Original

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

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

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

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

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

RETURN PROPOSAL TO:

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

or

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

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

DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:

MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI

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

SIGNATURE REQUIRED

AUTHORIZED SIGNATURE		DATE 2/8/11
PRINTED NAME Cecilia Rodriguez		TITLE Customer Service
COMPANY NAME Germaine Laboratories		
MAILING ADDRESS 11030 Wye Drive		
CITY, STATE, ZIP San Antonio, Tx 78217		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 74-283-7904
PHONE NO. 210-692-4192	FAX NO 210-692-4198.	E-MAIL ADDRESS Cs1@germainelabs.com

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS: IN ITS ENTIRETY AS SUBMITTED		
CONTRACT NO. OSCA 11-029-08		CONTRACT PERIOD July 1, 2011 through June 30, 2012
CONTACTS COORDINATOR Hebert J. Conner Jr	DATE 2-23-2011	STATE COURTS ADMINISTRATOR Gregory L. Linhares

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

RFP NO. OSCA 11-029-00
AMENDMENT: 001
TITLE: Drug/Alcohol Testing Equipment & Services
ISSUE DATE: January 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)		(Courier Service)
Office of State Courts Administrator		Office of State Courts Administrator
Contracts Unit	or	Contracts Unit
PO Box 104480		2112 Industrial Dr
Jefferson City Mo 65110 - 4480		Jefferson City Mo 65109

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

DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:

MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI

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

SIGNATURE REQUIRED

AUTHORIZED SIGNATURE		DATE
PRINTED NAME Cecilia Rodriguez		TITLE Customer Service Representative
COMPANY NAME Germaine Laboratories, Inc.		
MAILING ADDRESS 11030 Wye Drive		
CITY, STATE, ZIP San Antonio, Tx 78217		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 74-283-7904
PHONE NO. 210-692-4192	FAX NO. 210-692-4198	E-MAIL ADDRESS CS1@GERMAINELABS.COM

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS:		
CONTRACT NO.	CONTRACT PERIOD	
CONTACTS COORDINATOR	DATE	STATE COURTS ADMINISTRATOR

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.

Response: Germaine Laboratories, Inc. will provide alcohol and drug testing products and related services for the OSCA and the various Drug Courts of the Missouri Judiciary in accordance with the internal policy/procedure of the Drug Court and the provisions and requirements stated herein.

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.

Response: Please see Attachment GLI-01 for copies of our active FDA 510K notification documents. The FDA has not cleared any medical devices for Rapid saliva based DOA testing. Refer to the following pages for additional information about the Non-Instrument based immunoassay products that will be provided by Germaine laboratories.

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.

Response: Germaine Laboratories, Inc. understands that the contract is not exclusive and the OSCA and the Drug Courts may obtain alternate products and services 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.

Response: Germaine Laboratories, Inc. will comply with all confidentiality requirements established by statute and the Drug Court and as otherwise stated herein. Germaine Laboratories, Inc. will release the results of testing only to the Drug Court or as otherwise instructed by the Drug Court

The contractor shall provide the required products and/or services on an as needed, if needed, basis as requested by the Treatment Court.

Response: Germaine Laboratories, Inc. will provide the required products and services on an as needed, if needed basis as requested by the Drug Court.

OSCA makes no commitments or guarantees as to the quantity of the testing or laboratory tests that may be required.

Response: Germaine Laboratories, Inc. understands that OSCA makes no commitments or guarantees as to the quantity of testing or laboratory testing it may require.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. will provide routine courier pick-up of urine analysis samples within 24 hours of a Drug Court drop call. Additionally, Germaine Laboratories, Inc. will provide courier service for overnight delivery to the laboratory, to treatment programs located within 5 miles of the Drug Court.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.**

- The contractor must be Substance Abuse and Mental Health Services Administration (SAMHSA) or Clinical Laboratory Improvement Act (CLIA) certified**.**

- The contractor must be approved by the Commission on Inspection and Accreditation of the College of American Pathologists or Certified by the American Association of Bioanalyst.

- If the contractor is a hospital, the hospital must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The hospital laboratory must be licensed to operate in interstate commerce by the U.S. Department of Health and Human Services under the Clinical Laboratory Improvement Act (CLIA).

- If the contractor is an independent reference laboratory, the contractor must meet CLIA license requirements. In addition, the contractor should be approved by Medicare to provide medial laboratory services.

The contractor shall understand and agree that any information, record, report, or data derived, compiled, obtained, prepared, or developed by the contractor from services performed pursuant to the contract shall not be released, disseminated, or otherwise disclosed without prior written consent of OSCA.

On-Site Drug Testing Kits Non-Instrument Based Immunoassay (both urine and saliva):
The contractor must be able to provide testing devices in both single and multi-drug combinations. At a minimum, these drug tests must be available for the following drugs: Amphetamines, Methamphetamines, Cocaine, Opiates, Phencyclidine (PCP), THC (cannabinoids), Methadone, Barbiturates, Benzodiazepines, Oxycodone, propoxyphene, synthetic cannabinoids and MDMA (Ecstasy). Testing for additional items may be requested during the contract period. If requested, pricing shall be mutually agreed upon between the contractor and OSCA.

Each kit shall contain all elements necessary to complete the test in the field.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: The tests kits provided by Germaine Laboratories, Inc. are of the most advanced technology and do not require electricity, special plumbing, instrumentation, calibration, laboratory environment or refrigeration of reagents.

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.

Response: All test kits provided by Germaine Laboratories, Inc. will have an expiration date clearly marked on each kit and have a minimum shelf life of eighteen (18) months from date of manufacture. Germaine Laboratories, Inc. understands and aggress that the state agency will receive test kits at least twelve (12) months prior to the expiration date, or they may be rejected at Germaine Laboratories, Inc.'s expense.

The test kits must be self contained, completely portable and packaged for field use.

Response: The test kits provided by Germaine Laboratories, Inc. will be completely portable and conveniently packaged for field use. Each test device is individually packaged in a foil pouch or envelope and will remain ready to use until the foil is opened.

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.

Response: All testing devices used by Germaine Laboratories, Inc. follow the current SAMHSA cut-off levels for detection of positive drug screens. Germaine Laboratories, Inc. will have additional cut off levels for the following drugs: Opiates will have both 2000 ng/ml and 300 ng/ml cut-off levels and Benzodiazepines and Barbiturates will have a 300 ng/ml cut-off level available and thus defensible by gas chromatograph/mass spectrometer (GC/MS) confirmatory cut-off levels. Cocaine will also be available with both a 150 ng/ml and 300 ng/ml cut off level to meet the more stringent standards of Drug Court testing.

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.

Response: All multi-drug test kits provided by Germaine Laboratories, Inc. will include the integrated collection cup for the SafeCup™ product and an optional collection cup for the AimScreen™ device. Cups are available and include an ID label and temperature strip. A tamper evident seal for maintaining chain of custody is available, and a bag for the easy, clean disposal of a urine sample after testing is complete are available.

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.

Response: The testing devices at Germaine Laboratories, Inc. do not require any pretreatment of the urine sample prior to testing and are able to be run on a sample immediately after collection. Also, the tests do not require that samples reach room temperature unless it has been refrigerated. The tests are not be affected by abnormal pH levels; this quality is scientifically stated on the product insert.

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.

Response: The testing devices of Germaine Laboratories, Inc. have a low volume procedure, which requires 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.

Response: The testing devices of Germaine Laboratories, Inc. have an indicator/control line.

The testing devices must be available for reading results in seven (7) minutes or less.

Response: The testing devices of Germaine Laboratories, Inc. will be available for reading results in three (5) minutes or less.

The test results must be stable for a minimum of thirty (30) minutes.

Response: The test results of the testing devices used by Germaine Laboratories, Inc. will be stable for at least 30 minutes.

The test results must be easy to read with test result interpretation of positive or negative clearly defined on the device.

Response: The test results of the testing equipment used by Germaine Laboratories, Inc. is easy to read with test result interpretation of positive and negative clearly defined on the device. One line on the equipment equals a negative result. Two lines equal a presumptive positive.

The testing devices must be highly accurate and reliable with performance data comparable to gas chromatograph/mass spectrometer (GC/MS) testing.

Response: The testing devices used by Germaine Laboratories, Inc. are highly accurate and reliable with performance data comparable to gas chromatograph/mass spectrometer (GC/MS) testing. Please see the package insert on our AimScreen™ and SafeCup™ devices.

The testing devices shall minimize false positive results caused by over-the-counter medications.

Response: The testing devices used by Germaine Laboratories, Inc. minimize false positive results caused by over-the-counter medications. Please see our package insert on our AimScreen™ and SafeCup™ devices.

The test results must be able to be photocopied or scanned creating either a paper or an electronic permanent file copy for retention.

Response: The test results given by Germaine Laboratories, Inc. will be able to be photocopied or scanned, creating either a paper or 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.

Response: Germaine Laboratories, Inc. will, if required by the Drug Court, develop and administer procedures and protocols for random drug and alcohol testing.

The contractor shall maintain proper chain of custody procedures.

Response: Germaine Laboratories, Inc. will maintain proper chain of custody procedures. All specimens sent to the laboratory for analysis will be processed in a locked/secured facility utilizing the highest standards for electronic COC verification throughout the analysis procedure.

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.

Response: Germaine Laboratories, Inc. will provide a facility(s) for urine sample collection to insure 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. An example of collection site locations is included on the pricing page located in Attachment GLI-06. Collection sites for individual Drug Courts will be assigned on an as needed, if needed basis according to the needs of each Drug Court.

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.

Response: Germaine Laboratories, Inc. will, if required by the Drug 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 Drug Court.

The contractor shall provide routine courier pick-up of urine analysis samples within 24 hours of a Treatment Court drop call.

Response: Germaine Laboratories, Inc. will provide routine courier pick-up of urine analysis samples within 24 hours of a Drug Court drop call.

The contractor shall provide urine analysis results to the Treatment Court within 24 hours of pick-up.

Response: Germaine Laboratories, Inc. will provide urine analysis results 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.

Response: Germaine Laboratories, Inc. agrees that the cutoff levels are set at a sufficient level as desired by the Drug Courts to minimize false positive readings. The cutoff levels are set in accordance with industry standards 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.

Response: Germaine Laboratories, Inc. concurs.

Electronic Alcohol Monitoring
Contractor shall provide a service, to include all necessary equipment, for electronic alcohol monitoring of approved court participants. The system shall use web-based software to allow remote electronic monitoring and supervision. The monitoring may be offered in a variety of options. The following are approved systems for this purpose:

- In-home breath alcohol testing sytems – such as iSecure Trac or Smart Start
- transdermal alcohol monitoring – such as SCRAM or Transdermal Alcohol Detector (TAD)

Any system proposed shall have a proprietary secure web-based software to allow random monitoring of participant.

Alcohol testing shall be accurate to within +/- .005% of actual blood alcohol levels and be acceptable as court admissible evidence. Results generated by the system shall stand on their own without secondary or backup testing needed. All systems shall meet the Daubert standard of scientific evidence admissibility.

3.0 CONTRACTUAL REQUIREMENTS

Contract
A binding contract shall consist of: (1) the RFP, amendments thereto, and any Best and Final Offer (BAFO) request(s) with RFP changes/additions, (2) the vendor's proposal including any vendor BAFO response(s), (3) clarification of the proposal, if any, and (4) OSCA acceptance of the proposal by "notice of award". All Exhibits and Attachments included in the RFP shall be incorporated into the contract by reference.

a. A notice of award issued by OSCA does not constitute an authorization for shipment of equipment or supplies or a directive to proceed with services. Before providing equipment, supplies and/or services for OSCA or the Treatment Courts, the vendor must receive an authorized order.

b. The contract expresses the complete agreement of the parties and performance shall be governed solely by the specifications and requirements contained therein.

c. Any change to the contract, whether by modification and/or supplementation, must be accomplished by a formal contract amendment signed and approved by and between the duly authorized representative of the vendor and OSCA. The vendor expressly and explicitly understands and agrees that no other method and/or no other document, including correspondence, acts, and oral communications by or from any person, shall be used or construed as an amendment or modification to the contract.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

Price:
All prices shall be as indicated on the Pricing Page. OSCA shall not pay nor be liable for any other additional costs including but not limited to taxes, shipping charges, insurance, interest, penalties, termination payments, attorney fees, liquidated damages, etc.

Prices offered shall remain valid for 90 days from proposal opening unless otherwise indicated. If the proposal is accepted, prices shall be firm for the specified contract period.

Invoicing and Payment Requirements:
Immediately upon award of the contract, the vendor needs to submit or must have already submitted a properly completed State Vendor ACH/EFT Application. It is the vendor's responsibility to insure the information is current. OSCA intends to make all contract payments through the use of Electronic Funds Transfer.

a. If not already submitted, the vendor needs to obtain a copy of the State Vendor ACH/EFT Application and completion instructions from the Internet at: http://www.oa.mo.gov/purch/vendorinfo/vendorach.pdf

b. The vendor must submit invoices on the vendor's original descriptive business invoice form and must use a unique invoice number with each invoice submitted. The unique invoice number will be listed on the State of Missouri's EFT addendum record to enable the vendor to properly apply the Treatment Court payment to the invoice submitted.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

The State of Missouri does not pay state or federal taxes unless otherwise required under law or regulation.

Response: Germaine Laboratories, Inc. concurs.

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).**

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs. According to our insurance carrier's policy.

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.

Response: Germaine Laboratories, Inc. concurs. According to our insurance carrier's policy.

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.

Response: Germaine Laboratories, Inc. concurs. According to our insurance carrier's policy.

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)

Response: **Germaine Laboratories, Inc. concurs.**

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.

Response: Germaine Laboratories, Inc. concurs.

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.

b. 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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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.

c. 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.

Response: Germaine Laboratories, Inc. concurs.

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.

d. The signed page one from the original RFP and all signed amendments should be placed at the beginning of the proposal.

Response: Germaine Laboratories, Inc. concurs.

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.

Response: Germaine Laboratories, Inc. concurs.

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:		___None_____ %

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.

SEE ATTACHMENT GLI-06_ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

_____ Product name $_____ firm, fixed price per each unit

Electronic Alcohol Montoring
Pricing per participant

per day: _____

per week: _____

per month: _____

Is there a minimum number of days? Yes_____ No_____

If yes, please indicate number of days:_____

Deposit or Start Up fee required? Yes_____ How much?_____No_____

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

_____

Please list counties you will provide this service:

PRICING

AimScreen™ Single Drug Screens (dipdevice, no cup)	**Cut-Off Level**	**# Tests per Box**	**Price per Box Includes shipping**
Amphetamine (AMP)	D-Amphetamine 1,000 ng/ml	25 tests	$14.67
Methamphetamine (MET)	D-Methamphetamine 1,000 ng/ml	25 tests	$14.67
Barbiturates (BAR)	Secobarbital 300 ng/ml	25 tests	$14.67
Benzodiazepines (BZO	Oxazepam 300 ng/ml	25 tests	$14.67
Buprenorphine (Bup)	Buprenorphine 10ng/ml	25 test	$14.67
Cocaine 150 ng/ml	Benzoylecgonine 150 ng/ml	25 tests	$18.67
Cocaine 300 ng/ml	Benzoylecgonine 300 ng/ml	25 tests	$14.67
Ecstasy (MDMA)	D,L Methylenedioxy methamphetamine 500 ng/ml	25 tests	$14.67
Marijuana (THC)	THC-9 COOH 50 ng/ml	25 tests	$14.67
Methadone (MTD)	Methadone 300 ng/ml	25 tests	$14.67
Opiate (OPI)	Morphine 300 ng/ml	25 tests	$14.67
Opiate (OPI)	Morphine 2000 ng/ml	25 tests	$14.67
Oxycodone (OXY)	Oxycodone 100 ng/ml	25 tests	$14.67
Phencyclidine (PCP)	Phencyclidine 25 ng/ml	25 tests	$14.67
Propoxyphene (PPX)	d-Propoxyphene 300ng/ml	25 tests	$14.67
Tricyclic antidepressants (TCA)	Nortriptyline 1,000 ng/ml	25 tests	$14.67
AimScreen™ 2-Drug Screens*	**Dipdevice (no cup)**		
COC & THC (cocaine & marijuana)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml	25 tests	$26.47
COC & THC (cocaine & marijuana)	Benxoylecgonine 150 ng/mL THC-9 COOH 50 ng/ml	25 tests	$31.47
AimScreen™ 3-Drug Screens*	**Dipdevice (no cup)**		
COC, MET, THC (cocaine, methamphetamine, marijuana)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL	25 tests	$36.97
AimScreen™ 4-Drug Screens*	**Dipdevice (no cup)**		
COC, MET, THC, OPI (cocaine, mehamphetamine, marijuana, opiates)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL Morphine 2,000 ng/mL	25 tests	$46.57
AimScreen™ 5-Drug Screens*	**Dipdevice (no cup)**		
COC, AMP, THC, OPI, PCP (cocaine, mehamphetamine, marijuana, opiates, phencyclidine) COC, MET, AMP, THC, OPI (cocaine, mehamphetamine, amphetamine, marijuana, opiates)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL Morphine 300 ng/mL Phencyclidine 25 ng/mL Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL D-Amphetamine 1,000 ng/mL Morphine 2,000 ng/mL	25 tests	$57.27

GERMAINE LABORATORIES, INC.

AimScreen™ 9-Drug Screen, Dipdevice (no cup)*	**Cut-Off Level**	**# Tests per Box**	**Price per Box Includes shipping**
COC, AMP, MET, THC, MTD, OPI, PCP, BAR, BZO (cocaine, amphetamine, methamphetamine, marijuana, methadone, opiates, pcp, barbiturates, benzodiazpines	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/ml D-Amphetamine 1,000 ng/ml Morphine 2,000 ng/ml Phencyclidine 25 ng/mL Methadone 300 ng/ml Secobarbital 300 ng/ml Oxazepam 300 ng/ml	25 tests	$98.47
AimScreen™ 10-Drug Screen*	**Dipdevice (no cup)**		
COC, AMP, MET, THC, MTD, OPI, PCP, BAR, BZO, TCA (cocaine, amphetamine, methamphetamine, marijuana, methadone, opiates, pcp, barbiturates, benzodiazpines, Tricyclic Antidepressants)	Benxoylecgonine 300 ng/ml THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/ml D-Amphetamine 1,000 ng/ml Morphine 2,000 ng/ml Phencyclidine 25 ng/ml Methadone 300 ng/ml Secobarbital 300 ng/ml Oxazepam 300 ng/ml Nortriptyline 1,000 ng/ml	25 tests	$107.77
AimScreen 12- Drug Screen*	**Dipdevice (no cup)**	25 tests	
COC, AMP, MET, THC, MTD, OPI, PCP, BAR, BZO, TCA, MDMA, OXY (cocaine, amphetamine, methamphetamine, marijuana, methadone, opiates, pcp, barbiturates, benzodiazpines, Tricyclic Antidepressants, ecstasy, oxycodone)	Benxoylecgonine 300 ng/ml THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/ml D-Amphetamine 1,000 ng/ml Morphine 2,000 ng/ml Phencyclidine 25 ng/ml Methadone 300 ng/ml Secobarbital 300 ng/ml Oxazepam 300 ng/ml Nortriptyline 1,000 ng/ml D,L Methylenedioxy methamphetamine 500 ng/ml Oxycodone 100 ng/ml		
***Other configurations may be available. Please inquiry.**			
SafeCup™ II 4-Drug Screen- cup		25 cups	
COC, MET, THC, OPI (cocaine, methamphetamine, marijuana, opiates)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL Morphine 2,000 ng/mL	25 cups	$82.57
SafeCup™ II 5-Drug Screen- cup			
COC, AMP, THC, OPI, PCP (cocaine, mehamphetamine, marijuana, opiates, Phencyclidine)	Benxoylecgonine 300 ng/ml THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/ml Morphine 2,000 ng/ml Phencyclidine 25 ng/mL	25 cups	$83.70
COC, MET, AMP, THC, OPI, (cocaine, mehamphetamine, amphetamine, marijuana, opiates,)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL	25 cups	$83.70

	D-Amphetamine 1,000 ng/mL Morphine 2,000 ng/mL		

SafeCup-II™ 10-Drug Screen-integrated cup	**Cut-Off Level**	**# Tests per Box**	**Price per Box Includes shipping**
COC, AMP, MET, THC, MTD, OPI, PCP, BAR, BZO, MDMA (cocaine, amphetamine, methamphetamine, marijuana, methadone, opiates, pcp, barbiturates, benzodiazpines, ecstasy)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL D-Amphetamine 1,000 ng/mL Opiates/Morphine 2,000 ng/mL Phencyclidine 25 ng/mL Methadone 300 ng/ml Secobarbital 300 ng/ml Oxazepam 300 ng/ml Methylenedioxymethamphetamine 500 ng/ml	25 tests	$121.70
COC, MET, THC, MTD, OPI, BAR, BZO, TCA, OXY, BUP (cocaine, amphetamine, methamphetamine, marijuana, methadone, opiates, pcp, barbiturates, benzodiazpines, ecstasy)	Benxoylecgonine 300 ng/mL THC-9 COOH 50 ng/ml D-Amphetamine 1,000 ng/mL Opiates/Morphine 2,000 ng/mL Methadone 300 ng/ml Secobarbital 300 ng/ml Oxazepam 300 ng/ml Methylenedioxymethamphetamine 500 ng/ml Oxycodone 100 ng/ml Buprenorphine 10ng/ml	25 tests	$121.70
***Other configurations may be available. Please inquiry.**			

AimScreen™ Oral MultiDrug (6 drug saliva test)	**Cut-off Level & Calibrator**	**25 Tests/Box**	**$193.70 per Box of 25**
Amphetamine (AMP), Methamphetamine (MET), Marijuana (THC), Phencyclidine (PCP), Cocaine (COC), Opiates (OPI)	50 ng/mL d-Amphetamine 50ng/mLd-ethamphetamine 12 ng/mL THC-COOH 10 ng/mL Phencyclidine 20ng/mL benxoylecogonine 40 ng/mL Morphine		*Includes:* Collection, device, applicator, and 6-drug instant screen.
AimStep® Saliva 5 (5 drug saliva test)			**$174.70 per Box of 25**
Amphetamine (AMP), Benzo (BZO), Marijuana (THC), Cocaine (COC), Opiates (OPI)	50 ng/mL d-Amphetamine 50 ng/mL Oxazepam 12 ng/mL THC-COOH 20ng/mL benxoylecogonine 40 ng/mL Morphine		

GERMAINE LABORATORIES, INC.

Accessories for non-instrumented devices:

1. Collection Cup 90mL w/o Temp. Strip — Price: $0.25/cup, $98.00/case
   Cat. #10102, 400 cups/case
2. Collection Cup 90mL w/Security Seal & Temp Strip — Price: $0.40/cup, $160.00/case
   Cat. #10113, 400 cups/case
3. Collection Cup 90mL w/Temp Strip — Price: $0.27/cup, $108.00/case
   Cat. #10114, box of 400 cups
4. Tamper evident security seal — Price: $5.00 per box
5. Disposal bag for completed test — Price: $5.00 per box
6. Adulteration Strips, 25/bottle Cat. #40007 — Price: $17.20 per bottle

Alcohol Detection:

1. QED A-150 — Price: $75.00 box of 10 devices
2. Alcohol Saliva, rapid test — Price: $43.75 box of 25 devices
3. Breath Alcohol Detector, rapid test — Price: $39.70 box of 20 devices

Drug & Alcohol Laboratory Urine Testing Services:

1. Laboratory Based Drug Testing Panels: — Price: $16.94 per specimen
   5, 8, or 10 panel test
   Includes: Collection supplies, chain of custody form, overnight transportation to laboratory, screening for specific panel, GC/MS confirmation of screened positives, electronic delivery of results.

2. Statistical Reporting — Price: No Charge

3. Laboratory Confirmation of Screened Positives: — Price: $34.00 per confirmation
   Includes: specimen shipment supplies, overnight transportation to laboratory, GC/MS confirmation for specific drug, & electronic delivery of result.

Specimen Collection Services:

1. Collection Services (M-F 8AM-5PM) — Price: $20.00 per collection

(Example of Collection Sites & Operation Hours in Missouri)

GERMAINE LABORATORIES, INC.

Springfield	3000 E. Division	Springfield	MO	65802	8:00 A.M.-7:00P.M. (Mon.-Fri.) 8:00 A.M.-12:00 P.M. (Sat.)
Midtown	6726 Manchester Road	St. Louis	MO	63139	8:00 A.M.-8:00 P.M. (Mon.-Fri.)
Westport	83 Progress Parkway	Maryland Heights	MO	63043	8:00 A.M.-8:00 P.M. (Mon.-Fri.)
North Broadway	8340 N. Broadway	St. Louis	MO	63147	8:00 A.M.-5:00 P.M. (Mon.-Fri.)
Airport	7927 N. Lindbergh Boulevard	Hazelwood	MO	63042	8:00 A.M.-5:00 P.M. (Mon.-Fri.)
Soulard	1617 South 3rd St.	St. Louis	MO	63104	7:30 A.M.-5:00 P.M. (Mon.-Fri.)
Fenton	1709 Gilsinn Lane	Fenton	MO	63026	8:00 A.M.-5:00 P.M. (Mon.-Fri.)
SAMS	1709 Gilsinn Lane	Fenton	MO	63026	8:00 A.M.-5:00 P.M. (Mon.-Fri.)

2. After Hours Collection Services — Price: $55.00 per collection

3. On-site collection Services — Price: $35.00 per collection (minimum 10 collections per location) plus $35.00 set up fee and $0.35 per mile (round trip)

4. 24/7 collection Services (Conducted at local hospitals) — Price: $150.00 per collection

Random Testing Program Management:

1. Creation of Data Base — Price: $1.00 per name/ID number entry.

2. Maintenance of Data Base — Price: $1.00 per name/ID number entry on monthly update

3. Random Pulls — Price: $0.50 per name for random pull and notification by email to drug court.

MRO Services:

1. Review of Laboratory Confirmed Positive Results Only — Price: $30.00 per specimen
2. Review of all Laboratory Results — Price: $5.00 per specimen
3. Telephonic Technical Assistance — Price: No Charge

Training Services:

1. Initial Training 3 locations within State/same week — Price: No Charge
2. Additional Training within State — Price: $500.00 per trip
3. Technical Consulting (by Phone) — Price: No Charge
4. Technical Consulting (in Person) — Price: $500.00 per trip

GERMAINE LABORATORIES, INC.

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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.

Response: Founded in 1990 in San Antonio, Texas, the company incorporated and became Germaine Laboratories, Inc. in 1997. That same year was also a landmark year in the growth of the company, when we completed our initial clinical trials for the AccuHome®-urine pregnancy test and received our first 510 (k) clearances from the Food & Drug Administration (FDA). Over the last 10 years our product lines have grown to include diagnostic tests for pregnancy, drugs of abuse, febrile antigens, H. pylori, ovulation, serology, strep A and urinalysis. Our product line includes the brand names AimScreen™ on-site Drugs of Abuse screens, SafeCup™ on-site integrated split cup and drug screens, AccuHome®, Aim™, AimStep®, AimStick®, CellFix™ and StrepAim®.

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

Response: See response above

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.

Response: See Exhibit B

c. Describe the structure of the organization including any board of directors, partners, top departmental management, corporate organization, corporate trade affiliations, any parent/subsidiary affiliations with other firms, etc.

Response: The Germaine Laboratories Inc. structure of the organization is a follows: General Manager, Quality Management Representative, Administrative, Customer Service Reps, Manufacturing & Production, and Sales & Marketing. Germaine Laboratories, Inc. does not have any parent/subsidiary affiliation.

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.

Response: Germaine Laboratories, Inc. currently does not have any pending litigation, civil or criminal judgments, bankruptcy proceedings, or etc.

a.

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.

Response: See Attachment GLI-08

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EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: _Germaine Laboratories_____	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Advantage Medical Supply Company
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	5126 Service Center Drive San Antonio, TX 78218
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Len Neeper 210-599-1991 len@advantagemedicalsupply.com
Dates of Prior Services:	1998-current
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Purchaser of drug of abuse test, pregnancy test, strep A tests, urinalysis test, and serology tests.

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

_____ _____

Signature of Reference Contact Person *Date of Signature*

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EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: Germaine Laboratories	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Craig Medical Distribution
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	1185 Park Center Drive, Suite P Vista, CA 92081
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Craig Munson 760-598-7170 customerservice@craigmedical.com
Dates of Prior Services:	1998-current
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Purchaser of drug of abuse test, pregnancy test, and strep A tests.

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

_____ _____

Signature of Reference Contact Person *Date of Signature*

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EXHIBIT B

PRIOR EXPERIENCE

The vendor should copy and complete this form for each reference being submitted as demonstration of the vendor and subcontractor's prior experience. In addition, the vendor is advised that if the contact person listed for the reference is unable to be reached during the evaluation, the listed experience may not be considered.

Vendor Name or Subcontractor Name: Germaine Laboratories	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	State of Missouri Office of State Courts Administrator
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	2112 Industrial Drive Jefferson City, MO 65110
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Russell Rottmann 573-522-6766 Russell.rottmann@courts.mo.gov
Dates of Prior Services:	2004-current
Dollar Value of Prior Services:	
Description of Prior Services Performed:	Purchaser of drug of abuse test

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by OSCA for additional discussions regarding my company's association with the vendor referenced above:

_____ _____

Signature of Reference Contact Person *Date of Signature*

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EXHIBIT C
PERSONNEL EXPERTISE SUMMARY
(Complete this Exhibit for personnel proposed. Resumes or summaries of key information may be provided)

Personnel	Background and Expertise of Personnel and Planned Duties
1. Martin O'Connor (Name) General Manager (Title) (Proposed Role/Function)	SEE ATTACHMENT GLI-02
2. Cecilia Rodriguez (Name) Customer Service Representative (Title) (Proposed Role/Function)	SEE ATTACHMENT GLI-02
3. Craig Waldrip (Name) Operations manager (Title) (Proposed Role/Function)	SEE ATTACHMENT GLI-02
4. Emily Wang (Name) Accountant (Title) (Proposed Role/Function)	SEE ATTACHMENT GLI-02
5. Amy N. MacCrindle (Name) Quality Manager (Title) (Proposed Role/Function)	SEE ATTACHMENT GLI-02
6. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	

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EXHIBIT D

METHOD OF PERFORMANCE

The vendor should use this Exhibit, or similar format, to present a written plan for performing the requirements specified in this Request for Proposal.

1. Describe what is provided with which to collect the each sample (cups, chain of custody forms, mailing packets).

   Response: Germaine Laboratories, Inc. provides the All-In-One Drug Cups with the instructions and directions on how to use and perform the test. When the sample needs to be sent to the lab chain of custody forms and mailing packets are provided as well.

2. Describe the instruction or training provided to treatment court staff pertaining to properly collecting a sample and completing necessary documentation.

   Response: Germaine Laboratories, Inc. will provide training on all testing devices identified herein. This training shall include, but is not limited to, basic drug testing training and training on current drug testing issues.

3. Describe how the sample is transported to the testing laboratory (U S Postal, Fed Ex, UPS, etc.).

   Response: See Attachment GLI-03

4. Describe the methods of testing which are employed (LC/MS/MS, GS/MS, LC/MS, and/or Immunoassay methods).

   Response: See Attachment GLI-03

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

   Response: See Chart Below

Examples of Laboratory Urine Drug Testing Panels:

DOT 5 –Drug Panel		
Panel Components	Screen Cut Off Level	Confirmation Cut Off Level
THC	50 ng/mL	15 ng/mL
Amphetamines	1000 ng/mL	500 ng/mL
Cocaine	300 ng/mL	150 ng/mL
Opiates	2000 ng/mL	2000 ng/mL
PCP	25 ng/mL	25 ng/mL

Non-regulated 5-Drug Panel		
Panel Components	Screen Cut Off Level	Confirmation Cut Off Level
THC	50 ng/mL	15 ng/mL
Amphetamines	1000 ng/mL	500 ng/mL
Cocaine	300 ng/mL	150 ng/mL

Opiates	2000 ng/mL	2000 ng/mL
PCP	25 ng/mL	25 ng/mL

Non-regulated 8-Drug Panel		
Panel Components	Screen Cut Off Level	Confirmation Cut Off Level
THC	50 ng/mL	15 ng/mL
Amphetamines	1000 ng/mL	500 ng/mL
Cocaine	300 ng/mL	150 ng/mL
Opiates	2000 ng/mL	2000 ng/mL
PCP	25 ng/mL	25 ng/mL
Barbiturates	300 ng/mL	200 ng/mL
Benzodiazepines	300 ng/mL	200 ng/mL
Propoxyphene	300 ng/mL	200 ng/mL

Non-regulated 10-Drug Panel		
Panel Components	Screen Cut Off Level	Confirmation Cut Off Level
THC	50 ng/mL	15 ng/mL
Amphetamines	1000 ng/mL	500 ng/mL
Cocaine	300 ng/mL	150 ng/mL
Opiates	2000 ng/mL	2000 ng/mL
PCP	25 ng/mL	25 ng/mL
Barbiturates	300 ng/mL	200 ng/mL
Benzodiazepines	300 ng/mL	200 ng/mL
Propoxyphene	300 ng/mL	200 ng/mL
Methadone	300 ng/mL	200 ng/mL
Methaqualond	300 ng/mL	200 ng/mL

Club Drug Panel		
Panel Components	Screen Cut Off Level	Detection Times
Oxycodone	500 ng/mL	1-3 days
Ecstasy – MDMA	500 ng/mL	1-3 days
Ketamine	200 ng/mL	1-2 days
GHB (Gammahydroxybutyrate)	20 ng/mL	8-24 hours

6. Describe the turnaround time for results.

Response: See Attachment GLI-03

7. Describe how test results will be reported (telephone, fax, or e-mail).

Response: Germaine Laboratories, Inc. can report drug test results through telephone, fax, e-mail, or electronically, based on the preference of OSCA and the Drug Courts.

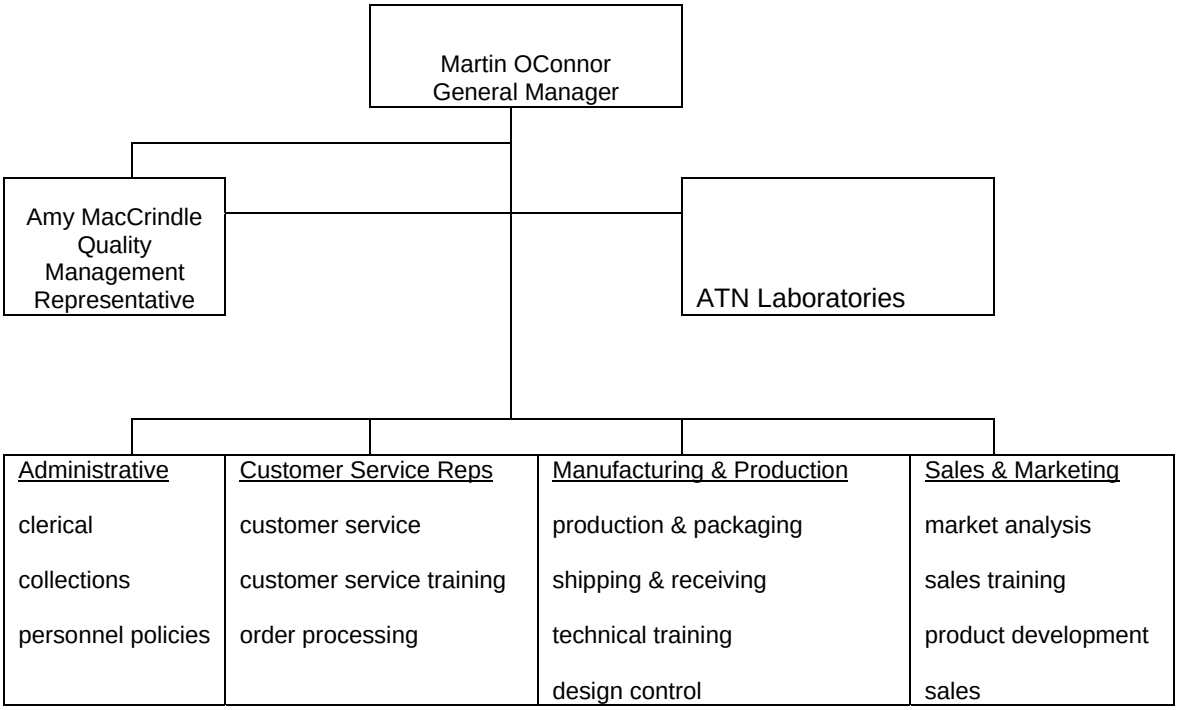
8. Organizational Chart - The vendor should provide an organizational chart showing the staffing and lines of authority for the key personnel to be used. The organizational chart should include (1) The relationship of service

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.

Response:

Organizational Chart



9. Along with a detailed organizational chart, the vendor should describe the following:

- How services of the contract will be managed, controlled, and supervised in order to ensure satisfactory contract performance.
- Total Personnel Resources - The vendor should provide information that documents the depth of resources to ensure completion of all requirements on time and on target. If the vendor has other ongoing contracts that also require personnel resources, the vendor should document how sufficient resources will be provided to the STATE OF MISSOURI.

Response: Germaine Laboratories, Inc. general manager will oversee the contract and that the contract is carried out accordingly.

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	Yes _X___	No ____

or performed at sites outside the United States?		
Describe and provide details: Germaine Laboratories, Inc., a USA based corporation, is considered the legal manufacturer per FDA guidelines, 21 CFR 807.3(d) of all products. Some products contain components that are manufactured outside the USA. Some products contain a majority of components that are manufactured outside the USA.		

STATE OF MISSOURI
OFFICE OF STATE COURTS ADMINISTRATOR

TERMS AND CONDITIONS -- REQUEST FOR PROPOSAL

1. TERMINOLOGY/DEFINITIONS

Whenever the following words and expressions appear in a Request for Proposal (RFP) document or any amendment thereto, the definition or meaning described below shall apply.

a. **Agency and/or State Agency** means the statutory unit of state government in the State of Missouri for which the equipment, supplies, and/or services are being purchased. The agency is also responsible for payment.
b. **Amendment** means a written, official modification to an RFP or to a contract.
c. **Attachment** applies to all forms which are included with an RFP to incorporate any informational data or requirements related to the performance requirements and/or specifications.
d. **Proposal Opening Date and Time** and similar expressions mean the exact deadline required by the RFP for the receipt of sealed proposals.
e. **Contractor** means the person or organization that responds to an RFP by submitting a proposal with prices to provide the equipment, supplies, and/or services as required in the RFP document.
f. **Contract** means a legal and binding agreement between two or more competent parties, for a consideration for the procurement of equipment, supplies, and/or services.
g. **Contractor** means a person or organization who is a successful contractor as a result of an RFP and who enters into a contract.
h. **Exhibit** applies to forms which are included with an RFP for the contractor to complete and submit with the sealed proposal prior to the specified opening date and time.
i. **Request for Proposal (RFP)** means the solicitation document issued to potential contractors for the purchase of equipment, supplies, and/or services as described in the document. The definition includes these Terms and Conditions as well as all Pricing Pages, Exhibits, Attachments, and Amendments thereto.
j. **May** means that a certain feature, component, or action is permissible, but not required.
k. **Must** means that a certain feature, component, or action is a mandatory condition. Failure to provide or comply will result in a proposal being considered non-responsive.
l. **Pricing Page(s)** applies to the form(s) on which the contractor must state the price(s) applicable for the equipment, supplies, and/or services required in the RFP. The pricing pages must be completed and submitted by the contractor with the sealed proposal prior to the specified proposal opening date and time.
m. **Shall** has the same meaning as the word must.
n. **Should** means that a certain feature, component and/or action is desirable but not mandatory.

2. APPLICABLE LAWS AND REGULATIONS

a. The contract shall be construed according to the laws of the State of Missouri. The contractor shall comply with all local, state, and federal laws and regulations related to the performance of the contract to the extent that the same may be applic ble.
b. To the extent that a provision of the contract is contrary to the Constitution or laws of the State of Missouri or of the United States, the provisions shall be void and unenforceable. However, the balance of the contract shall remain in force between the parties unless terminated by consent of both the contractor and the Office of State Courts Administrator.
c. The contractor must be registered and maintain good standing with the Secretary of State of the State of Missouri and other regulatory agencies, as may be required by law or regulations.
d. The contractor must timely file and pay all Missouri sales, withholding, corporate and any other required Missouri tax returns and taxes, including interest and additions to tax.

e. The exclusive venue for any legal proceeding relating to or arising out of the RFP or resulting contract shall be in the Circuit Court of Cole County, Missouri.

3. OPEN COMPETITION/REQUEST FOR PROPOSAL DOCUMENT

a. It shall be the contractor's responsibility to ask questions, request changes or clarification, or otherwise advise the Office of State Courts Administrator if any language, specifications or requirements of an RFP appear to be ambiguous, contradictory, and/or arbitrary, or appear to inadvertently restrict or limit the requirements stated in the RFP to a single source. Any and all communication from contractors regarding specifications, requirements, competitive proposal process, etc., must be directed to the Contract and Grant Coordinator, unless the RFP specifically refers the contractor to another contact. Such communication should be received at least ten calendar days prior to the official proposal opening date.
b. Every attempt shall be made to ensure that the contractor receives an adequate and prompt response. However, in order to maintain a fair and equitable procurement process, all contractors will be advised, via the issuance of an amendment to the RFP, of any relevant or pertinent information related to the procurement. Therefore, contractors are advised that unless specified elsewhere in the RFP, any questions received less than ten calendar days prior to the RFP opening date may not be answered.
c. Contractors are cautioned that the only official position of the State of Missouri is that which is issued in the RFP or an amendment thereto. No other means of communication, whether oral or written, shall be construed as a formal or official response or statement.
d. The Office of State Courts Administrator monitors all procurement activities to detect any possibility of deliberate restraint of competition, collusion among contractors, price-fixing by contractors, or any other anticompetitive conduct by contractors which appears to violate state and federal antitrust laws. Any suspected violation shall be referred to the Missouri Attorney General's Office for appropriate action.
e. The Office of State Courts Administrator reserves the right to officially amend or cancel an RFP after issuance.

4. PREPARATION OF PROPOSALS

a. Contractors **must** examine the entire RFP carefully. Failure to do so shall be at contractor's risk.
b. Unless otherwise specifically stated in the RFP, all specifications and requirements constitute minimum requirements. All proposals must meet or exceed the stated specifications and requirements.
c. Unless otherwise specifically stated in the RFP, any manufacturer's names, trade names, brand names, information and/or catalog numbers listed in a specification and/or requirement are for informational purposes only and are not intended to limit competition. The contractor may offer any brand which meets or exceeds the specification for any item, but must state the manufacturer's name and model number for any such brands in the proposal. In addition, the contractor shall explain, in detail, (1) the reasons why the proposed equivalent meets or exceeds the specifications and/or requirements and (2) why the proposed equivalent should not be considered an exception thereto. Proposals which do not comply with the requirements and specifications are subject to rejection without clarification.
d. Proposals lacking any indication of intent to offer an alternate brand or to take an exception shall be received and considered in complete compliance with the specifications and requirements as listed in the RFP.
e. In the event that the contractor is an agency of state government or other such political subdivision which is prohibited by law or court decision from complying with certain provisions of an RFP, such a contractor may submit a proposal which contains a list of statutory limitations and identification of those prohibitive clauses which will be modified via a clarification conference between the Office of State Courts Administrator and the contractor, if such contractor is selected for contract award. The clarification conference will be conducted in order to agree to language that reflects the intent and compliance of such law and/or court order and the RFP. Any such contractor needs to include in the proposal, a complete list of statutory references and citations for each provision of the RFP which is affected by this paragraph.
f. All equipment and supplies offered in a proposal must be new, of current production, and available for marketing by the manufacturer unless the RFP clearly specifies that used, reconditioned, or remanufactured equipment and supplies may be offered.
g. Prices shall include all packing, handling and shipping charges FOB destination, freight prepaid and allowed unless otherwise specified in the RFP.
h. Prices offered shall remain valid for 90 days from proposal opening unless otherwise indicated. If the proposal is accepted, prices shall be firm for the specified contract period.

5. SUBMISSION OF PROPOSALS

a. Proposals must be submitted hard copy, delivered to the Office of State Courts Administrator, Contract and Grant Coordinator. All proposals must (1) be submitted by a duly authorized representative of the contractor's organization, (2) contain all information required by the RFP, and (3) be priced as required. Delivered proposals must be sealed in an envelope or container, and received in the Office of State Courts Administrator no later than the exact opening time and date specified in the RFP.

b. The sealed envelope or container containing a proposal should be clearly marked on the outside with (1) the official RFP number and (2) the official opening date and time. Different proposals should not be placed in the same envelope, although copies of the same proposal may be placed in the same envelope.
c. A proposal which has been delivered to the Office of State Courts Administrator may be modified by signed, written notice which has been received by the Contract and Grant Coordinator prior to the official opening date and time specified. A proposal may also be modified in person by the contractor or its authorized representative, provided proper identification is presented before the official opening date and time. Telephone or telegraphic requests to modify a proposal shall not be honored.
d. A proposal which has been delivered to the Office of State Courts Administrator may only be withdrawn by a signed, written notice or facsimile which has been received by the Contract and Grant Coordinator prior to the official opening date and time specified. A proposal may also be withdrawn in person by the contractor or its authorized representative, provided proper identification is presented before the official opening date and time. Telephone or telegraphic requests to withdraw a proposal shall not be honored.
e. Contractors delivering a hard copy proposal to Office of State Courts Administrator must sign and return the RFP cover page or, if applicable, the cover page of the last amendment thereto in order to constitute acceptance by the contractor of all RFP terms and conditions. Failure to do so may result in rejection of the proposal unless the contractor's full compliance with those documents is indicated elsewhere within the contractor's response.

6. PROPOSAL OPENING

a. Proposal openings are public on the opening date and at the opening time specified on the RFP document. Only the names of the respondents shall be read at the proposal opening. The contents of the responses shall not be disclosed at this time.
b. It is the contractor's responsibility to ensure that the proposal is received by Office of State Courts Administrator by the official opening date and time.
c. Proposals which are not received by the Office of State Courts Administrator prior to the official opening date and time shall be considered late, regardless of the degree of lateness, and normally will not be opened. Late proposals may only be opened under extraordinary circumstances in accordance with 1 CSR 40-1.050.

7. PREFERENCES

a. By virtue of statutory authority, a preference will be given to materials, products, supplies, provisions and all other articles produced, manufactured, made or grown within the state of Missouri. Such preference shall be given when quality is equal or better and delivered price is the same or less.
b. In accordance with Executive Order 98-21, contractors are encouraged and may be required per the RFP to utilize certified minority and women-owned businesses in selecting subcontractors.

8. EVALUATION/AWARD

a. Any clerical error, apparent on its face, may be corrected by the Contract and Grant Coordinator before contract award. Upon discovering an apparent clerical error, the Contract and Grant Coordinator shall contact the contractor and request clarification of the intended proposal. The correction shall be incorporated in the notice of award. Examples of apparent clerical errors are: 1) misplacement of a decimal point; and 2) obvious mistake in designation of unit.
b. Any pricing information submitted by a contractor shall be subject to evaluation if deemed by the Office of State Courts Administrator to be in the best interest of the State of Missouri.
c. Unless otherwise stated in the RFP, cash discounts for prompt payment of invoices shall not be considered in the evaluation of prices. However, such discounts are encouraged to motivate prompt payment.
d. Awards shall be made to the contractor whose proposal (1) complies with all mandatory specifications and requirements of the RFP and (2) is the lowest and best proposal, considering price, responsibility of the contractor, and all other evaluation criteria specified in the RFP and any subsequent negotiations.
e. In the event all contractors fail to meet the same mandatory requirement in an RFP, the Office of State Courts Administrator reserves the right, at its sole discretion, to waive that requirement for all contractors and to proceed with the evaluation. In addition, the Office of State Courts Administrator reserves the right to waive any minor irregularity or technicality found in any individual proposal.
f. The Office of State Courts Administrator reserves the right to reject any and all proposals.
g. When evaluating a proposal, the State of Missouri reserves the right to consider relevant information and fact, whether gained from a proposal, from a contractor, from contractor's references, or from any other source.
h. Any information submitted with the proposal, regardless of the format or placement of such information, may be considered in making decisions related to the responsiveness and merit of a proposal and the award of a contract.

i. Negotiations may be conducted with those contractors who submit potentially acceptable proposals. Proposal revisions may be permitted for the purpose of obtaining best and final offers. In conducting negotiations, there shall be no disclosure of any information submitted by competing contractors.
j. Any award of a contract shall be made by notification from the Office of State Courts Administrator to the successful contractor. The Office of State Courts Administrator reserves the right to make awards by item, group of items, or an all or none basis. The grouping of items awarded shall be determined by Office of State Courts Administrator based upon factors such as item similarity, location, administrative efficiency, or other considerations in the best interest of the State of Missouri.
k. Pursuant to Section 610.021 RSMo, proposals and related documents shall not be available for public review until after a contract is executed or all proposals are rejected.
l. The Office of State Courts Administrator reserves the right to request clarification of any portion of the contractor's response in order to verify the intent of the contractor. The contractor is cautioned, however, that its response may be subject to acceptance or rejection without further clarification.

9. CONTRACT/PURCHASE ORDER

a. By submitting a proposal, the contractor agrees to furnish any and all equipment, supplies and/or services specified in the RFP, at the prices quoted, pursuant to all requirements and specifications contained therein.
b. A binding contract shall consist of: (1) the RFP, amendments thereto, and/or Best and Final Offer (BAFO) request(s) with RFP changes/additions, (2) the contractor's proposal including the contractor's BAFO, and (4) Office of State Courts Administrator's acceptance of the proposal by "notice of award" or by "purchase order."
c. A notice of award does not constitute an authorization for shipment of equipment or supplies or a directive to proceed with services. Before providing equipment, supplies and/or services, the contractor must receive a properly authorized purchase order.
d. The contract expresses the complete agreement of the parties and performance shall be governed solely by the specifications and requirements contained therein. Any change, whether by modification and/or supplementation, must be accomplished by a formal contract amendment signed and approved by and between the duly authorized representative of the contractor and the Contract and Grant Coordinator or by a modified purchase order prior to the effective date of such modification. The contractor expressly and explicitly understands and agrees that no other method and/or no other document, including correspondence, acts, and oral communications by or from any person, shall be used or construed as an amendment or modification.

10. INVOICING AND PAYMENT

a. The State of Missouri does not pay state or federal taxes unless otherwise required under law or regulation.
b. The statewide financial management system has been designed to capture certain receipt and payment information. Therefore, each invoice submitted must reference the purchase order number and must be itemized in accordance with items listed on the purchase order. Failure to comply with this requirement may delay processing of invoices for payment.
c. The contractor shall not transfer any interest in the contract, whether by assignment or otherwise, without the prior written consent of the Office of State Courts Administrator.
d. Payment for all equipment, supplies, and/or services required herein shall be made in arrears. The State of Missouri shall not make any advance deposits.
e. The State of Missouri assumes no obligation for equipment, supplies, and/or services shipped or provided in excess of the quantity ordered. Any unauthorized quantity is subject to the State's rejection and shall be returned at the contractor's expense.
f. All invoices for equipment, supplies, and/or services purchased by the State of Missouri shall be subject to late payment charges as provided in Section 34.055 RSMo.

11. DELIVERY

Time is of the essence. Deliveries of equipment, supplies, and/or services must be made no later than the time stated in the contract or within a reasonable period of time, if a specific time is not stated.

12. INSPECTION AND ACCEPTANCE

a. No equipment, supplies, and/or services received pursuant to a contract shall be deemed accepted until the Office of State Courts Administrator has had reasonable opportunity to inspect said equipment, supplies, and/or services.
b. All equipment, supplies, and/or services which do not comply with the specifications and/or requirements or which are otherwise unacceptable or defective may be rejected. In addition, all equipment, supplies, and/or services which are discovered to be defective or which do not conform to any warranty of the contractor upon inspection (or at any later time if the defects contained were not reasonably ascertainable upon the initial inspection) may be rejected.
c. The State of Missouri reserves the right to return any such rejected shipment at the contractor's expense for full credit or replacement and to specify a reasonable date by which replacements must be received.

d. The State of Missouri's right to reject any unacceptable equipment, supplies, and/or services shall not exclude any other legal, equitable or contractual remedies the State may have.

13. WARRANTY

a. The contractor expressly warrants that all equipment, supplies, and/or services provided shall: (1) conform to each and every specification, drawing, sample or other description which was furnished to or adopted by the Office of State Courts Administrator, (2) be fit and sufficient for the purpose expressed in the RFP, (3) be merchantable, (4) be of good materials and workmanship, and (5) be free from defect.
b. Such warranty shall survive delivery and shall not be deemed waived either by reason of the State's acceptance of or payment for said equipment, supplies, and/or services.

14. CONFLICT OF INTEREST

a. Officials and employees of the state agency, its governing body, or any other public officials of the State of Missouri must comply with Sections 105.452 and 105.454 RSMo regarding conflict of interest.
b. The contractor hereby covenants that at the time of the submission of the proposal the contractor has no other contractual relationships which would create any actual or perceived conflict of interest. The contractor further agrees that during the term of the contract neither the contractor nor any of its employees shall acquire any other contractual relationships which create such a conflict.

15. REMEDIES AND RIGHTS

a. No provision in the contract shall be construed, expressly or implied, as a waiver by the State of Missouri of any existing or future right and/or remedy available by law in the event of any claim by the State of Missouri of the contractor's default or breach of contract.
b. The contractor agrees and understands that the contract shall constitute an assignment by the contractor to the State of Missouri of all rights, title and interest in and to all causes of action that the contractor may have under the antitrust laws of the United States or the State of Missouri for which causes of action have accrued or will accrue as the result of or in relation to the particular equipment, supplies, and/or services purchased or procured by the contractor in the fulfillment of the contract with the State of Missouri.

16. CANCELLATION OF CONTRACT

a. In the event of material breach of the contractual obligations by the contractor, the Office of State Courts Administrator may cancel the contract. At its sole discretion, the Office of State Courts Administrator may give the contractor an opportunity to cure the breach or to explain how the breach will be cured. The actual cure must be completed within no more than 10 working days from notification, or at a minimum the contractor must provide the Office of State Courts Administrator within 10 working days from notification a written plan detailing how the contractor intends to cure the breach.
b. If the contractor fails to cure the breach or if circumstances demand immediate action, the Office of State Courts Administrator will issue a notice of cancellation terminating the contract immediately.
c. If the Office Of State Courts Administrator cancels the contract for breach, the Office of State Courts Administrator reserves the right to obtain the equipment, supplies, and/or services to be provided pursuant to the contract from other sources and upon such terms and in such manner as the Office of State Courts Administrator deems appropriate and charge the contractor for any additional costs incurred thereby.
d. The contractor understands and agrees that funds required to fund the contract must be appropriated by the General Assembly of the State of Missouri for each fiscal year included within the contract period. The contract shall not be binding upon the State for any period in which funds have not been appropriated, and the State shall not be liable for any costs associated with termination caused by lack of appropriations.

17. COMMUNICATIONS AND NOTICES

Any notice to the contractor shall be deemed sufficient when deposited in the United States mail postage prepaid, transmitted by facsimile, transmitted by e-mail or hand-carried and presented to an authorized employee of the contractor.

18. BANKRUPTCY OR INSOLVENCY

a. Upon filing for any bankruptcy or insolvency proceeding by or against the contractor, whether voluntary or involuntary, or upon the appointment of a receiver, trustee, or assignee for the benefit of creditors, the contractor must notify the Office of State Courts Administrator immediately.
b. Upon learning of any such actions, the Office of State Courts Administrator reserves the right, at its sole discretion, to either cancel the contract or affirm the contract and hold the contractor responsible for damages.

19. INVENTIONS, PATENTS AND COPYRIGHTS

The contractor shall defend, protect, and hold harmless the State of Missouri, its officers, agents, and employees against all suits of law or in equity resulting from patent and copyright infringement concerning the contractor's performance or products produced under the terms of the contract.

20. NON-DISCRIMINATION AND AFFIRMATIVE ACTION

In connection with the furnishing of equipment, supplies, and/or services under the contract, the contractor and all subcontractors shall agree not to discriminate against recipients of services or employees or applicants for employment on the basis of race, color, religion, national origin, sex, age, disability, or veteran status. If the contractor or subcontractor employs at least 50 persons, they shall have and maintain an affirmative action program which shall include:

a. A written policy statement committing the organization to affirmative action and assigning management responsibilities and procedures for evaluation and dissemination;
b. The identification of a person designated to handle affirmative action;
c. The establishment of non-discriminatory selection standards, objective measures to analyze recruitment, an upward mobility system, a wage and salary structure, and standards applicable to layoff, recall, discharge, demotion, and discipline;
d. The exclusion of discrimination from all collective bargaining agreements; and
e. Performance of an internal audit of the reporting system to monitor execution and to provide for future planning.

If discrimination by a contractor is found to exist, the Office of State Courts Administrator shall take appropriate enforcement action which may include, but not necessarily be limited to, cancellation of the contract, suspension, or debarment by the Office of State Courts Administrator until corrective action by the contractor is made and ensured, and referral to the Attorney General's Office, whichever enforcement action may be deemed most appropriate.

21. AMERICANS WITH DISABILITIES ACT

In connection with the furnishing of equipment, supplies, and/or services under the contract, the contractor and all subcontractors shall comply with all applicable requirements and provisions of the Americans with Disabilities Act (ADA).

22. TITLES

Titles of paragraphs used herein are for the purpose of facilitating reference only and shall not be construed to infer a contractual construction of language.

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The offeror should copy and complete this form for each reference being submitted as demonstration of the offeror and subcontractor's prior experience. In addition, the offeror 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.

Offeror Name or Subcontractor Name: Germaine Laboratories, Inc.	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Advantage Medical Supply Company
Address of Reference Company ✓ Street Address ✓ City, State, Zip	5126 Service Center Drive San Antonio, TX 78218
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Len Neeper 210-599-1991 len@advantagemedicalsupply.com
Dates of Prior Services:	1998-current
Dollar Value of Prior Services	
Description of Prior Services Performed	Purchaser of drug of abuse test, pregnancy test, strep A tests, urinalysis test, and serology tests.

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by the OSCA for additional discussions regarding my company's association with the offeror referenced above:

Len Neeper
Signature of Reference Contact Person

7/26/2007
Date of Signature

EXHIBIT B

PRIOR EXPERIENCE

The offeror should copy and complete this form for each reference being submitted as demonstration of the offeror and subcontractor's prior experience. In addition, the offeror 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.

Offeror Name or Subcontractor Name: __Germaine Laboratories, Inc._____

Reference Information (Prior Services Performed For:)	
Name of Reference Company:	State of Missouri Office of State Courts Administrator
Address of Reference Company ✓ Street Address ✓ City, State, Zip	2112 Industrial Drive Jefferson City, MO 65110
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Shirley Morfeld 573-526-0482 shirley.morfeld@courts.mo.gov
Dates of Prior Services:	2004-current
Dollar Value of Prior Services	
Description of Prior Services Performed	Purchaser of drug of abuse test

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 the OSCA for additional discussions regarding my company's association with the offeror referenced above:

_____ _____

Signature of Reference Contact Person *Date of Signature*

OSCA 11 - 029

EXHIBIT B

PRIOR EXPERIENCE

The offeror should copy and complete this form for each reference being submitted as demonstration of the offeror and subcontractor's prior experience. In addition, the offeror 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.

Offeror Name or Subcontractor Name: Germaine Laboratories, Inc.	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Craig Medical Distribution
Address of Reference Company ✓ Street Address ✓ City, State, Zip	1185 Park Center Drive, Suite P Vista, CA 92081
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Craig Munson 760-598-7170 customerservice@craigmedical.com
Dates of Prior Services:	1998-current
Dollar Value of Prior Services	
Description of Prior Services Performed	Purchaser of drug of abuse test, pregnancy test, and strep A tests.

As the contact person for the reference provided above, my signature below verifies that the information presented on this form is accurate. I am available for contact by the OSCA for additional discussions regarding my company's association with the offeror referenced above:

Signature of Reference Contact Person

07/27/07
Date of Signature

Glossary of Terms

Drug Metabolism: Most drugs are changed by the body (metabolized) prior to elimination in the urine. In some cases both the parent drug and its metabolite(s) are present, in other cases only the metabolite is present.

Drug Detection and Identification:

Screens: Are performed by **Immunoassay**. This test is based on the biological interaction of an antibody with a drug and/or its metabolite. This test is sensitive to drug groups as opposed to a specific drug or its metabolite. Immunoassay can provide qualitative results only and is only relied upon to give NEGATIVE results.

Confirmation Testing: Is performed by **Gas Chromatography** with **Mass Spectrometry** detection (**GC/MS**). This test is based on the physical and chemical properties of the specific drug or metabolite to be measured. Drug identification is achieved BOTH by chromatographic retention time and by Mass Spectrum, which is the "drug fingerprint." This test is very specific and robust with respect to interference. This confirmation test is legally defensible evidence of drug use.

GC/MS Confirmation Reporting: Results are reported as POSITIVE according to SAMHSA cut-off levels. GC/MS results can be reported in as a qualitative result in ng/mL

Ng/mL: Nanograms per milliliter (parts per billion). This is the unit of measure for reporting the quantitative confirmed positive result.

Specimen Validity Testing: Specimen validity testing is checking a urine specimen to make sure it is not too **dilute** or that it has been **adulterated** by the addition of a chemical substance that can interfere with the testing. Testing for dilution and adulteration of the urine specimens is known as specimen validity testing, i.e. making sure the specimen is valid for testing.

Dilution Testing: checking each urine specimen for dilution by measuring the amount of creatinine.

Creatinine: is a normal metabolic waste product of muscle activity that a person excretes into their urine all the time. A person produces and excretes about the same amount of creatinine each day. A person that produces a lot of urine will spread that creatinine over a high volume of urine, and the creatinine concentration will be low. A person that does not produce much urine will have a more concentrated urine and the creatinine concentration will be high. Creatinine is measured in units of milligrams per deciliter or mg/dl. For drug testing purposes, the expected concentration of creatinine is equal to or greater than 20 mg/dl. It can be as high as 300 to 400 mg/dl in a very concentrated urine, which will be a deep yellow-brown color. If the creatinine is less than 20 mg/dl, we do a second test for dilution called specific gravity.

Specific Gravity: This test measures the amount of dissolved substances in the urine. Specific gravity ranges from very dilute at 1.000 (the same as water) to over 1.030 (concentrated).

Adulteration: occurs when a foreign substance is added to the urine specimen in order to interfere with the testing. Adulteration of the specimen has been attempted by some donors for years. Early on, substances like bleach, acids, Drano, salt and Visine were used to adulterate specimens. In recent years, commercial products are sold specifically to adulterate urine specimens. Brand names include Klear, Urine Luck, Whizzies and THC Free. These products are advertised on the Internet and in magazines such as High Times. The most common adulterants today are oxidants, acids and bases.

Oxidants: are chemicals that react primarily to destroy marijuana metabolites in the urine. The marijuana metabolites cannot then be detected with the drug test. Oxidants include **nitrite, chromium, bleach** and many others.

Nitrites: have been the most common oxidant used over the last five years. New oxidants are packaged and sold as adulterants each year. It is very difficult for laboratories to keep up with these new oxidant products.

Acids and **bases** drastically change the **pH** of the urine. Acids cause a low pH and bases cause a high pH value. In both cases, the drug test may not work properly. Specimens are considered adulterated if the pH is too low (less than or equal to 3.0) or if the pH is too high (greater than or equal to 11.0).

MRO: Medical Review Officer (MRO). A Physician (Medical Doctor or Osteopath) who has special training and expertise is drugs of abuse. All MRO's must have additional training and certification from a DHHS approved organization that provides training, written & oral testing, and continuing education. The most recognized certifying body is the American Association of Medical Review Officers (AAMRO).

Chain-of-Custody: The multi-copy document that is completed by the certified collector at the time of the specimen collection. This document when correctly completed provides legal defensibility and ties the urine specimen to the document. Multiple copies are designed to: 1) accompany the specimen to the laboratory 2) sent to employer 3) sent to MRO 4) retained by collector 5) provided to donor as a receipt.

Split Specimen: Required for DHHS mandated testing (DOT). The collected specimen is poured off into an A and B bottle that are sealed and sent to the laboratory with the chain of custody.

Cocaine

Classification: Stimulant

Street Names: Blow, Coke, Crack, Flake, Snow

Mode of Use: Snorting, intravenous injection, free-base (crack) smoking

Physiological Effects: Desirable effects of cocaine include euphoria, anorexia, and sexual stimulation. Direct cardiotoxic effects may be the contributory factor in cocaine-induced deaths.

Psychological Effects: Prolonged and intense use can lead to paranoia, hallucinations and violent behavior. The central nervous system stimulation (rush) is followed by depression (crash). This rush and crash cycle is the principle reason for the development of chronic cocaine abuse.

Legally Obtained as: Cocaine is still used as a local anesthetic. Medicinal cocaine use is rarely found outside hospital settings because of the high potential for abuse, the difficulty maintaining the license to store cocaine and the availability of suitable substitutes. Cocaine is not contained in any prescription medications from a pharmacy or in any over-the-counter medications. As late as 1986 an herbal tea sold under the name of "Health Inca Tea" contained enough cocaine to cause positive urine test. The DEA continues to seize herbal teas containing cocaine.

Metabolism: Cocaine is metabolized to benzoylecgonine. The presence of Benzoylecgonine is accepted evidence of cocaine use and can be detected in the urine for as long as 2-5 days.

Summary: Commonly used local topical anesthetics such as lidocaine, novocaine and benzocaine are structurally unrelated to cocaine and its metabolites and do not result in a positive screen or confirmation. There are no known medications that cause a false positive screen or confirmation. Studies have shown that although cocaine can be absorbed through the skin, even intense exposure is insufficient to cause a positive urine test result.

Marijuana

Classification: Hallucinogen

Street Names: Weed, Doobie, Grass

Mode of Use: Smoking & ingestion

Physiological Effects: Munchies after use.

Psychological Effects: Euphoria

Legally Obtained as: Dronabinol and Marinol.

Metabolism: THC in marijuana is broken down into at least 5 different compounds (metabolites) that are excreted in the urine. The metabolite commonly in the greatest abundance (accounting for greater than 30% of all the metabolites) is carboxy-THC (THCC). The parent drug (THC) does not pass into the urine. The presence of marijuana metabolites in urine is accepted evidence of marijuana use.

Summary: There are no known drugs that cause false positive results wither on the screen or confirmation test.

Opiates

Classification: Narcotics

Street Names: Heroin: Horse, H, Smack, White Lady and Skag.
Morphine: Junk, Morphai, Morphium and Morpho.

Mode of Use: Heroin: Smoked, snorted, or injected.
Morphine: Oral ingestion, injected, suppositories, liquid
Codeine: Oral ingestion, elixirs.
Hydrocodone: Oral ingestion.
Hydromorphone: Oral ingestion, elixirs, injection and suppositories.
Oxycodone: Oral ingestion and elixirs.

Physiological Effects: Analgesia (pain relief), respiratory slowing and constipation are common effects for most users. Respiratory slowing, or even complete cessation, presents the greatest immediate risk associated with opiate abuse. Death due to complete respiratory arrest is common with overdoses. There is also the long-term risk of AIDS and other infectious diseases associated with illicit intravenous drug use. Tolerance is the property by which a dramatic increase in the dose is necessary to achieve the same effect. Tolerance begins to build after the initial dose, but is usually significant only after the second week of chronic use. Up to a 35 fold increase in dose may be necessary. Withdrawal symptoms begin 6-8 hours after the last dose and reach a peak at 36-72 hours.

Psychological Effects: Mental alterations are primarily sedation and euphoria, the heightened feeling of well being. Long-term use leads to dependence (addiction) and tolerance.

Legally Obtained as: The following table contains commonly used opiates and opiate-like drugs.

Metabolism: In the body, heroin is converted to 6-Acetylmorphine (6-AM) within a few minutes. 6-AM is further metabolized to morphine within a few hours. Heroin usually contains 5-10% codeine because it is manufactured from opium, which contains morphine and codeine. Heroin itself is so rarely detected in the urine following use that laboratories do not normally test for it. 6-AM is a unique metabolite of heroin and is usually only detected during the first 12 hours after use. When present it is evidence of heroin use.

Summary: The terms “narcotics” and “opiates” are often used interchangeably but are not exactly the same. Narcotics are drugs that numb the senses and induce sleepiness. Some non-opiate drugs also have narcotic properties. Opiates are compounds derived from opium, the milky residue of the opium poppy plant. Opium contains morphine and codeine. The naturally occurring morphine and codeine can be altered in the laboratory to produce “semi-synthetic” opiates, of which there are many. The most notable semi-synthetics are heroin, hydrocodone, hydromorphone and oxycodone. Poppy seeds contain enough codeine and morphine so that their consumption can cause both morphine and codeine to be

detected in the urine. Poppy seed consumption rarely results in a morphine level greater than 2000 ng/mL, whereas use of heroin or morphine usually leads to much higher levels.

Drug	Trade Name	Class	Legal Use
Buprenorphine	Buprenes	Opiate narcotic	Pain relief
Butorphanol	Stadol	Opiate narcotic	Pain relief
Codeine	Empirin, Tylenol 3	Opiate narcotic	Pain relief
Dextromethorphan	Robitussne DM	Opiate non-narcotic	Cough suppression
Heroin	None	Opiate narcotic	No legal use
Hydrocodone	Vicodin, Lortab	Opiate narcotic	Pain relief
Hydromorphone	Dilaudid	Opiate narcotic	Pain relief
Lrvorphanol	Dromoran	Opiate narcotic	Pain relief
Meperidine	Demerol	Non-opiate narcotic	Pain relief
Methadone	Dolophine	Non-opiate narcotic	Opiate dependency
Morphine	MS-Contin	Opiate narcotic	Pain relief
Nalbuphine	Nubian	Opiate narcotic	Pain relief
Naloxone	Narcan	Opiate anti-narcotic	Narcotic overdose
Naltrexone	Trexan	Opiate anti-narcotic	Narcotic overdose
Oxycodone	Percodan, Roxicet	Opiate narcotic	Pain relief
Oxymorphone	Numorphan	Opiate narcotic	Pain relief
Propoxyphene	Darvon	Non-opiate narcotic	Pain relief

Phencyclidine (PCP)

Classification: Hallucinogen

Background: Phencyclidine was fist synthesized in 1926 and was used as an anesthetic for humans and animals. A number of toxic central nervous system effects were discovered over time and production was completely discontinued in 1978 due to the high rate of toxicity. It is currently only produced for research purposes and as a laboratory drug standard. Legally Prescribed forms: There are currently no legal forms of the drug which are accepted for medical or veterinary use. Illicit Use: PCP is usually snorted as a white powder or injected. It may also be smoked, often as a mixture with marijuana. Intravenous use and oral consumption are also possible.

Street names: are "angel dust", "hog" and "love boat". It may be misrepresented by drug dealers as another hallucinogen, i.e. mescaline or THC.

Effects on the User: PCP is a strong hallucinogen. Auditory or visual illusions may develop. The drug may induce altered perception of time and distance. Desired effects may be exciting and dreamy.

Toxic Side Effects: Like dreams, there may also be terrifying nightmares of unpredictable duration. Flashbacks have been reported. The hallucinations may lead to irrational acts, which place the user in grave danger. Episodes of uncontrollable violence may develop. Long-lasting mental alterations may persist after the drug has been completely metabolized. Most commonly these take the form of depression, suicidal ideation, speech impairment and social withdrawal. Actual physical addiction has not been proven with certainty.

Drug Testing Results: PCP is readily absorbed into the body's fat stores and may be detected for prolonged periods. Detection interval may be as long as two weeks following brief use and as long as 30 days for chronic abuse. High doses of the cough suppressant, dextromethorphan, may produce false positive screen results. However, confirmation by GC/MS will rule out this compound.

Tables of Abused Drugs

Stimulants	
Drug Name	**Trade Name**
Amphetamine	Benzedrine, Dexedrine
Methamphetamine	Desoxyn, Methedrine, Gradumet
Cocaine	None

Hallucinogens	
Drug Name	**Trade Name**
Cannaboids (Marijuana, THC)	Dronabinol, Marinol
LSD	None
Mescaline (peyote)	None
Phencyclidine	None
Psilocybin (mushrooms)	None

Depressants/ Sedatives/ Hypnotics	
Drug Name	**Trade Name**
Barbiturates	
Amobarbital	Amytal
Butabarbital	Butisol
Butalbital	Fiorinal, Esgic
Pentobarbital	Nembutal
Phenobarbital	Donnatal, Luminal
Secobarbital	Seconal
Benxodiazepines	
Alprazolam	Xanax
Bromazepam	Lexotan
Chlordiazepoxide	Librium
Diazepam	Valium
Flunitrazepam	Rohypnol, Roofies
Lorazepam	Ativan
Oxazepam	Serax
Temazepam	Restoril
Triazoiam	Halcion
Methaqualone	Mandrax, Normi-Nox, Quaalude, Rouqualone, Tualone

Narcotics/ Analgesics/ Opioids	
Drug Name	**Trade Name**
Meperidine (Synthic)	Demerol, Demer-Idine
Methadone	Dolophine, L-Polamidon, Methadone, Physeptone
Opiates (more info)	
Codeine	Tylenol-3, Empirin, AC
Heroin	None
Hydrocodone	Vicodin, Lortab, DH
Hydromorphone	Dilaudid
Morphine	MS Contin, Rectal, Astramorph
Oxycodone	Percodan
Propoxyphene	Darvon, Novopropoxyn, Wygesic

QUALITY ASSURANCE
And
OPERATIONS OVERVIEW

ADVANCED TOXICOLOGY NETWORK
3560 Air Center Cove, Suite 101
Memphis, TN 38118

The goal of a good quality assurance program is to assure that all aspects of the testing laboratory be as error free as possible. This includes specimen acquisition, processing, specimen storage, testing, data entry, reporting, and data storage. There must be established protocols for all phases of testing. There must be a comprehensive quality control system that includes acceptable methods of recording control data, determining control limits, review of control data, and proper storage of data. Measurable indicators should be determined throughout the laboratory and systems put into place to properly monitor them.

Quality assurance is the responsibility of all employees. In order to maintain an acceptable program all control data is reviewed on a daily basis in the departments and weekly or monthly by the QA/QC officer. Any errors or problems detected must be brought to the attention of all employees involved and corrective action documented and records maintained for a minimum of two years. All equipment is on a preventive maintenance program and all function checks are recorded and reviewed. Quality control samples are included in each batch of specimens analyzed. The QC program is overseen and reviewed by the QA/QC Officer on a continual basis.

Advanced Toxicology Network (ATN) complies with all federal drug-testing regulations and is certified by the Substance Abuse and Mental Health Services Administration (SAMHSA). ATN is inspected for this certification twice each year. The laboratory also maintains licensure with several states that have individual requirements. These include Florida, Maryland, Iowa, New York, Pennsylvania and Oklahoma.

Advanced Toxicology Network (ATN) has received and submitted the Texas Department of Public Safety Laboratory Accreditation Application Form.

SPECIMEN RECEIPT AND PROCESSING:

When specimens arrive at Advanced Toxicology Network (ATN) each bag is inspected for proper seal. The bag is opened and the bottle seal is checked. The specimen numbers on the bottle and the custody and control form (CCF) are compared. The CCF is checked for other required information. At this point the specimens are grouped into batches of up to forty specimens for DOTs, Look-alikes, and Florida workplace and up to ninety specimens for non-DOTs.

Another processor takes the tray containing the batch and enters some of the demographic data into the computer. A barcode is printed and affixed onto a test tube. A portion of the sample is poured into the barcode-labeled tube and racked to be sent to the screening department. Only one sample is handled and opened at the time to avoid any cross contamination or mix-up. The original specimens never leave the processing room and nothing is ever poured back into them.

A third processor takes the CCFs for a batch and checks the data previously entered by the second processor and adds other demographics to the sample file. The CCFs are placed in a folder and sent to the screening department to be reviewed by a certifying scientist at the time that the screening results are reviewed and released.

All of the activities in the processing area are recorded both by signature and computer audit trail so that the person performing each step can be identified.

SCREENING ANALYSIS:

The batch of samples is received by a screener who assigns the batch to an instrument for analysis. A load list generated by the computer in processing itemizes the samples that are included in the batch. The racks of tubes are loaded on the instrument along with appropriate control material designed to check each drug that is tested. Positive and negative controls just above and below the various cutoffs are utilized to be sure that the instrument is functioning properly. Any control failure stops the run and all the samples in the batch are repeated. Instrumentation currently in use in the screening department includes seven Abbott Aerosets. The reagent methodology utilized is Microgenics CEDIA™ recombinant DNA enzyme immunoassay. Calibrations are performed at least once in twenty-four hours with additional calibrations being performed as needed. Drug analyses available include amphetamines, cocaine, opiates, PCP, THC, barbiturates, benzodiazepines, methadone, methaqualone, propoxyphene, and both urine and blood alcohol. Validity testing that is available includes creatinine, specific gravity, nitrite, and pH. Regulated specimens conform to the DOT cutoffs and non-regulated specimens are evaluated based on the cutoffs requested by the client.

When the screener is satisfied with the test results, the data and specimen list are signed by the screener and passed on to a certifying scientist for further review. Control results are reviewed again. The CCFs that belong to these samples are reviewed for completeness and any presumptive positives are pulled out. The data is checked in the computer to be sure that it matches the hardcopy. All negative samples are released for report at this point. Regulated samples are released to the MRO and non-regulated samples are released based on the requests of the client. The sample portions used to perform the screening analysis are discarded. The negative certifiers sign all hard copies and an audit trail is created in the computer.

Specimens received each night by direct air flight and Federal Express are screened throughout the night. Over 90% of negatives are reported by 8:00 AM CT. Specimens received in the morning by Airborne are screened during the day. Over 95% of negatives are reported by 1:00 PM CT. The screening department is in operation from 5:00 AM on Monday through 9:00 AM on Saturday.

CONFIRMATION ANALYSIS:

The CCFs of the presumptive positives are returned to the processing department along with the hardcopy of the screening data and the specimen lists for each batch. Processors retrieve the original samples, matching the sample numbers and creating new batches of each drug that requires confirmation. New portions of each sample are used to perform the confirmation test. Pulling this new portion provides another check of the correctness of the sample being tested. The extraction staff members process the new aliquots following validated SOP procedures preparing the samples for GC/MS analysis. Their signatures on the internal CCFs document this portion of the testing.

The confirmation department utilizes eight Hewlett Packard GC/MS instruments with capillary inlet systems, EI ionization, and quadrupole ion focus. SIM technique is used to establish the identities of the analytes and internal standards. Three ions are monitored for the analyte – a quantitation ion plus two qualifiers. Qualifiers must be within 20% of target. Two ions are monitored for the internal standard – a quantitation ion plus one qualifier. Retention time (RT) of peaks must be within +/-2% of the calibrator RT. Chromatography must be clean. All confirmation methods are validated annually to include limit of detection (LOD), limit of quantitation (LOQ), precision, accuracy, upper limit of linearity (ULOL) and carryover.

The results of the confirmation data are checked thoroughly and signed, first by a reviewer and then by a certifying scientist. The certifier reviews all the work, including the screening data, which leads up to the final result that is reported. When the certifier is satisfied with everything, the results are signed and released to the client or the MRO as dictated by regulations and client requests. MROs have the option to receive quantitative values and their preference is programmed into the client file. Quantitations on

codeine or morphine greater than 15,000 ng/ml are automatically reported. Computer-generated reports are transmitted and/or mailed to the client. For specimens received at night, over 30% are confirmed by 3:00 PM CT the following day and over 95% by 3:00 PM CT the next day. The confirmation department operates from 7:00 AM on Monday through 7:00 AM on Sunday.

EXTERNAL QUALITY CONTROL:

SAMHSA certification is handled through the National Laboratory Certification Program (NLCP). In addition to the inspections the laboratory is required to participate in a proficiency-testing program. This program involves the testing of twenty samples that are prepared by the NLCP on a quarterly basis. These samples target the five drugs tested on regulated specimens. The samples contain various levels of drugs as well as commonly used adulterants. Failure to correctly analyze these samples can jeopardize certification.

The laboratory also subscribes to a voluntary peer program provided by the College of American Pathologists (CAP) in which ten additional proficiency samples are tested four times a year. These samples target all ten of the drugs routinely offered by ATN as well as blood alcohols. The states of Florida, Pennsylvania and New York send their own proficiency samples for testing several times a year. The state surveys also target all ten drugs and blood and/or urine alcohols.

STAFF:

Employees must complete a comprehensive training checklist before they are allowed to work unsupervised. Each position has a checklist tailored for the specific duties of the position. The inspection teams review employee qualifications during each on-site inspection.

RECORDS/SPECIMEN STORAGE:

All testing records and CCFs are maintained for two years. They are routinely transferred to an off-site secure storage facility where they remain until destruction. All transactions on the computer are archived daily. LIMS backups are performed weekly and the tapes are removed to a secure box in the vault of a nearby bank. A stand-by generator is available to maintain power in the event of power failure. The servers have a UPS battery system that will keep them operational so that an orderly shutdown can occur if necessary.

Positive specimens are retained at –20°C for one year. They may be held longer if the client makes a request prior to the scheduled destruction date.

CONCLUSION:

The number of checks and controls that are in place make it virtually impossible for an incorrect result to be reported. Of course, the quality is always dependent upon everyone in the chain of individuals involved in the handling and testing of a sample. This includes the people setting up the account (both from the lab and the client), the use of the proper CCF with correct documentation by the collector, each individual who is involved at the laboratory, and the MRO. Every employee at ATN constantly strives to provide an accurate and defensible report on every specimen received.

AimStep®
Breath Alcohol Detector

PRINCIPLE

The Breath Alcohol Detector is for the semi-quantitative, rapid detection of alcohol in the exhaled breath. It indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels. The test is based on a chemical reaction. Alcohol reacts with the crystals in the detector to produce a color change. The color change depends on the amount of alcohol in the breath.

REAGENTS

The test contains Acids, Oxidants, and other non-reactive additives.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For diagnosing intoxication.
- Do not use after the expiration date printed on the sealed pouch.
- Keep out of reach of children.
- Do not swallow or eat the crystals.
- Do not reuse the test.
- Do not use if the Inner Glass Tube has been broken.
- Do not use if the crystals are not yellow.
- Results are affected by color perception and the lighting conditions when the test is read.
- Do not immerse in liquid.
- Dispose of properly.

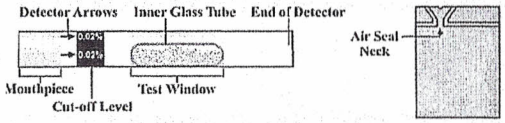
STORAGE AND HANDLING

Store as packaged. Keep detector in the sealed pouch until use. Store at room temperature or refrigerated (2-30°C or 36-86°F). DO NOT FREEZE. Do not leave the test in direct sunlight or near heat sources.

PRODUCT FEATURES AND INTENDED FOR USE

The Breath Alcohol Detector is a screening test. It can be used to diagnose intoxication or to help prevent drunk driving.

- Accurate and reliable
- Easy to use
- Individually packaged
- Results in 2 minutes



MATERIALS PROVIDED

- Detectors
- Blow bags (REF C031-031 only)
- Package insert

MATERIALS REQUIREDBUT NOT PROVIDED

- Timer

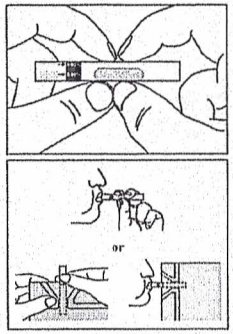
INSTRUCTIONS FOR USE

Wait 15 minutes after last alcohol intake or drink a glass of water before testing.

1. Bring the pouch to room temperature (15-30°C or 59-86°F) before opening. Remove the detector from the sealed pouch. Do not touch the Mouthpiece to avoid contamination.
2. Hold the middle of the detector. Firmly squeeze the detector to break the Inner Glass Tube. Perform the test as soon as possible to avoid the affects of humidity. **Do not crush or bend the detector.** Refer to the picture at right.
3. Breathe into the detector.
   - **For Breath Alcohol Detector <u>without blow bag</u>:**
     - Hold the middle of the detector horizontally. Take a deep breath. Blow hard into the Mouthpiece, in the same direction as the Detector Arrows. Blow hard in **one continuous breath for 12 seconds**.

       Note: Failure to blow hard, or in one continuous breath for 12 seconds, may cause false results. Do not inhale while blowing into the detector. Refer to the picture at right. Shake the detector slightly to distribute the crystals evenly in the Test Window.
   - **For Breath Alcohol Detector <u>with blow bag</u>**
     - Insert the detector into the Air Seal Neck of the blow bag in the same direction as the Detector Arrows. Roll the detector into the blow bag until the Test Window is completely covered. Ensure the End of the Detector is past the Air Seal Neck of the blow bag. Refer to the illustration at right.
     - Hold the middle of the detector horizontally. Take a deep breath. Blow hard into the Mouthpiece of the detector **until the blow bag is completely inflated**.

       Note: Failure to blow hard, or to inflate the blow bag completely, may cause false results. Do not inhale while blowing into the detector.



   - Remove the detector from the blow bag. Shake the detector slightly to distribute the crystals evenly in the Test Window.
4. **Read results at 2 minutes** by looking at the color of the majority of crystals. Do not read results after 5 minutes.

INTERPRETATION OF RESULTS

For best results, compare the crystals from the used detector to the crystals from an unused detector of same cut-off level.

NEGATIVE: Majority of the crystals remain yellow-orange. The relative BAC is below the cut-off level of the detector. The crystals may be lighter than the crystals from an unused detector.

POSITIVE: Majority of the crystals are green-blue. The relative BAC is at or above the cut-off level of the detector.

LIMITATIONS

1. Alcohol impairs judgment. The test should be performed by someone who is not under the influence of alcohol.
2. The Breath Alcohol Detector is screening test. It cannot detect exact BAC. Confirm results with an approved alcohol test before taking legal action. Actions of any person, based on the outcome of the test, are at the person's own risk.
3. Failure to wait 15 minutes after the last alcohol intake, or to drink a glass of water, before testing may cause false results.
4. Wait 15 minutes after using over-the-counter products, eating, smoking, or chewing gum before testing. Such items may cause false positive results.
5. People who are color-blind or visually impaired should not read results.
6. Read the test under incandescent, fluorescent, or indirect sunlight. Do not read under streetlights. Sodium vapor from streetlights can cause colors to appear differently. Use a flashlight to read the results. Shine the light on the side of the detector and not directly on it.
7. Sex, age, physical condition, and the amount of food or drugs consumed may affect the test. A person under the influence of alcohol may test negative.
8. The test is highly sensitive to alcohol and alcohol vapors in the air. Perform the test in an area free of vapors.

PERFORMANCE CHARACTERISTICS

The Breath Alcohol Detector will react with certain reductive substances, such as ethyl alcohol in human breath. Other reductive substances do not normally interfere with Breath Alcohol Detector in sufficient quantity.

Index of Symbols

⚠	Attention, see instructions for use	⌛	Use by	②	Do not reuse
2°C–30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
Σ	Tests per kit	EC REP	Authorized Representative		Manufacturer

GERMAINE® LABORATORIES, INC.
San Antonio, Texas USA
www.germainelabs.com
800.854.8446
210.692.4192
210.692.4198 fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

MAR 26 1999

Robert F. Foery, Ph.D.
Advanced Toxicology Network
3560 Air Center Cove, Suite 101
Memphis, Tennessee 38118

Dear Dr. Foery:

I am pleased to inform you that Advanced Toxicology Network, Memphis, Tennessee, has successfully met all of the requirements for laboratory certification as specified in the Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29908).

Advanced Toxicology Network, Memphis, Tennessee, will be placed on the list of laboratories certified as eligible to bid on contracts to perform drug testing for Federal Drug-Free Workplace Programs. The list of laboratories certified by the Substance Abuse and Mental Health Services Administration on behalf of the Department will be sent to all Federal Agencies. Updates to this list will be published every month in the Federal Register, and made available to the general public upon request.

To maintain certification from HHS, Advanced Toxicology Network, Memphis, Tennessee, must continue to meet all the requirements of the Federal Guidelines as specified in Subpart C--Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies. Maintenance of certification requires participation in a quarterly performance testing program plus periodic, on-site inspections (see § 3.2(b), 3.17, 3.18, 3.19 and 3.20).

If you have any questions concerning the HHS National Laboratory Certification Program, please contact the Division of Workplace Programs at (301) 443-6014.

The HHS laboratory standards for urine drug testing certification were designed to assure Federal Agencies and their employees that the laboratories and the scientific and methodological procedures used are of the highest quality. Your laboratory is to be congratulated for meeting all the requirements of the Department's program.

Sincerely yours,

Nelba Chavez, Ph.D.
Administrator

Advanced Toxicology Network

Chief Executive Officer/
Laboratory Director: **Stuart C. Bogema, Jr., PhD**

Education:

GEORGE MASON UNIVERSITY, Fairfax, VA
Master of Business Administration 1991-1993
MEDICAL COLLEGE OF VIRGINIA –
VIRGINIA COMMONWEALTH UNIVERSITY, Richmond, VA
PhD in Pathology and Toxicology 1979-1983
GEORGE WASHINGTON UNIVERSITY, Washington, DC
Graduate study in Biochemistry 1977-1979
UNIVERSITY OF RICHMOND, Richmond, VA
Bachelor of Science in Chemistry and Biology 1970-1974

Certifications/Licenses/Affiliations:

American Board of Forensic Toxicology
Certificate of Qualification and Diplomate 1988 to present
American Board of Clinical Chemistry in Toxicological Chemistry
Certificate of Qualification and Diplomate 1988 to present
American Academy of Forensic Sciences
Fellow
Society of Forensic Toxicologists
Full Member
American Association for Clinical Chemistry
Member
American Society of Clinical Pathologists
Member
Certified Laboratory Director for the following states:
New York, New Jersey, Florida, Pennsylvania, Maryland, Maine, Vermont, Virginia

Special Skills:

Expert witness in toxicology in Federal, state and local courts for criminal and civil proceedings – 1983 to present

Laboratory inspector and consultant for the National Laboratory Certification Program, US DHHS

Toxicology-Related Work Experience:

ADVANCED TOXICOLOGY NETWORK, MEMPHIS, TN 1999 – to present
Serving as Chief Executive Officer

FORENSIC TESTING, INC. 1996 – to present
Serving as president of a company providing toxicology consulting and research services.

FORENSIC QC, INC. 1992 – to present
Serving as vice president of a company providing quality control consulting.

PRINCETON DIAGNOSTIC LABORATORIES (PDLA),
EDITEK, INC., SOUTH PLAINFIELD, NJ 1994 - 1996
Served as laboratory director and vice president of operations.

AMERICAN MEDICAL LABORATORIES, INC., CHANTILLY, VA 1983 - 1993
Served in various positions to include Director of clinical and forensic toxicology, Director of industrial hygiene and environmental testing, Director of sales and marketing of the toxicology services, Responsible Person for the NIDA/SAMHSA certified laboratory division, Vice president of toxicology and research and development

MEDICAL COLLEGE OF VIRGINIA, RICHMOND, VA 1980 - 1981
Served as a laboratory specialist in the department of pathology and clinical toxicology

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 0 8 2002

Re: k020313
Trade/Device Names: One Step Multi-Drug Multi-Line Screen Test Card
One Step Multi-Drug Multi-Line Screen Test Device
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3250; 21 CFR 862.3870; 21 CFR 862.3650; 21 CFR 862.3610
Regulation Name: Amphetamine test system; Cocaine and cocaine metabolite test System; Cannabinoid test system; Opiate test system; Methamphetamine test system
Regulatory Class: Class II; Class II; Class II; Class II, Class II
Product Code: DKZ; DIO; LDJ; DJG; LCM; LAF
Dated: April 8, 2002
Received: April12, 2002

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

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

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

This letter will allow you to begin marketing your device as described in your 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 Gutman

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

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

c/o Mr. Howard Mann
1 Congressional Drive, Apt. C
Greenville, DE 19807

AUG 25 2010

Re: k093175
Trade/Device Name: Wondfo One Step Bruprenorphine Urine Test
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, JXN
Dated: August 20, 2010
Received: August 24, 2010

Dear Mr. Mann:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2005

c/o Mr. Howard Mann
Sherbo Associates
8903 Spruce Mill Drive
Yardley, PA 19067

Re: k050024
Trade/Device Name: Multiple Drugs of Abuse Assays
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DPK, DJG, LCM, LFG
Dated: October 2, 2005
Received: October 5, 2005

Dear Mr. Mann:

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

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

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

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

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

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 2004

Re: k032903
Trade/Device Name: COC-150 One Step Cocaine Test Strip
COC-150 One Step Cocaine Test Device
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: November 25, 2003
Received: January 6, 2004

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

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

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

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

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

Sincerely yours,

Steven Gutman

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

Enclosure

Martin P. O'Connor

944444444444444444444444444444444444444444444444444444444444444444448
11030 Wye Drive • San Antonio, Texas 78217 USA • 210-692-4192

Profile

Goal directed, results oriented professional with a strong medical background and education. Skilled communicator, persuasive and adaptable. Areas of strength include:

- ✓ Entrepreneur
- ✓ Organizational Management
- ✓ Financial Management
- ✓ cGMP Compliance
- ✓ 510(k) Submissions
- ✓ Clinical Trial Management
- ✓ IVD Market Analysis
- ✓ IVD Test Development
- ✓ Personnel Management
- ✓ Product Development

Experience

GENERAL MANAGER - PRESIDENT (1997 – present)
Germaine Laboratories, Inc., San Antonio, Texas USA

Designed & developed IVD tests. Developed & managed comprehensive drug testing programs. Designed and coordinated clinical trials for OTC & professional use IVD's. Submitted 510(k)'s for IVD tests. Managed worldwide marketing and sales. Managed financial assets. Established & implemented comprehensive cGMP Quality System.

GENERAL MANAGER - PRESIDENT (1990 – 1997)
Adam Diagnostic Laboratories, San Antonio, Texas USA

Managed worldwide marketing & sales of IVD tests. Established & implemented comprehensive cGMP Quality System. Designed and coordinated clinical trials for OTC & professional use IVD's. Submitted 510(k)'s for IVD tests.

DIAGNOSTIC SALES REPRESENTATIVE (1984 – 1990)
Carter Wallace Inc., Wampole Laboratories, Inc., Cranbury, New Jersey

Managed sales of IVD test and equipment to hospitals, reference laboratories, clinics, POL's. Conducted sales training of distributor sales reps. Designed and conducted in-service IVD training of laboratory personnel. Awards: President's Club, 2 years, Rookie of the Year.

TECHNICAL COORDINATOR (1978 – 1984)
International Cancer Screening Laboratories, Inc., San Antonio, Texas

Managed 30 Cytotechnologists. Developed and supervised quality control programs. Researched and developed new products and services. Developed and implemented cost control programs.

CYTOTECHNOLOGIST INSTRUCTOR (1975 – 1978)
Brooke Army Medical Center, Ft. Sam Houston, Texas

Supervised and instructed students during lectures, seminars, and classroom activities. Prepared and presented in-depth lesson plans. Advised and provided guidance to students. Managed processing personnel.

Martin P. O'Connor

Education

PARK UNIVERSITY, Parkville, Missouri (1983)
B.S. Health Care Management
Magna Cum Laude
Strong concentration in business
Personally paid 100% of college expenses

BROOKE ARMY MEDICAL CENTER, Ft. Sam Houston, Texas (1977)
Cytotechnology degree
Chosen as instructor

ACADEMY OF HEALTH SCIENCES, Ft. Sam Houston, Texas (1975)
Medical Technologist Specialist

VENANGO CHRISTIAN H.S., Oil City, Pennsylvania (1973)
Graduate

Professional Organizations

American Society of Clinical Pathologists
American Society of Cytotechnologists

Professional / Personal Development

ISO 13485 & FDA QSR Certified Training, 2005
Xerox Professional Selling Skills Training, 1985
Computer software trained in MS Word, Excel, Outlook, WordPerfect, CorelDraw, 1990-2005
Eagle Scout, Fryburg, Pennsylvania, 1969

Volunteer Activities

Vice President, Junior Baseball, McAllister Park Little League, San Antonio, Texas, 2004-2005
Vice President, 9-10 Baseball, McAllister Park Little League, San Antonio, Texas, 2002-2003
Board of Directors, McAllister Park Little League, San Antonio, Texas, 1998-2005

Advanced Toxicology Network

Confirmation Certifier: **John Sidwell**

Education:

DAVID LIPSCOMB UNIVERSITY – Nashville, TN 1984

Bachelor of Science in applied chemistry and a minor in mathematics

Certifications/Licenses/Affiliations:

State of Tennessee – Chemistry Supervisor 1986

Special Skills:

Provide expert witness testimony.

Toxicology-Related Work Experience:

ADVANCED TOXICOLOGY NETWORK – MEMPHIS, TN 1998 - to present
Serving as a Certifying Scientist

LABORATORY CORPORATION OF AMERICA – MEMPHIS, TN 1997 – 1998
Served as a certifying scientist

LABORATORY SPECIALISTS, INC – GRETNA, LA April – Sept 1997
Served as a GC/MS operator and extractor.

MERETEK DIAGNOSTICS – NASHVILLE, TN Jan – Feb 1997
Served as a chemistry analyst working with GC/MS

QUEST DIAGNOSTICS – NASHVILLE, TN 1996
Served as a technologist in the toxicology and chemistry departments

NATIONAL REFERENCE LABORATORY – NASHVILLE, TN 1989 – 1996
Served as a technologist in the special chemistry and toxicology departments

SPECIALIZED ASSAYS – NASHVILLE, TN 1984 – 1988
Served as a technologist in the special chemistry and toxicology departments

Wei-Chun Wang

11030 Wye Drive, San Antonio, Texas 78217 **(210) 692-4192**

POSITION: Accounting Manager

SKILLS SET

- **Technical**: Peachtree, ADP, QuickBooks, SAS, SPSS, MS Excel, MS Word, MS PowerPoint, MS Access, Outlook, C++, QBASIC.
- **Work Ethic**: Highly organized person who can prioritize tasks to meet critical project deadlines and enhance organizational effectiveness. Attention to detail with accuracy, efficiency and consistency.

EDUCATION

- **Master of Science, Mathematics/Computer Science**, Texas Woman's University, Denton, Texas, December 2000
  Thesis: *An Investigation of Benford's Law* (using both SPSS and SAS in the probabilities of digits numbers); GPA 4.0
- **Pre-MBA in Management**, University of Dallas, Dallas, Texas, December 1998
- **Bachelor of Science in Statistics**, Tamkang University, Taipei, Taiwan, June 1994; GPA 3.55
- **Associate Degree of Business in Accounting**, Chih-Lee College of Business (5-year accountant training), Taipei, Taiwan, June 1991

EXPERIENCE

Accounting Manager – Germaine Laboratories, Inc., San Antonio, TX, May '07 - Present

- Manage the accuracy and productivity of day-to-day activities of A/P, A/R, Payroll, human resources, cash disbursement, invoicing/billing, customer credits and collections, tax, G/L management and inventory
- Maintains chart of accounts for financial transactions
- Perform monthly review of all open purchase orders files to ensure outstanding status is valid
- Managed and prepared payroll to issue paychecks, payroll reporting, quarterly taxes, W-2 and 1099s
- Prepared financial statements and monthly reports.
- Conducted multiple bank reconciliations and maintained cash management functions

Financial Analyst / Accountant – TAMC (Technology Associate Management Company) and NPIC (Natural Polymer International Corporation), Dallas/Plano, TX **,** March '01 – June '04

- Reconciled and processed A/P and A/R, including cost coding and ensuring payment dates are met
- Entered, prepared, verified and controlled integrity of the general ledger

- Maintained monthly journal entries, executed monthly closing entries and the month-end general ledger
- Prepared financial statements
- Generated monthly analyses for budget and historical variances
- Created monthly balance sheets and profit-and-loss statements
- Processed and made decisions on quantities for purchase orders
- Prepared, entered, and reviewed payroll data for all new hire and existing employees
- Collected/analyzed financial information to fit company's current needs
- Assisted departmental personnel with proper expenditure coding, document preparation and other accounting-related activities
- Reviewed and selected health care provider insurance for the company; assisted employees with claims settlements and queries
- Collected/analyzed costs by product line
- Entered sales orders for customers; prepared shipping documentation
- Prepared, reviewed, and entered all types of reports: managers' expense reports, commission spreadsheets and statements, inventory statement, fixed assets, forecasts, annual audits and taxes schedules
- Analyzed trends in manufacturing, sales, finance, general business conditions and other areas
- Performed economic research work and generated analysis of subjects such as rates of investment and financial and expense performance comparisons
- Analyzed financial info for company's investment requirements
- Designed and coordinated company's web site

Financial Analyst – OTIS Elevator Company, Taipei, Taiwan, June '96 – March '97

- Performed/statistical analysis of financial reports/data
- Developed/analyzed various financial reports
- Controlled the company's financial budget
- Analyzed the company strategy
- Evaluated past and present contract agreements
- Calculated/analyzed return rate of profit and depreciation
- Collected/analyzed financial information to fit company's current needs
- Conducted multiple bank reconciliations
- Entered, prepared, verified and controlled integrity of the general ledger
- Prepared commission spreadsheets and statements

Teaching Assistant – Statistics Department of Tamkang University, Taipei, Taiwan, August '94 – June '96

- Instructed students using Strategy Application System (SAS) in data analysis/ program design
- Designed and implementation Marketing survey
- Completed experimental design and implementation in regression analysis, analysis of variance, and multivariate analysis of variance
- Instructed students in Probability Theory/Mathematical Statistics

CRAIG WALDRIP

EXPERIENCE

2001–Present Germaine Laboratories, Inc. San Antonio, TX

Laboratory Technician/ Production Supervisor

- Implementing QA/QC Testing
- Planning, organizing, and managing production personnel to ensure quality standards.
- Coordinate QA/QC implementations.
- Calibration of all equipment.

2001-2004 Coker United Methodist San Antonio, TX

Gym Supervisor

- Responsible for all activities during Saturday basketball games.
- Opening and closing the gymnasium.

1999-2001 Panther Springs Golf San Antonio, TX

Cashier

- Stocking Inventory for Clubhouse
- Responsible for all cashier duties.
- Responsible for setting up golf lessons.

EDUCATION

- In process BBA Degree in Business from UTSA
- Graduated Castle Hills First Baptist High School

REFERENCES

Paul Roth-Roffy, Partner/CPA (210) 342-8000
Carneiro, Chumney & Co

Jodie Sell, Accounting (210) 494-3455
Coker United Methodist

Billy Lemmons, Vice President (210) 494-6777
Flatrock Energy Advisors

11030 WYE DRIVE • SAN ANTONIO, TX 78217
PHONE MOBILE (210) 692-4192

CECILIA V. RODRIGUEZ

11030 Wye Drive, San Antonio, Texas 78217
210-692-4192
Cs1@germainelabs.com

Detail oriented bi-lingual professional Administrative Assistant with significant experience in customer service. Dynamic team player who fosters interpersonal relationships with key personnel at all levels of an organization while maintaining confidentiality of sensitive information. Applies critical thinking skills and broad knowledge base in business processes and procedures to expertly solve problems that extend beyond traditional administrative job duties

EDUCATION / TRAINING

- TSTC, Harlingen, Texas 02/06- 06/06
- San Antonio College, San Antonio, Texas ,Current
- Software Proficiency:

Microsoft Word, Outlook, Interdoc, Transware, Access, EDI, Manulogistrics, WMS 7.8, Client Profiles, Exceed, ADP, KRONOS, JD Edwards AS400, Bullhorn, PayChex, SARMA, E Verify

EMPLOYMENT

05/10 – 08/10 **Accounting/Management Receptionists**; K Partners Hospitality Group

- Screened calls and Visitors
- Ordered and maintained office supplies
- Assisted with payroll
- Conducted background checks for employees
- All other receptionist duties as assigned by the department supervisor

08/09 – 02/10 **Administrative Assistant**; Roerig, Oliveira & Fisher, McAllen, TX

- Maintained calendars, scheduled meetings, ordered refreshments
- Responsible for conference room setup and copying of meeting agenda.
- Screened calls, visitors, and mail;
- Ordered and maintained office supplies.
- Purchased materials for group, such as computer, software or anything needed for projects.
- Prepared and maintained filing system for file room.
- All other administrative assistant duties as assigned by the department supervisor

- Manage and maintain mail room and all office supplies, submit UPS request for pick -up and delivery.

12/07 – 02/09 **Weight Loss Counselor**; Body Scripts, McAllen, TX

- Corresponded with Patients about programs and support group meetings
- Sent out daily and monthly specials via email
- Performed product inventory
- Processed billing statements

11/06 – 11/07 **Legal Assistant**; Law Office of Jesse Contreras, Weslaco, TX

- Prepared letters and legal documents from dictation
- Updated Open/Closed file spreadsheet
- Screened incoming calls
- Ordered and maintained office supplies
- Scheduled depositions and attorney's court appearances

05/06 – 11/06 **Sales Associate**; Casa Linda Homes, Harlingen, TX

- A range of responsibilities including putting together weekly bid lists, typing and sending out submittal data, order entry and maintaining all the required duties of the front desk.
- Experience in dealing with credit applications, as well as handling and mailing of invoices to our corporate office.
- Interact with manufacturers, installers, trucking/shipping companies and customers daily to ensure that excellent service is achieved.
- Presented homes with professionalism and detailed specifications
- Continuously met and exceeded company and personal quotas

SKILLS

Bilingual, Computer Literate, Problem Resolution, Good Communication Skills, Great Customer Service, 10Key, Cashier, Data Entry, Filing and Preparing legal and regular documents, Ability to adapt to new environment, Excellent interpersonal skills, Team player, and superior organizational skills

Amy N. MacCrindle

11030 Wye Drive, San Antonio, Texas 78217

Job Title Quality Management Representative

Education

Master of Science in Education - Northwestern University, Evanston, Illinois, 2008

BM Education, Trinity University San Antonio, Texas, 2007

Professional Highlights

ISO 13485:2003 Certification

- Quality Management System Development and Implementation
- Implement and Maintain ISO 13285 Standards

FDA QSR Audits

- Quality Management System Development and Implementation
- Implement and Maintain FDA QSR Standards

CE Mark Certification

- CE Mark Documentation Development and Implementation

Professional and Technical Skills

- Quality Management System Implementation and Maintenance
- Quality Management System Document Control
- Performance of Internal Audits
- Supervise and Evaluate Complaints, CAPA, Non Conformities
- Maintain Trend Analysis
- Strong Analytical Ability
- Strong Writing Ability
- Excellent Interpersonal communication skills
- Strong Team Building Skills
- Excellent Customer Service Skills

Employment History

Quality Management Representative	Germaine Laboratories, Inc., San Antonio, TX	June 2006-Current
Middle School Interim Youth Director	Coker UMC San Antonio, TX	May 2004-December 2006
Customer Service Representative	HEB, San Antonio, TX	August 2001 – May 2003

Advanced Toxicology Network

Chief Executive Officer/
Laboratory Director: **Stuart C. Bogema, Jr., PhD**

Education:

GEORGE MASON UNIVERSITY, Fairfax, VA
Master of Business Administration 1991-1993
MEDICAL COLLEGE OF VIRGINIA –
VIRGINIA COMMONWEALTH UNIVERSITY, Richmond, VA
PhD in Pathology and Toxicology 1979-1983
GEORGE WASHINGTON UNIVERSITY, Washington, DC
Graduate study in Biochemistry 1977-1979
UNIVERSITY OF RICHMOND, Richmond, VA
Bachelor of Science in Chemistry and Biology 1970-1974

Certifications/Licenses/Affiliations:

American Board of Forensic Toxicology
Certificate of Qualification and Diplomate 1988 to present
American Board of Clinical Chemistry in Toxicological Chemistry
Certificate of Qualification and Diplomate 1988 to present
American Academy of Forensic Sciences
Fellow
Society of Forensic Toxicologists
Full Member
American Association for Clinical Chemistry
Member
American Society of Clinical Pathologists
Member
Certified Laboratory Director for the following states:
New York, New Jersey, Florida, Pennsylvania, Maryland, Maine, Vermont, Virginia

Special Skills:

Expert witness in toxicology in Federal, state and local courts for criminal and civil proceedings – 1983 to present

Laboratory inspector and consultant for the National Laboratory Certification Program, US DHHS

Toxicology-Related Work Experience:

ADVANCED TOXICOLOGY NETWORK, MEMPHIS, TN 1999 – to present
Serving as Chief Executive Officer

FORENSIC TESTING, INC. 1996 – to present
Serving as president of a company providing toxicology consulting and research services.

FORENSIC QC, INC. 1992 – to present
Serving as vice president of a company providing quality control consulting.

PRINCETON DIAGNOSTIC LABORATORIES (PDLA),
EDITEK, INC., SOUTH PLAINFIELD, NJ 1994 - 1996
Served as laboratory director and vice president of operations.

AMERICAN MEDICAL LABORATORIES, INC., CHANTILLY, VA 1983 - 1993
Served in various positions to include Director of clinical and forensic toxicology, Director of industrial hygiene and environmental testing, Director of sales and marketing of the toxicology services, Responsible Person for the NIDA/SAMHSA certified laboratory division, Vice president of toxicology and research and development

MEDICAL COLLEGE OF VIRGINIA, RICHMOND, VA 1980 - 1981
Served as a laboratory specialist in the department of pathology and clinical toxicology