/mL)	None
Storage	2°C to 8°C until expiration date	Room temperature or refrigerated (2 to 8°C).
Stability	Until expiration date noted on vial label and Package Insert for Kit and reconstituted reagents.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the DRI[®] Oxycodone Assay is substantially equivalent to the Rapidone-Oxy Test (K014101) manufactured by American Bio Medica Corp (Columbia, MD) for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by gas chromatography/mass spectrometry, an independent analytical method.. The information supplied in this pre-market notification provides reasonable assurance that the DRI[®] Oxycodone Assay is safe and effective for its stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 27 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Microgenics Corp.
46360 Fremont Blvd
Fremont, CA 94538

Re: k040411
Trade/Device Name: DRI[®] Oxycodone Assay
DRI[®] Oxycodone Calibrators
DRI[®] Oxycodone Controls
Regulation Number: 21 CFR 862.3650
Regulation Name: Lithium test system
Regulatory Class: Class II
Product Code: LAS, DLJ, DJG
Dated: February 17, 2004
Received: March 2, 2004

Dear Dr. Casal:

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.

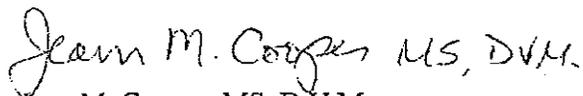
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2

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,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

K040411

510(k) Number (if known): ~~K040411~~

Device name: DRI® Oxycodone Assay

Indications for Use:

The DRI® Oxycodone Assay is intended to be used for the qualitative and semi-quantitative determination of the presence of oxycodone in human urine at cutoffs of 100 and 300 ng/mL. The assay provides a simple and rapid analytical screening procedure to detect oxycodone in human urine.

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

The DRI® Oxycodone Calibrators are used to calibrate the DRI® Oxycodone Assay in human urine.

The DRI® Oxycodone Controls are used to qualify the DRI® Oxycodone Assay in human urine.

Prescription Use X
(Part 21 CFR §801 Subpart D)

AND/OR

Over-the Counter Use _____
(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)

Alberto Soto
Division Sign-Off

Page 1 of ____

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040411

NOV 26 2001

K013180

510(k) Summary

Submitter's Name/Address:
American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106

Contact Person:
Henry Wells
VP Product Development
Phone: 518 758 8158
Fax: 518-758 8171

Date of Preparation of this Summary:

September 21, 2001

Device Trade or Proprietary Name:

'RapidOne'-Ecstasy' Test

**Device Common/Usual Name or
Classification Name:**

MDMA test system

Classification Number/Class

[no classification regulation]/ClassII

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K013180

Predicate Device: MedTox Diagnostics, Inc., Verdict II-Methamphetamine Test.
(510(k) No. K-010226).

Test Description:

The assay employed in the 'RapidOne'-Ecstasy' Test is based on the same principle of highly specific reaction between antigens and antibodies.

This assay is a one-step, immunoassay in which a specially labeled drug (drug conjugate) competes with drug that may be present in the sample for the limited number of binding sites on the antibody. The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of a membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of a visible line in the 'test' area occurs when the test is negative.

When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-antibody complex. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug

conjugate. An absence of a color band (line) in the 'test' area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The 'control' line is not influenced by the presence or absence of drug in the urine, and therefore, should be present in all reactions.

Intended use:

'RapidOne'-Ecstasy' Test is used for the qualitative detection of MDMA in human urine. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., GC/MS.

Performance Characteristics:

'RapidOne'-Ecstasy' Test will detect 1000 ng/ml of MDMA in urine.

'RapidOne'-Ecstasy' Test was compared to MedTox Verdict II-Methamphetamine Test. One hundred (100) samples were selected for evaluation. Of the 100 specimens, fifty (50) were found to be drug-free by Syva Emit II. Both immunoassays correctly identified all the specimens that contained no drug as negative. GC/MS analyses were performed on samples that were screened as positive for the amphetamine group. Specimens containing only MDMA (395 to 19496 ng/ml) were selected for this study. All specimens that contained MDMA concentrations of 1009 ng/ml or greater were found to be positive by both systems. Verdict II did determine three specimens which contained 816, 895 and 958 ng/ml as positive.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Eighty (80) replicates were run at each concentration.

Concentration (ng/ml)	#	RDS Result	
		Pos	Neg
No drug	80	0	80
500	80	8	72
750	80	40	40
1000	80	78	2
1250	80	80	0

Conclusion:

'RapidOne'-Ecstasy' Test is substantially equivalent to MedTox Verdict II-Methamphetamine Test for the qualitative detection of MDMA in human urine.

**Comparison Between 'RapidOne'-Ecstasy Test and MedTox Verdict II-
Methamphetamine Test**

	'RapidOne'	'Verdict II'
Intended Use:	For professional use	For professional use
Type of Assay	Lateral flow immunoassay	Lateral flow immunoassay
Analyte:	MDMA	MDMA
Cut-off	1000 ng/ml	1000 ng/ml
Sample Application:	Dipping in specimen	Specimen added dropwise
Assay time:	5-10 minutes	3-8 minutes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 2001

Mr. Henry Wells
V.P. Product Development
American Bio Medica Corporation
9110 Red Branch Road
Columbia, MD 21045

Re: k013180
Trade/Device Name: 'RapidOne-Ecstasy' Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC
Dated: September 21, 2001
Received: September 24, 2001

Dear Mr. Wells:

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.

Page 2 -

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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" (21 CFR 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013180

Device Name: 'RapidOne-Ecstasy' Test

Indications For Use:

'RapidOne-Ecstasy' Test is a one-step, lateral flow immunoassay for the detection of 3,4-methylenedioxymethamphetamine (MDMA, 'Ecstasy') at 1000 ng/ml in urine.

'RapidOne-Ecstasy'-Test is intended for the qualitative detection of MDMA in human urine.

'RapidOne-Ecstasy' Test is intended for professional use. It is not intended for over-the-counter sales to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified, qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas chromatography/mass spectrometry (GC/MS).

'RapidOne-Ecstasy' Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013180

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

NOV 20 2001

K012164

510(k) Summary

Submitter's Name/Address:
American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106

Contact Person:
Henry Wells
VP Product Development
Phone: 518 758 8158
Fax: 518-758 8171

Date of Preparation of this Summary:

September 21, 2001

Device Trade or Proprietary Name:

'RapidOne'-Methadone Test

**Device Common/Usual Name or
Classification Name:**

Methadone test system

Classification Number/Class

[no classification regulation]/ClassII

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K012164

Predicate Device: Forefront Diagnostics, Inc. 'InstaCheck' Drug Screen-Methadone Test. (510(k) No. K992325)

Test Description:

The assay employed in the 'RapidOne'-Methadone' Test is based on the same principle of highly specific reaction between antigens and antibodies.

This assay is a one-step, immunoassay in which a specially labeled drug (drug conjugate) competes with drug that may be present in the sample for the limited number of binding sites on the antibody. The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of a membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of a visible line in the 'test' area occurs when the test is negative.

When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-antibody complex. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the 'test' area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The 'control' line is not influenced by the presence or absence of drug in the urine, and therefore, should be present in all reactions.

Intended use:

'RapidOne'-Methadone Test is used for the qualitative detection of methadone in human urine. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., GC/MS.

Performance Characteristics:

'RapidOne'-Methadone Test will detect 300 ng/ml of methadone in urine.

'RapidOne'-Methadone Test was compared to 'InstaCheck'-Drug Screen-Methadone Test. Ninety (90) samples were selected for evaluation, fifty (50) of which were found to be drug-free and forty (40) tested as positive by Syva Emit II. The forty positive specimens were confirmed as positive and quantified by GC/MS. Both immunoassays correctly identified all the specimens that contained no drug as negative. GC/MS analyses were performed on samples that were screened as positive. Specimens, ranging in concentration of 146 to 1072 ng/ml were shown to be positive by both immunoassays.

Reproducibility was evaluated using control urines containing methadone concentrations above and below the stated cut-off. Forty (40) replicates were run at each concentration by three different operators.

Concentration (ng/ml)	#	RDS Result	
		Pos	Neg
No drug	120	0	120
150	120	6	114
225	120	106	14
375	120	120	0

Conclusion:

'RapidOne'-Methadone Test is substantially equivalent to Forefront Diagnostics, Inc. 'InstaCheck'-Methadone Test for the qualitative detection of methadone in human urine.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Henry Wells, Ph.D.
American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106

NOV 20 2001

Re: k012164
Trade/Device Name: 'RapidOne' – Methadone Test
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: September 28, 2001
Received: October 4, 2001

Dear Dr. Wells:

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.

Page 2 -

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 20 2001

510(k) Number (if known): K012164

'RapidOne'-Methadone Test
Device Name: _____

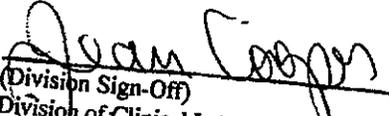
Indications For Use:

'RapidOne'-Methadone Test is a one-step, lateral flow immunoassay for the detection of methadone in urine.

'RapidOne'-Methadone Test is intended for the qualitative detection of methadone in human urine at 300 ng/ml.

'RapidOne'-Methadone Test is intended for professional use. It is not intended for over the counter sale to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas-chromatography/mass spectrometry (GC/MS).

'RapidOne'-Methadone Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012164

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use