



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

**RFP NO. OSCA 11-029-00**  
**TITLE: Drug/Alcohol Testing**  
**Equipment & Services**  
**ISSUE DATE: January 6, 2011**

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

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

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

**RETURN PROPOSAL TO:**

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

or

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

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

**DELIVER SUPPLIES/SERVICES FOB DESTINATION TO THE FOLLOWING ADDRESS:**

**MISSOURI TREATMENT COURTS THROUGHOUT THE STATE OF MISSOURI**

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

**SIGNATURE REQUIRED**

AUTHORIZED SIGNATURE <i>Jeanne Maples</i>		DATE February 4, 2011
PRINTED NAME Jeanne Maples		TITLE President
COMPANY NAME Global Drug Testing Services of Midwest, LLC		
MAILING ADDRESS 112 N Kansas		
CITY, STATE ZIP Edwardsville IL 62025		
VENDOR NO. (IF KNOWN) 77058315300		FEDERAL EMPLOYER ID NO. 27-4727167
PHONE NO. 618-692-9055	FAX NO. 618-692-9066	E-MAIL ADDRESS corporate@globaldrugtestingservices.com

**NOTICE OF AWARD (OSCA USE ONLY)**

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS: <b>IN ITS ENTIRETY AS SUBMITTED</b>		
CONTRACT NO. OSCA 11-029-09	CONTRACT PERIOD July 1, 2011 through June 30, 2012	
CONTACTS COORDINATOR <i>Robert J. Conna J</i>	DATE 2-23-2011	STATE COURTS ADMINISTRATOR <i>Gregory P. Liberman</i>

**Proposal to RFP No. OSCA 11-029-00  
Drug /Alcohol Testing Equipment & Services**



**February 10, 2011  
5:00 PM**



**Global Drug Testing Services**

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CONTACTS COORDINATOR	DATE	STATE COURTS ADMINISTRATOR

**PRICING PAGE**

<b><u>Service</u></b>	<b><u>Price Per Unit</u></b>
Drug Court Random Testing Program	\$15.00
GS/MS Confirmation	\$25.00
Samples Picked up at Providers	Free of Charge
Court Personnel Training	\$20.00 per trainee
Hair Testing	\$100.00
EtG Testing	\$15.00

Global Drug Testing Services agrees to participate in the State of Missouri's Cooperative Procurement Program as described in RFP NO. OSCA 11-029-00.

**EXECUTIVE SUMMARY**

Global Drug Testing Services specializes in providing drug testing services tailored to meet the unique needs of treatment courts and probation departments. For 16 years, Global has served adult and juvenile drug courts, DWI courts, family courts, Veterans courts, mental health courts, and probation departments, collecting and testing over 250,000 specimens per year. Global is a current preferred OSCA vendor and has had a Missouri based office since November 2000, when we initially began serving the St. Louis City drug court. Since opening the St. Louis office, Global has opened additional offices in St. Charles County, St. Louis County, Greene County, and Montgomery County. Global is also a dedicated member of the Missouri Association of Drug Court Professionals. Global manages all relationships locally with regional general managers and significant day-to-day involvement from the executive management and ownership team. The Company's current Missouri court clients know that they can reach a decision maker who will provide them with what they need and that Global will resolve any potential issues at a moment's notice.

We provide a comprehensive drug testing program that is comprised of the components noted below and described throughout this proposal.

- Random schedule management
- Testing available 365 days per year
- Testing schedule notification
- Co-located collection and laboratory facilities
- Same gender observed collections
- Protocols to prevent adulteration, tampering and substitution
- State-of-the-art instrument based laboratory
- Same day results reporting
- Expert and lay testimony
- Drug court staff training and consultation

Global's drug testing services address every aspect of drug testing, enabling the drug court professionals to focus on the judicial and treatment process. We take a collaborative approach and work to tailor each of the above mentioned components to meet the specific needs of each drug court. In addition, to drug court services, we also provide pre-employment, for cause, and random testing services for regulated (e.g. Department of Transportation) and non-regulated industries.

OSCA is a top priority that is important to our company. We look forward to continuing to serve OSCA for years to come and to easing the burden on the drug court team and helping drug court participants achieve recovery.

Sincerely,

Jeanne Maples  
President

**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. <ul style="list-style-type: none"><li>Global was founded more than 16 years ago with an initial focus on employment and DOT drug testing and testing program administration. Soon after its inception, Global expanded its offering to serve the unique testing program needs of treatment courts, which quickly became the Company's primary end market. Global's program capabilities enabled the formation of its first treatment court client in California, which is still a customer today, and the Company now supports more than 34 treatment court programs. Global expanded its operations into Missouri when it started providing testing program administration to the St. Louis City Treatment Court in 2001. Global is currently a preferred vendor of drug testing services in Missouri and serves 22 different Missouri court programs. Global has created more than 20 jobs in Missouri and is in the process of creating additional Missouri based jobs by expanding its services to more Missouri courts.</li></ul>
b) Describe the nature of the vendor's business, type of services performed, etc. <ul style="list-style-type: none"><li>Global provides comprehensive drug testing services and program administration to treatment courts. The Company has one of the most effective programs, specifically designed for treatment court recovery programs. Every element of the program is designed to maximize the integrity and accuracy of the testing to ensure program participants shift their focus from "beating" the test to the proper steps for recovery; all of which is accomplished while treating the program participants with dignity and respect. We are a vital partner to all of the courts we serve and a critical component to the success of their programs.</li><li>The Global drug testing program consists of participant orientation, random schedule management, same gender observed collections, full enzyme multiplied immunoassay ("EMIT") drug analysis on each sample, customized results reporting within 12 to 24 hours (sooner if requested), expert testimony, and court staffing/planning meeting participation (if desired), among other elements. <u>An overview of our program is provided in Exhibit A.1.</u></li><li>An important value-added element of our offering is our local presence. We serve each court locally. Depending on the desired program, which is tailored for each court, Global conducts collections in our conveniently located offices and completes the lab work in the same office thereby expediting results reporting and reducing potential chain of custody issues.</li><li>Additionally, Global partners with contracted SAMSHA and/or CLIA accredited laboratories for confirmation testing as well as for alternative testing methods.</li></ul>
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. <ul style="list-style-type: none"><li>Global has not lost any customers in the past two years and has only lost one treatment court customer in its history. This court decided to try a lower priced testing alternative that ultimately could not meet the court's needs. The court reengaged Global and is a customer today.</li><li>Global has started serving the Audrain County, Franklin County and Montgomery County, Missouri courts within the last two years.</li><li>Please see <u>Exhibit A.2 for a complete treatment court client and reference listing.</u></li></ul>
d) Describe the structure of the organization including any board of directors, partners, top departmental management, corporate organization, corporate trade affiliations, any parent/subsidiary affiliations with other firms, etc. <ul style="list-style-type: none"><li>All treatment court customers have direct access to the Company's owners and final decision makers, which also serve as the board of directors and top departmental management.</li><li>Global is a privately owned small business with no corporate trade affiliations or affiliations with other firms.</li><li>See <u>Exhibits C and D (question 8) for additional information on Global's personnel and organization.</u></li></ul>
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.

- Global does not have any pending litigation, civil or criminal judgments, bankruptcy proceedings, etc.

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.

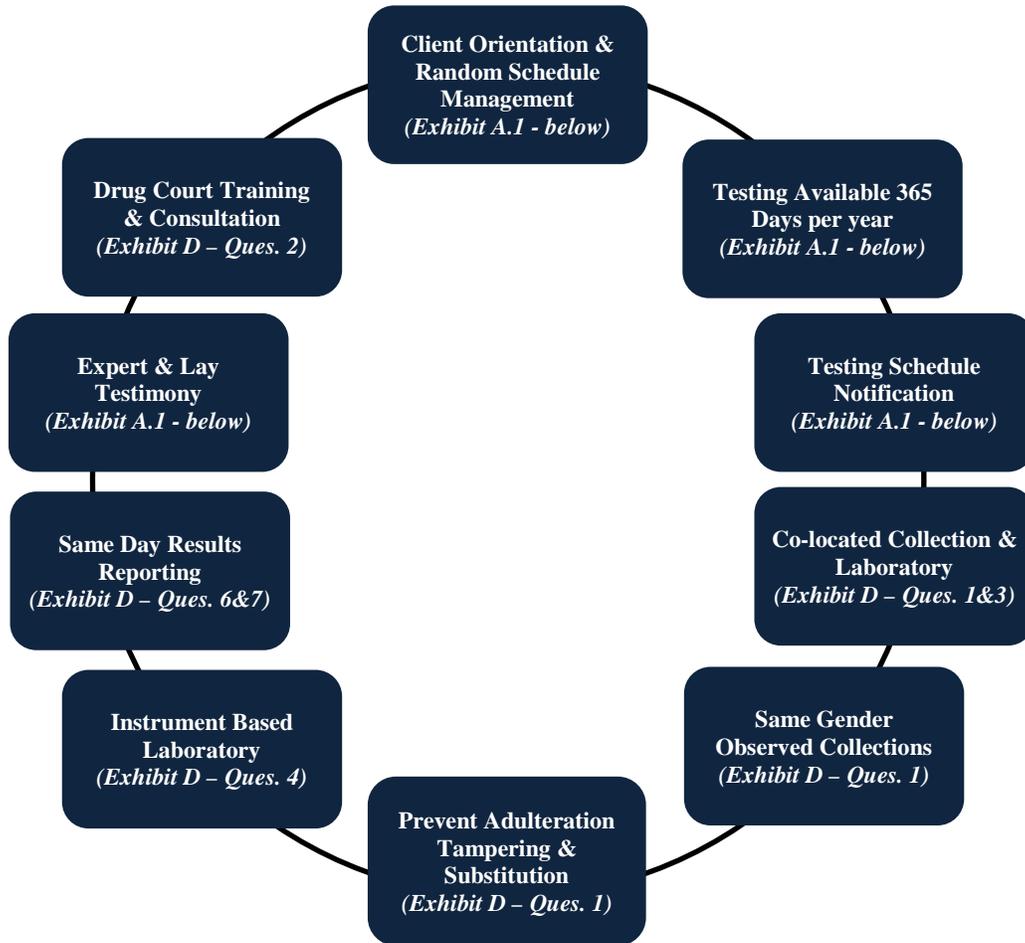
- Global has served treatment courts without fail for more than 16 years, including Missouri courts for the last ten years. Global has no bank debt and is in good standing with all of its vendors.
- As a privately owned company, Global does not publish financial results for public review and only shares financial information with the Company's owners.
- Exhibit B provides a list of our top vendors all of which can provide a reference for Global's financial solvency.
- We are happy to discuss our financial strength with OSCA, however we cannot share our financial statements in this form as they will become public information.

**EXHIBIT A.1**

**GLOBAL'S DRUG TESTING PROGRAM OVERVIEW**

**Value Added Considerations**

Global provides a comprehensive drug testing program that is tailored to meet the specific needs of each drug court, as illustrated by the following graphic. These value added services are designed to address every aspect of drug testing, enabling the treatment court professionals to focus on the judicial and treatment process. An overview of each element of Global's service offering is provided in this proposal where indicated in the graphic below.



**EXHIBIT A.1**

**CLIENT ORIENTATION**

Global’s drug testing program starts with client orientation. Client orientation is designed to provide the drug court participant with all of the necessary information to participate in random drug testing. Upon entry into treatment court all clients report to a Global office for orientation. Client orientation entails an explanation of the testing process, assignment of a group color or number, and the recording of the client’s relevant information and photo in Global’s management information system. The electronic photo serves as a redundant identification check. Groups are assigned a color or number that is used to segment clients according to gender, phase in the program, and other relevant attributes. Participants are assigned to new groups as they advance to the next phase of the program. Participants are also informed on the call in process to determine if they are to test on a given day. A participant’s group can be called on any day of the week, which serves as a strong deterrence to drug abuse and provides participants with a built in excuse to overcome peer pressures.

**RANDOM SCHEDULE MANAGEMENT**

At the start of every month, Global creates a confidential testing calendar. The testing calendar is only shared with select management level employees. Most of our drug courts prefer not to see this calendar to prevent accidental information sharing with the client (e.g., “Don’t forget you have to test tomorrow”). The frequency of the testing schedule is based on the drug court’s requirements and are set on a monthly schedule (e.g. 6 to 9 tests per month) allowing for multiple tests per week. At times, clients are tested on back to back days and on rare occasions three days in a row. Global has conducted testing on holidays at the request of the drug court, but generally test all clients the day after a major holiday. The following graphic illustrates a sample calendar by separate testing groups.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1 □	2	3	4
			41, 61	42, 63, 71	51, 52	
5	6	7	8	9	10	11
	41, 52, 61, 71	42, 51, 72	71, 72, 73	51, 62	41, 53, 61	71, 81, 82, 83, 91
12	13	14	15	16	17	18
	42, 51, 61, 63	41, 62	73, 81, 92, 91	71, 81, 82, 92, 93	41, 62	
19	20	21	22	23	24	25
62, 72, 73	52, 71, 72	81, 82, 91, 92	41, 51, 61	41	51, 61, 63	
26	27	28	29	30		
51, 52	42, 82, 92	41, 51, 83	61, 71	62		

### ***Notification System***

Global provides and maintains a notification system. The above mentioned random calendar is used to determine the clients that are scheduled to test on a given day. The daily announcement is recorded with the following language, “*Today is Friday, November 12<sup>th</sup>, Groups 51, 52, 61, and 62 must test today.*” At the determination of the court, some clients must test on every day that testing is being conducted and those clients are instructed to call the testing notification number every morning to determine if testing is being conducted. If testing is taking place clients that are required to test on every day that testing is being conducted know that they have to report for testing on that day.



### ***Drug Court Training and Consultation***

Global provides consultation and training sessions for its drug court partners. Periodic training sessions with judges, attorneys, case workers, and treatment providers facilitates an efficient and effective drug testing program. Training sessions are conducted in a classroom or in the laboratory, allowing the drug court team to visualize the testing process and protocols. Classroom sessions cover topics such as interpretation of results, understanding how to properly judge patterns of drug abuse, cross reactivity issues, and other such topics.

## **COURT TESTIMONY**

Global has provided expert, unbiased testimony for over 100 cases in judicial districts throughout California and Missouri. Global’s expert testimony experience includes hearings on substituted samples, child custody, “no-show”, and violation of parole hearings. A Global professional is available to appear in court with minimal notification and on a same day basis if personnel are available. Expert testimony at a moment’s notice is a key value added service that we provide to all of our drug court customers for no additional charge.

Global’s proprietary data base and reporting system was designed specifically for the reporting needs of the criminal justice and treatment agencies. Drug testing results are available on a daily basis and are provided to the drug court before the start of the next business day for all testing completed the day prior. Results are available within minutes if needed for emergency response testing, spot tests, etc. The system allows for custom reports tailored to the specific needs of each drug court. Results are available 24 hours a day, seven days a week via secure electronic communication channels or if preferred traditional ink and paper is also available. We maintain all records, allowing for a complete history as well as custom reports and analyses.

**Exhibit A.2**

<b>Customer Reference List</b>		
<b>Global Location</b>	<b>Agencies Served</b>	<b>References</b>
400 N Tucker St. Louis, MO 63101	St. Louis City Adult Drug Court St. Louis City Family Drug Court St. Louis City Juvenile Drug Court St. Louis City Juvenile THC Court	M. Keithley Williams Drug Court Administrator (314) 589-6702
205 N Fifth Street St. Charles, MO 63301	St. Charles Co. Adult Drug Court St. Charles Co. Adult DWI Court St. Charles Co. Family Drug Court St. Charles Co. Mental Health Court St. Charles Co. Reentry Court	Julie Seymore Drug Court Administrator (636) 949-7458
306 E Commercial, Suite A Springfield, MO 65803	Greene Co. Adult Drug Court Greene Co. Adult DWI Court Greene Co. Family Treatment Court Greene Co. Juvenile Drug Court Greene Co. Mental Health Court Greene Co. Mothers Choosing Change Court	Marilyn Gibson Drug Court Administrator (417) 829-6159
7317 Olive Boulevard University City, MO 63130	St. Louis Co. Adult Drug Court  St. Louis Co. Family Drug Court	Glenda Gill Drug Court Administrator (314) 615-2678  Mona Ackles Drug Court Administrator (314) 615-1586
38 W Morton Avenue Porterville, CA 93257	Porterville Drug Court Tulare Co. Juvenile Drug Court Tulare Co. Health & Human Services Tulare Co. Recovery Court	Glade Roper Superior Court Judge (559) 782-4710
2640 W Mineral King, #105 Visalia, CA 93277	Visalia Drug Court Tulare Co. Juvenile Drug Court Tulare Co. Health & Human Services Tulare Co. Recovery Court	Gary Paden Superior Court Judge (559) 730-5000 Ext. 1295
564 E Kern Street Tulare, CA 93274	Tulare Drug Court Tulare Co. Juvenile Drug Court Tulare Co. Health & Human Services Tulare Co. Recovery Court	Glade Roper Superior Court Judge (559) 782-4710
2350 W Shaw Avenue, #105 Fresno, CA 93711	Fresno Co. Family Drug Court	Clyde Gosser Drug Court Administrator (559) 905-1320
1029 Armory Road Warrenton, MO 63383	12 <sup>th</sup> Judicial Adult Drug Court 12 <sup>th</sup> Judicial DWI Court  20 <sup>th</sup> Judicial Drug Court 20 <sup>th</sup> Judicial DWI Court  45 <sup>th</sup> Judicial Adult Drug Court 45 <sup>th</sup> Judicial Adult DWI Court 45 <sup>th</sup> Judicial Co-Occurring Court 45 <sup>th</sup> Judicial DWI-Misdemeanor Court 45 <sup>th</sup> Judicial Family Drug Court	Christie Becker-Markovich Drug Court Administrator (636) 456-7136  Beth Billington Drug Court Administrator (636) 583-1550  Heather Thompson Drug Court Administrator (314) 704-7976

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

OSCA 11 - 029

**EXHIBIT B**

**PRIOR EXPERIENCE**

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

<b>1) Vendor Name or Subcontractor Name: Global Drug Testing Services</b>	
<b>Reference Information (Prior Services Performed For:)</b>	
Name of Reference Company:	Microgenics (Thermo Fisher Scientific)
Address of Reference Company: <input checked="" type="checkbox"/> Street Address <input checked="" type="checkbox"/> City, State, Zip	(Reference Contact Person Address:) Thermo Fisher Scientific 1002 Sunnybrook Drive Edmond, OK 73034-4855
Reference Contact Person Information: <input checked="" type="checkbox"/> Name <input checked="" type="checkbox"/> Phone # <input checked="" type="checkbox"/> E-mail Address	Terry Walser Cell: 405-850-2342 Office: 405-844-8143 terry.walser@thermofisher.com
Dates of Prior Services:	>5 years
Dollar Value of Prior Services:	>\$100,000 annually
Description of Prior Services Performed:	Supplies reagents and analyzer lab equipment

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

  
 Signature of Reference Contact Person

2/2/11  
 Date of Signature

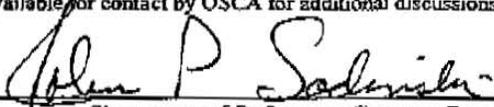
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<b>1) Vendor Name or Subcontractor Name: Global Drug Testing Services</b>	
<b>Reference Information (Prior Services Performed For:)</b>	
Name of Reference Company:	Siemens Healthcare Diagnostics
Address of Reference Company: <input checked="" type="checkbox"/> Street Address <input checked="" type="checkbox"/> City, State, Zip	1717 Deerfield Road Deerfield, IL 60015-0778
Reference Contact Person Information: <input checked="" type="checkbox"/> Name <input checked="" type="checkbox"/> Phone # <input checked="" type="checkbox"/> E-mail Address	Jack Sadinski 801-272-7504 john_sadinski@siemens.com
Dates of Prior Services:	>10 years
Dollar Value of Prior Services:	>\$200,000
Description of Prior Services Performed:	Supplies reagents and laboratory analyzer equipment

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

  
 Signature of Reference Contact Person

2/4/2011  
 Date of Signature

**EXHIBIT C**  
**PERSONNEL EXPERTISE SUMMARY**

<b>Personnel</b>	<b>Background and Expertise of Personnel and Planned Duties</b>
Jeanne Maples President and Owner	<ul style="list-style-type: none"> <li>• 16 years of experience with establishing and managing drug court testing programs</li> <li>• Siemens/Dade Behring Certified Laboratory Technician</li> <li>• Random Drug Testing Program Coordinator</li> <li>• Certified Breath Alcohol Technician</li> <li>• Member of the Missouri Association of Drug Court Professionals</li> </ul>
Bryce Maples Chief Operating Officer and Owner	<ul style="list-style-type: none"> <li>• 16 years of experience with establishing and managing drug court testing programs</li> <li>• Certified American Society for Clinical Laboratory Science</li> <li>• Siemens/Dade Behring Certified Laboratory Technician</li> <li>• Certified Trainer for Drug and Alcohol Testing Industry</li> <li>• Certified Breath Alcohol Technician</li> <li>• Member of the Missouri Association of Drug Court Professionals</li> </ul>
Joseph Crifasi Laboratory Director	<ul style="list-style-type: none"> <li>• 33 years of forensic toxicology laboratory experience</li> <li>• Bachelors in Medical Technology from the University of Illinois at Springfield</li> <li>• Masters in Analytical Toxicology from the University of Illinois at Springfield</li> <li>• Member of American Society of Clinical Pathologists</li> <li>• Member of American Board of Forensic Toxicology</li> <li>• Certified by Missouri Department of Health Laboratory Analysis</li> <li>• Certified by Illinois State Policy Laboratory Analysis</li> </ul>
Jeanne Merli, RN Regional Manager (Midwest)	<ul style="list-style-type: none"> <li>• 7 years of experience with drug court testing programs</li> <li>• Siemens/Dade Behring Certified Laboratory Technician</li> <li>• Registered Nurse</li> <li>• Certified Breath Alcohol Technician</li> </ul>
Thomas DiMaio, Rph Senior Laboratory Technician	<ul style="list-style-type: none"> <li>• 6 years of experience with drug court testing programs</li> <li>• Siemens/Dade Behring Certified Laboratory Technician</li> <li>• Registered Pharmacist</li> <li>• Certified Breath Alcohol Technician</li> </ul>
Michael Warden Quality Control Manager	<ul style="list-style-type: none"> <li>• 6 years of experience managing drug court testing programs</li> <li>• Siemens/Dade Behring Certified Laboratory Technician</li> <li>• Certified Trainer for Drug and Alcohol Testing Industry</li> <li>• Certified Breath Alcohol Technician</li> <li>• Random Drug Testing Program Coordinator</li> </ul>
Dr. David Wells Technical & Clinical Consultant	<ul style="list-style-type: none"> <li>• Bachelors and Masters in Chemistry from Furham University</li> <li>• Ph.D. in Biochemistry from Vanderbilt University</li> <li>• Member of National Academy of Clinical Biochemistry</li> <li>• Member of American Association of Clinical Chemistry</li> </ul>

**EXHIBIT D**  
**METHOD OF PERFORMANCE**

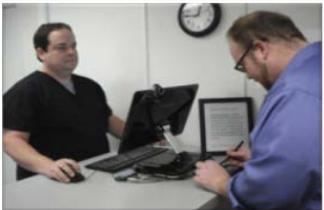
**1. Describe what is provided with which to collect each sample (cups, chain of custody forms, mailing packets).**

Global provides Missouri based urine sample collection facilities that are located in close proximity to each treatment court served. These facilities are staffed with Missouri residents that are DATIA certified and trained. In addition, Global provides all of the materials and supplies necessary to collect and analyze urine samples. When possible Global procures collection and laboratory materials and supplies from Missouri based suppliers. For example, Global purchases its collection cups from Integrity Products, a manufacturer located in Grandview, Missouri.

As described below, Global employs strict chain of custody protocols for the pre-collection, collection, post collection, and laboratory analysis processes. These protocols are designed to ensure that a valid sample is collected, appropriately tested, and accurately reported to the drug court team. Through more than 16 years of experience, Global has developed a drug testing program that prevents adulteration, tampering, and substitution – once clients realize they cannot beat the testing program, they start to embrace the important steps toward recovery.

***Pre-collection Process***

As outlined below, Global uses an efficient six step pre-collection process designed to capture a valid sample while minimizing the time a client is at a site – allowing the client to maintain employment and or attend school with minimal interference.

	<p>1. Clients are processed immediately upon entering a testing site – if the client is prepared to provide a sample the entire process will take less than 2 minutes.</p>
	<p>2. The client’s identity is confirmed with a valid photo I.D. and if required the client’s Co-pay is collected.</p>
	<p>3. At every visit the client’s signature is captured electronically with time and date stamp that is stored for subsequent confirmation (if needed). The client’s signature is applied to a label that is affixed to the collection cup.</p>
	<p>4. The signed label is affixed to the collection cup in the client’s presence.</p>

	<p>5. At the option of the treatment court, Global will conduct a breath alcohol test on the client with a DOT approved breath alcohol device.</p>
	<p>6. The client is required to wash their hands completely under the supervision of the collector, minimizing the ability of the client to slip a foreign substance into the sample.</p>

***Collections Process***

Global performs same gender observed collections. The client and collector enter a specially designed bathroom after the client’s hands are completely washed. Collectors are trained to position themselves within 12 to 36 inches of the client and in a manner that provides a clear view, yet does not encroach on the client’s space. Clients provide a midstream sample that is collected after the client starts, stops, and start again – provides a sample – stops, and then finishes. It is absolutely critical to observe the urine coming directly from the client’s body. As a redundant step that strengthens court testimony, bluing devices make it impossible for a client to substitute a sample with toilet water and there are no sinks in the bathroom. **Through the entire process, clients are treated with respect and dignity – for many clients this is one of their first experiences to be treated in such a manner and plays a role in the recovery process.**



***Post Collection Process***

After collecting a sample, it is tested for specific gravity, creatinine, PH, color, odor, and temperature. Tests for specific gravity, creatinine, PH, color and odor are conducted to detect possible “flushing” patterns. “Flushing” does not constitute a positive test, but the court is notified and the client is monitored and tracked for abnormal behaviors. The temperature of all samples is tested to confirm that the sample falls within an appropriate temperature range, providing a redundant check. The pre-collection, collection, and post collection protocols often lead to the detection of devices or adulterants and if a sample does not pass these tests we often request that the client provide another sample.

Global’s professional collectors are trained to be intuitive and as equally creative as the client trying to trick the test. When substitution devices are observed the collector confiscates the device, takes a second sample, and prepares a detailed report for the treatment court.



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

Global provides all of the necessary sample collection and documentation services to allow the drug court team to focus on the judicial and treatment process. Global also provide consultation and training sessions for its drug court partners. Periodic training sessions with judges, attorneys, case workers, and treatment providers facilitates an efficient and effective drug testing program. Training sessions are conducted in a classroom or in the laboratory, allowing the drug court team to visualize the testing process and protocols. Classroom sessions cover topics such as interpretation of results, understanding how to properly judge patterns of drug abuse, cross reactivity issues, and other drug testing related topics.

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

Global co-locates its collection facility and laboratory in the same site, eliminating the need for the traditional chain of custody documentation since there is no change of custody from one person or location to another person or location. We provide a complete accounting of each sample to ensure that the integrity of the sample meets the standards necessary for a court proceeding.

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



All of Global's collectors are trained and certified as both collectors and laboratory technologist and all laboratory procedures and protocols are supervised by experienced, certified toxicologists. The collected sample is handled by the same person throughout the entire testing process, from collection to laboratory analysis and if positive, to secure frozen storage. In the event the sample is required to be sent to another independent laboratory, Global will prepare the appropriate chain of custody documentation to follow the sample from one location and person to another location and person.

Global's laboratory technologists perform a full enzyme multiple immunoassay ("EMIT") drug analysis on each sample for all drugs specified by the court. Drug testing laboratories are located in a secure area of each of our collection sites and are scientifically calibrated each day prior to the testing and analysis of samples.

Global's laboratory analyzes each sample and produces analytical equations that are interpreted by the lab technologist. The cut-off levels are set to meet standards specified by the drug court. Positive samples are retested a second time using the index sample in order to produce a statistically similar result (double EMIT confirmation). The final results are reviewed and scrutinized by a second trained lab technologist who must agree with the findings. All results are reported to the drug court on the same day or if necessary, within minutes of collecting a sample. All positive samples are then sealed and secured in frozen storage for later analysis if required. Negative samples are destroyed within 24 hours after they have been tested.

Confirmation testing serves as an important tool in the recovery process – clients that request a confirmatory test that are subject to harsher sanctions or fines if the test confirms positive are more likely to speak the truth and confront the reason for their use. Confirmation testing can be made available to all clients. The secure, frozen storage of positive samples for a predetermined time period (often



30 days) facilitates the confirmation testing option. Global outsources confirmations to Medtox Laboratories, a SAMHSA and CLIA certified laboratory that provides Gas Chromatography Mass Spectrometry (GC/MS) sample certifications. Medtox's SAMHSA and CLIA certifications are included in Appendix B. Samples are sent via overnight shipping along with the proper chain of custody packaging and documentation. Confirmation results are provided within 2 to 3 business days and are immediately reported to the drug court.

**5. Provide the testing cutoff levels which are available (100ng/mL, 250 ng/mL, 500ng/mL, 1000ng/mL). What cutoff level is recommended to safe guard against incidental false positive?**

Currently all of the Missouri drug courts that Global provides services for use the following cutoff levels:

Amphetamines – 1000 ng/mL	Methamphetamines – 1000 ng/mL
Baritourates – 300 ng/mL	Methadone – 300 ng/mL
Benzodiazepines – 200 ng/mL	Methaqualone – 300 ng/mL
Cannabinoids – 20 ng/mL	Opiates – 300 ng/mL
Cocaine – 300 ng/mL	PCP – 25 ng/mL
Breath Alcohol – .000	Propoxyphene – 300 ng/mL
EtG – 500 ng/mL	

Certain drugs can be tested at higher levels depending on the courts preferences, such as Cannabinoids at 50 ng/mL or Opiates at 2000 ng/mL (the DOT cutoff levels). At this time no Missouri drug courts have requested the higher cutoff levels.

**6. Describe the turnaround time for results. AND**

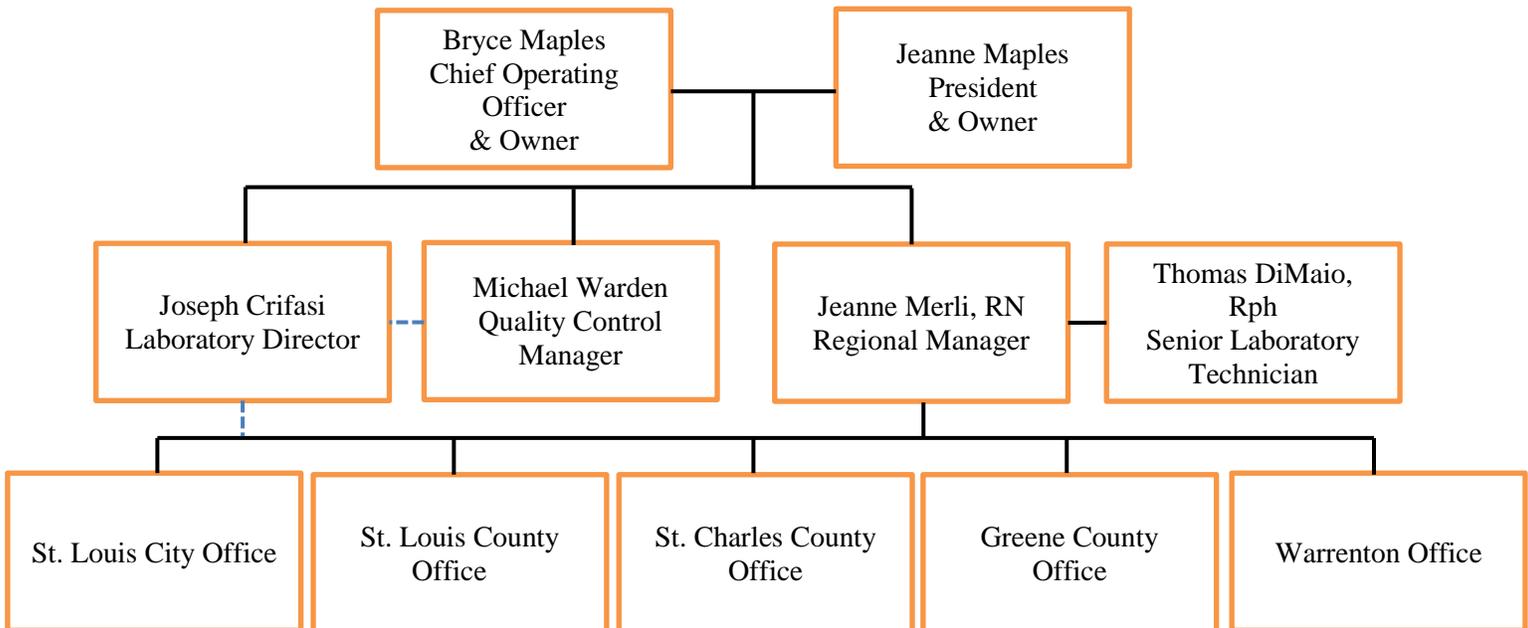
**7. Describe how test results will be reported (telephone, fax, or e-mail).**

Global's proprietary data base and reporting system were designed specifically for the reporting needs of the criminal justice and treatment agencies. Drug testing results are available on a daily basis and are provided to the drug court before the start of the next business day for all testing completed the day prior. Results are available within minutes if needed for emergency response testing, spot tests, etc. The system allows for custom reports tailored to the specific needs of each drug court. Results are available 24 hours a day, seven days a week via secure electronic communication channels or if preferred traditional ink and paper is also available. We maintain all records, allowing for a complete history as well as custom reports and analyses. Standard reports include:

- **Daily Exception Report** – provides qualitative and quantitative data for positive tests, identifies drug(s) detected, no show reporting, notes on any substitution or adulteration attempts, notes if test was diluted and dilute history (a single dilute does not constitute a positive test), and notes on any other adverse behavior.
- **Donor History** – provides the testing history for a specific donor.
- **Results by Case Manager** – testing results by case manager.

In addition to traditional results reporting, Global provides its court clients with relevant details regarding clients' behavior or any other observations that are helpful to the recovery process.

## 8. Organizational Chart



## 9. Assurance of Satisfactory Contract Performance and Sufficient Resources

- General requirements – As outlined in Exhibits A and D, Global satisfies all of the specified general requirements for providing alcohol and drug testing products and related services. Global’s testing program is delivered in accordance with industry standards and/or the local Treatment Courts’ internal policies with FDA approval wherever necessary. Test results are provided only as instructed by the Treatment Court Judge or Administrator and Global abides by all of the required confidentiality measures.
- Training & Support – While Global provides a comprehensive outsourced testing program and administration, the Company provides training, as outlined in Exhibit D, to improve the efficiency and effectiveness of the testing program’s integration into the overall recovery program. Technical and general customer support is available within and beyond the requested window of Monday through Friday 7:00 am to 7:00 pm Central Time Zone.
- Accreditation – Global adheres to the Drug and Alcohol Testing Industry Association (DATIA) and utilizes contracted SAMSHA, CLIA, and CAP certified laboratory partners, including Medtox, for confirmation testing or wherever necessary. In an effort to improve the already high standards and quality of Global’s service offering to the Missouri courts, the Company is also in the process of securing CLIA certification and COLA accreditation to provide further assurance that high quality standards are maintained. Global has also hired a laboratory director to conduct quality audits of collection procedures and laboratory results, track performance, and increase our high operating standards. The combination of Global and its contracted partners meets or exceeds all of the accreditation requirements and it is expected that Global (alone) will meet or exceed these requirements either before or shortly after the commencement of the new contract period. As part of this process, Global will also pursue approval by Medicare to provide the relevant laboratory services.
- Onsite Drug Testing Kits Non-Instrumental Based Immunoassay (both urine and saliva) – Global currently does not provide these products but will likely seek approval to include these products in the OSCA contract per the General Requirement language of this RFP.
- Testing Service Requirements, Transportation of Specimens, and Testing Service Result Reporting – As outlined in Exhibits A and D, Global satisfies all of these requirements.

- Test Order Forms and Billing Form – The Company current handles these forms and processes according to the specifications of the local Treatment Court and meets the outlined requirements.
- Electronic Alcohol Monitoring – Global does not currently provide electronic alcohol monitoring but may seek approval to include these products in the OSCA contract per the General Requirements language if this RFP.
- Contractual Requirements – Global understands and agrees to abide by the specified contractual requirements.
- Additional Information – Over Global’s sixteen years of operating history, the Company has developed and honed proven processes and protocols to ensure that Global provides a high service standard. Further, Global has been serving Missouri treatment courts for more than ten years and is a current preferred vendor for the state. Global manages all relationships locally with regional general managers and significant day-to-day involvement from the executive management and ownership team. The Company’s current Missouri court clients know that they can reach a decision maker who will provide them with what they need and that Global will resolve any potential issues at a moment’s notice.

#### **10. Outside United States.**

Nearly all of Global’s services performed for Missouri are completed within Missouri and all services are performed within the United States. Global does not perform any services at sites outside the United States.

## **Appendix A**

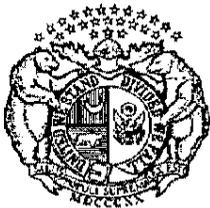
### **Proposal to RFP No. OSCA 11-029-00 Drug /Alcohol Testing Equipment & Services**



**February 10, 2011  
5:00 PM**



**Global Drug Testing Services**



## Eleventh Judicial Circuit - St. Charles County, Missouri

---

### Division 11

#### Adult Drug Court:

- diversion
- revocation
- DWI
- in-custody
- co-occurring illness

February 3, 2011

**Philip J. Ohlms**  
Associate Circuit  
Court Judge  
Drug Court Judge

**Julie R. Seymore**  
Administrator  
Drug Court

To Whom It May Concern,

I am writing in reference to Global Drug Testing Services. They have been the provider for drug testing services for the St. Charles County Drug Court Program for the past nine years and have done an excellent job. They are quick to accommodate our needs by putting information on their voicemail for our participants in regard to changes in court dates and times or other pertinent information. They are also quick to get us results on participants that we send for testing on non test days, usually in the midst of a court session when timeliness is of extreme importance. Global Drug Testing Services is a professional organization that treats each of the participants and staff of the St. Charles County Drug Court with the utmost dignity and respect. We are grateful to have them as part of our team and look forward to a long professional relationship with them.

If you have any questions or concerns please feel free to contact me at the number below. I would welcome any further discussion you might have in regard to Global Drug Testing Services and their work with our Drug Court Program.

Sincerely,

A handwritten signature in cursive script that reads "Julie R. Seymore".

Julie R. Seymore  
Administrator  
St. Charles County Drug Court

# 12<sup>th</sup> JUDICIAL CIRCUIT COURT Drug Court Divisions



**CARLA WOOD TANZEY**  
**COMMISSIONER**

**CHRISTIE BECKER-MARKOVICH**  
**ADMINISTRATOR**

WARREN COUNTY  
104 W Main Street  
Warrenton, Mo 63383  
(636) 456-7136  
(636) 456-0605 Fax

MONTGOMERY COUNTY  
211 E Third Street, Div II  
Montgomery City, Mo 63361  
(573) 564-3348  
(573) 564-8081 Fax

AUDRAIN COUNTY  
101 N Jefferson, Rm 205  
Mexico, Mo. 65265  
(573) 473-5850  
(573) 581-3364 Fax

We are a United Way Participating Agency

February 4, 2011

Office of State Courts Administrator  
Jefferson City, Missouri  
VIA e-mail

RE: Global Drug Testing Services

Dear Sir/Madame,

Global is submitting a bid to you for a new contract and asked that I contact you regarding my experience with the company. I absolutely can not say enough good things about the company. They started doing the drug testing for our Circuit a little over 3 years ago.

They report test results within a very short time frame after the testing has occurred (usually within a few hours). Their reports are easy to read and understand. They have been willing to work with us on the timing and place of the collections and have been very understanding when we have needed to change these things because of program requirements.

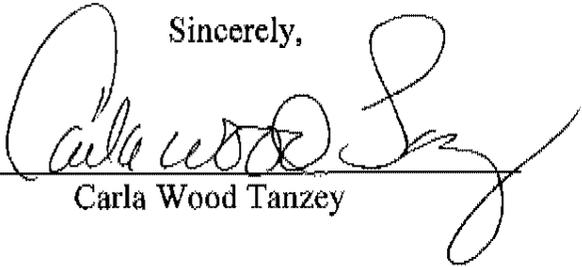
They are always willing to work with any special requests that we have (hair follicle testing, confirmation testing, etc).

However, Bryce and Jeanne are the best part of the "package" that we get when we hire Global. They are very knowledgeable about drug testing and the results. Time and again, Bryce has answered my questions about various results, procedures and best practices—breaking the difficult scientific information down so that I can understand it. They are knowledgeable about how drug courts work and what we should be looking for

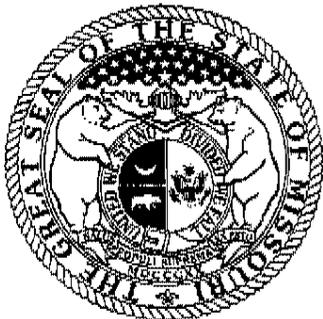
in test results. Bryce has been willing to talk to me one-on-one, come to a staffing to address an issue that was bothersome to the team, and to come to a team retreat and give us some education on certain issues. Bryce and Jeanne ALWAYS respond to questions promptly and professionally. I feel like we can trust them and their advice to keep our testing portion of the program on the right track.

In summary, our partnership with Global has been and continues to be beneficial to our program and I would highly recommend the company.

Sincerely,



Carla Wood Tanzey



## 12<sup>th</sup> JUDICIAL CIRCUIT COURT Drug Court Divisions

*Comprised of Audrain, Montgomery and Warren Counties*

February 4, 2011

Re: Midwest Laboratory Services, Inc.  
dba Global Drug Testing Services

Office of State Court Administration:

On behalf of the 12<sup>th</sup> Judicial Circuit Drug Court, I am pleased to write this letter of support for Global Drug Testing Services in reference to the proposal to the Office of State Courts Administrator to provide testing services for various Drug & DWI Courts in the State of Missouri. They have developed an excellent collaborative program in many communities and have been successful in delivering a professional alcohol and drug testing service.

Most importantly, they have been involved in the continued operations of Drug Courts throughout Missouri. I believe that Global Drug Testing Services is an organization capable of delivering quality drug court testing services for the Office of State Courts Administrator and would welcome the continued opportunity to have said services maintained within our Circuit as well.

I encourage the Office of State Courts Administrator to provide the ability to allocate funding to assist in providing a lab and services to all communities, and again I strongly support Global Drug Testing Services and their ability to provide Drug Court testing services for the Office of State Courts Administrator throughout the State of Missouri.

Sincerely

A handwritten signature in black ink, appearing to read 'CBM'.

Christie Becker-Markovich

Administrator

104 W Main Street, Suite G  
Warrenton, MO 63383  
(636) 456-7136  
(636) 456-0605 Fax

**Glenda J. Gill**

Drug Court Administrator  
Judicial Administration - St. Louis County  
7900 Carondelet Avenue  
Clayton, Missouri 63105

(314) 615-2678  
Fax (314) 615-8280  
glenda.gill@courts.mo.gov

February 4, 2011

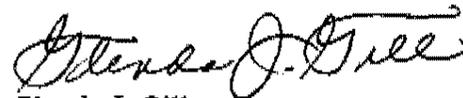
Office of State Courts Administrator  
Jefferson City, MO 65110

To Whom It May Concern:

This letter is in support of Global Drug Testing Services bid for a contract with the State of Missouri to provide drug testing services to the St. Louis County Drug Court. As St. Louis County Drug Court Administrator I have constant contact with Global's services and find them to be extremely professional in dealing with our drug court clients. We have worked with Global for a number of years and can always depend on them to be accurate, timely and very accommodating to our needs.

It would be difficult for us to find another company to surpass what they do for us. St. Louis County Adult Drug Court is in support of Global securing another contract with OSCA to provide St. Louis County Drug Court their services. We look forward to working with them in the future.

Sincerely,



Glenda J. Gill  
Drug Court Administrator



**James E. Sullivan**  
Commissioner  
(314) 622-4924  
jsulliv2@courts.mo.gov

**MISSOURI CIRCUIT COURT  
TWENTY-SECOND JUDICIAL CIRCUIT  
DRUG COURTS**

1114 MARKET ST., ROOM 526  
ST. LOUIS, MISSOURI 63101  
(314) 622-4924 • (314) 552-7667 fax

**Michael W. Noble**  
Commissioner  
(314) 552-2030  
mnoble1@courts.mo.gov

Dear OSCA:

We are pleased to recommend the services of Global Drug Testing Services to you.

They have been providing us with excellent service and have given us no cause for complaint. Their sincerity and dedication in providing us with a great service has in-turn allowed us to run an evidence based program.

Global Drug Testing Services has exceeded all of our expectations of a drug testing service. Not only have they provided reliable and consistent service, they have responded to our growing needs in a timely fashion.

It has been an absolute pleasure doing business with them and we sincerely recommend the services of Global Drug Testing Services to you.

Regards,

James Sullivan  
Drug Court Commissioner

Michael Noble  
Drug Court Commissioner



STATE OF MISSOURI  
CIRCUIT COURT, 31ST JUDICIAL CIRCUIT  
GREENE COUNTY JUDICIAL FACILITY  
1010 Boonville Avenue  
SPRINGFIELD, MISSOURI 65802-3804  
(417) 829-6602

PEGGY D. DAVIS  
Drug Court Commissioner

MARILYN GIBSON  
Drug Court Administrator  
(417) 829-6159

SHAWN BILLINGS  
Drug Court Administrator  
(417) 829-6107

JAYNE DAVIS  
Secretary

(417) 829-6602

KRISTI KIEBACH  
Secretary  
(417) 829-6240

BILL BURR  
Bailliff

February 4, 2011

To Whom It May Concern:

Prior to March 1, 2007, drug and alcohol testing for the Greene County Adult Drug Courts was the responsibility of the treatment providers. The providers set up a random schedule of testing and performed all drug testing using strip tests. There was a low rate of positive tests – about five to seven a month. Breathalyzer tests were utilized if the technician smelled alcohol.

On March 1, 2007, Global Drug Testing Services assumed the task of drug and alcohol testing for the Drug and DWI Courts. With the change, the Drug and DWI Court teams have been able to raise the level of accountability for the participants, sanction appropriately by discriminating between old and new uses, and accept defendants into the court who might have been ineligible due to medication issues.

The rate of positive tests has increased dramatically, especially positives for marijuana. During the first four days of testing by Global, there were seven positives. Global uses a cutoff for marijuana of 20 ng. The Drug and DWI Court participants admitted they had figured out they could "smoke a joint" every so often and test negative when the court was using the strip tests with a cutoff of 50 ng. Global staff has assisted the teams in determining "new" usage versus "old" usage that is still in the participant's system, thereby enabling the team to impose sanctions fairly. In addition, the change to Global has enabled the Drug and DWI Courts to accept participants on medication (such as Ritalin) that may result in a positive drug test because Global is able to monitor therapeutic levels of the prescription drug.

The financial cost of using a private company for drug testing increased the Drug/DWI Court budget dramatically, but the team members believe the high standard of professionalism of the testing staff and Global's testing procedures have resulted in a higher level of accountability and accuracy and also have lead to an increased confidence of the test results by the participants.

Sincerely,

Marilyn Gibson  
Drug Court Administrator



45<sup>th</sup> Judicial Circuit Drug Court  
45 Business Park Drive  
Troy, MO 63379

February 3, 2011

To Whom It May Concern:

I am pleased to write this letter of recommendation on behalf of Global Drug Testing Services. The 45<sup>th</sup> Judicial Circuit Drug Court utilized Global Drug Testing Services from 2006-2008 and resumed testing services with Global in April of 2009 due to their lab services, pricing, customer service and professionalism. Global testing services provides drug and alcohol testing services to the participants in the 45<sup>th</sup> Judicial Circuit Adult Drug Court, Co-Occurring program tract, DWI Court, DWI-misdemeanor tract and Family Dependency Treatment Court.

The 45<sup>th</sup> Judicial Circuit Drug Court continues to utilize Global Drug Testing services for their organization, dependability, efficiency and the accuracy of lab testing. Global is organized as evidenced by the phase set up of our monthly drug testing calendar and for providing separate test results for each program tract. Global is dependable in always placing the daily call in testing message outlining which program phases are scheduled to drop. Global is efficient in providing the test results in a timely manner with 24 to 48 hours after the testing date. Most importantly, all urinalysis samples collected at the drop site are tested in a lab for accuracy. I further receive calls at the end of each testing session to report any participant no shows to the drop site which is crucial for monitoring participant testing compliance. Global conducts EtG testing and hair follicle testing which is a testing requirement for all participants in drug court. The collection staff is professional, trained in observation and following the appropriate chain of custody with all test samples.

I have been pleased with customer service as whenever I have a question regarding participant testing, results of the drug/alcohol tests or the testing schedule I have an immediate response. I appreciate the prompt and detailed attention to all our program testing needs and the competitive pricing for drug testing services.

It is for the above reasons that I recommend Global Drug Testing Services.

Sincerely-

  
Heather Graham-Thompson  
45<sup>th</sup> Judicial Circuit Drug Court  
Drug Court Administrator

## **Appendix B**

### **Proposal to RFP No. OSCA 11-029-00 Drug /Alcohol Testing Equipment & Services**



**February 10, 2011  
5:00 PM**



**Global Drug Testing Services**

Drug & Alcohol Testing Industry Association

recognizes

Bryce Maples

as a

Certified Professional Collector Trainer

(CPCT)



A handwritten signature in black ink, appearing to read "M. A.", is written over a horizontal line.

*Executive Director*

Drug & Alcohol Testing Industry Association

Certificate of Membership

Global Drug Testing Services

IS

Recognized as a Regular member  
of the

Drug & Alcohol Testing Industry Association



A handwritten signature in dark ink, appearing to read "Jeffrey C. Smith".

Jeffrey C. Smith  
President  
DATIA, Alexandria, VA

DADE BEHRING  

---

---

  
UNIVERSITY

*certifies that*

***Bryce Maples***

*has completed a course of instruction on*  
**V-Twin™ Analyzer System  
Basic Training Course**

*January 14, 2004*



Program Number 208-599-04  
Contact Hours 18.5

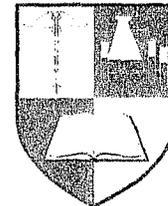


  
Farogh Nazari, Contact Manager

**California Accrediting Agency Number 0001.**

*This course is approved for CA licensed Clinical Laboratory Scientists and Personnel.*

American Society of Clinical Laboratory Sciences, 6701 Democracy Blvd., Suite 300, Bethesda, MD 20817-1574



# Certificate of Completion

May it be known that this Certificate has been presented to

**Bryce Maples**

---

for Successful Completion of

PSYCHEMEDICS SAMPLE COLLECTION TRAINING PROGRAM

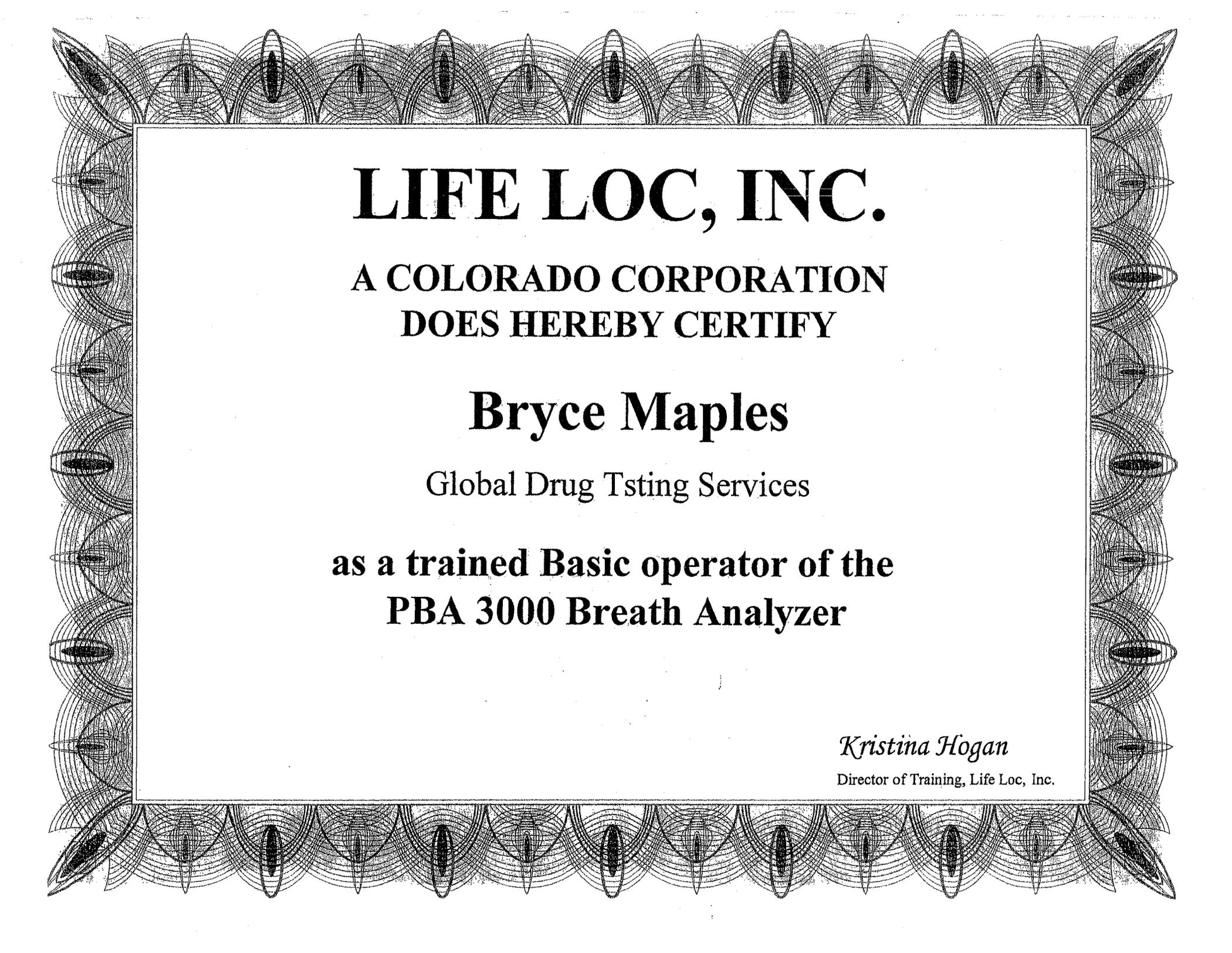
PRESENTED THIS

3rd DAY OF

March, 2003



DIRECTOR, CLIENT SERVICES



# **LIFE LOC, INC.**

**A COLORADO CORPORATION  
DOES HEREBY CERTIFY**

**Bryce Maples**

Global Drug Tsting Services

**as a trained Basic operator of the  
PBA 3000 Breath Analyzer**

*Kristina Hogan*

Director of Training, Life Loc, Inc.

# Declaration of Training



This confirms that

*Bryce Maples*

has participated in the

*30R Customer Training Program*

Awarded this 20th day of November, 1998

*Patty Winter*

*Patty Winter, Performance Technologist*

*Karen Call*

*Karen Call, Education and Training*

DADE BEHRING



Certificate  
of  
Completion

May it be known that this Certificate has been presented to

Jeanne Maples

---

for Successful Completion of

PSYCHEMEDICS SAMPLE COLLECTION TRAINING PROGRAM

PRESENTED THIS

10th DAY OF

March, 2003



---

DIRECTOR, CLIENT SERVICES

# Drug & Alcohol Testing Industry Association

recognizes

## Michael Warden

### Global Drug Testing Services - Porterville

as a

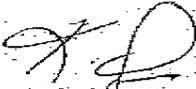
### Certified Professional Collector Trainer

### in Urine and Alternative Specimen Collections

*(valid through 6/1/2011)*



CPID 25893

  
Kristina Queen  
Programs Director

# Certificate of Completion

Awarded to

# Michael Warden

*Courses Completed in the Supervisor Series*

Hiring & Interview Skills

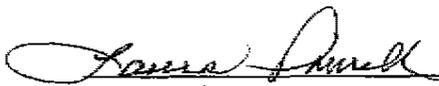
Managing Multiple Projects, People & Priorities

Disciplinary Action & Termination

Employee Motivation & Team Building

Violence in the Workplace

Effective Evaluations

  
EAC Chair

  
Chamber President/CEO





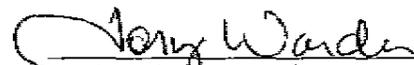
Global Drug Testing Services  
**Certificate of Completion**

This is To Certify That

**Michael Warden**

Has Successfully Completed Training For  
Certification as a Basic Operator of the  
EV 30 Breath Analyzer

This Certificate is effective as of May 1<sup>st</sup> 2008

  
Tory Warden  
Certifying Instructor

# ACHIEVEMENT SIEMENS

*This is to certify*

***Michael Warden***

*has completed a course of instruction on*

**V-Twin® Analyzer System  
Basic Education**

***August 27, 2008***



A handwritten signature in black ink, appearing to read "Farogh Nazari". The signature is written over a horizontal line.

Farogh Nazari, Manager

Category: Chemistry  
ASCLS Program #: 208-599-08  
Contact Hours: 18.5

California Provider Number 0001. This course is approved for CA licensed Clinical Laboratory Scientists and Personnel.  
American Society of Clinical Laboratory Sciences, 6701 Democracy Blvd., Suite 300, Bethesda, MD 20817-1574



**DADE BEHRING**  
**UNIVERSITY**

*Certifies that*

**Michael Warden**

*Has Successfully Demonstrated Proficiency  
in the Operation of the*

**Syva<sup>®</sup> V-Twin<sup>™</sup> Analyzer**

July 16<sup>th</sup>, 2007



---

Training Specialist: Louie T. Than, CAS





*Advancing Excellence*

# The College of American Pathologists

*certifies that the laboratory named below*

***MEDTOX Laboratories, Inc.***

***Saint Paul, Minnesota***

***Mark G. Catlin, MD***

***Jennifer A. Collins, PhD***

LAP Number: 3039202

AU-ID: 1192042

CLIA Number: 24D0665278

*has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Forensic Drug Testing Accreditation Program. Reinspection should occur prior to February 4, 2011 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

*Robert Killian, MD*

Chair, Commission on Laboratory Accreditation

*David R. Schwartz MD PhD FCAP*

President, College of American Pathologists

**Accredited  
Laboratory**



noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 26, 2010.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Peoples Bancorp, Inc.*, Prairie du Chien, Wisconsin; to acquire 100 percent of the voting shares of Woodhouse & Bartley Bank, Bloomington, Wisconsin.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Exchange Bancorp of Missouri, Inc.*, Fayette, Missouri; to become a bank holding company by acquiring 100 percent of the voting shares of Exchange Bank of Missouri, Fayette, Missouri.

Board of Governors of the Federal Reserve System, October 28, 2010.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2010-27684 Filed 11-2-10; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL MARITIME COMMISSION

### Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (<http://www.fmc.gov>) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 001941-003.

*Title:* Baltimore Marine Terminal Association.

*Parties:* Ports Baltimore, Inc.; Maryland International Terminals, Inc.; Mid-Atlantic Terminal LLC; Ceres Marine terminals, Inc.; Tartan Terminals, Inc. and Ports America Chesapeake, Inc.

*Filing Party:* JoAnne Zawitoski, Esq.; Baltimore Marine Terminal Association; 25 South Charles Street, Suite 1400, Baltimore, MD 21201.

*Synopsis:* The amendment restates the agreement and identifies the current members of the BTMA.

*Agreement No.:* 011435-014.

*Title:* APL/HLAG Space Charter

Agreement.

*Parties:* American President Lines, Ltd.; APL Co. Pte Ltd.; and Hapag-Lloyd AG.

*Filing Party:* Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street, NW., Suite 1100, Washington, DC 20006.

*Synopsis:* The amendment updates the corporate address for APL.

*Agreement No.:* 011741-015.

*Title:* U.S. Pacific Coast-Oceania Agreement.

*Parties:* ANL Singapore PTE Ltd.; A.P. Moller-Maersk A/S; CMA CGM S.A.; Hamburg-Süd; and Hapag-Lloyd AG.

*Filing Party:* Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street, NW., Suite 1100, Washington, DC 20006.

*Synopsis:* The amendment increases the amount of space CMA CGM is allotted from Pacific Northwest ports.

*Agreement No.:* 012077-001.

*Title:* APL/Maersk Line Reciprocal Space Charter Agreement.

*Parties:* American President Lines, Ltd.; APL Co. Pte, Ltd.; and A.P. Moller Maersk A/S.

*Filing Party:* Eric. C. Jeffrey, Esq.; Counsel for APL; Goodwin Procter LLP; 901 New York Avenue, NW., Washington, DC 20001.

*Synopsis:* The amendment updates the corporate addresses of American President Lines, Ltd. and APL Co. Pte Ltd.

*Agreement No.:* 012108.

*Title:* The World Liner Data Agreement.

*Parties:* A.P. Moller-Maersk A/S; CMA CGM S.A.; Compania Chilena de Navegacion Iberoceanica S.A.; Hamburg-Sud; Hapag-Lloyd AG; Orient Overseas Container Line Ltd.; and United Arab Shipping Company S.A.G.

*Filing Party:* Wayne Rohde, Esq.; Cozen O'Connor; 627 I Street, NW., Suite 1100, Washington, DC 20006.

*Synopsis:* The pending agreement has been changed to include CCNI and Orient Overseas Container Line Ltd as parties to the Agreement.

*Agreement No.:* 201209.

*Title:* Marine Terminal Lease and Operating Agreement Between Broward County and Seafreight Agencies (USA), Inc.

*Parties:* Broward County and Seafreight Agencies (USA), Inc.

*Filing Party:* Candace J. Running; Broward County Board of County Commissioners; Office of the County Attorney; 1850 Eller Drive, Suite 502, Fort Lauderdale, FL 33316.

*Synopsis:* The agreement provides for the lease and operation of terminal facilities at Port Everglades in Broward County, Florida.

By Order of the Federal Maritime Commission.

Dated: October 29, 2010.

**Karen V. Gregory,**  
*Secretary.*

[FR Doc. 2010-27777 Filed 11-2-10; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the Laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently certified Laboratories and Instrumented Initial Testing Facilities (IITF) is published in the **Federal Register** during the first week of each month. If any Laboratory/IITF's certification is suspended or revoked, the Laboratory/IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any Laboratory/IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires {or set} strict standards that Laboratories and Instrumented Initial Testing Facilities (IITF) must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies.

To become certified, an applicant Laboratory/IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a Laboratory/IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and Instrumented Initial Testing Facilities (IITF) in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A Laboratory/IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

*Instrumented Initial Testing Facilities (IITF):*

None.

*Laboratories:*

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150.

Aegis Analytical Laboratories, 345 Hill Ave., Nashville, TN 37210, 615-255-2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.).

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130 (Formerly: Kroll

Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I-30, Little Rock, AR 72209-7056, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281.

DrugScan, Inc. P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310.

DynaLIFE Dx \*, 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876 (Formerly: Dynacare Kasper Medical Laboratories).

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.

Gamma-Dynacare Medical Laboratories\*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

Maxxam Analytics\*, 6740 Campbell Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700 (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7.

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800-729-6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 800-877-2520 (Formerly: SmithKline Beecham Clinical Laboratories).

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505-727-6300/800-999-5227.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574-234-4176 x1276.

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602-438-8507/800-279-0027.

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052.

Sterling Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800-442-0438.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573-882-1273.

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085.

\*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: October 28, 2010.

**Elaine Parry,**

*Director, Office of Management, Technology, and Operations, SAMHSA.*

[FR Doc. 2010-27728 Filed 11-2-10; 8:45 am]

BILLING CODE 4162-20-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-5055-N]

#### Medicare Program: Community-Based Care Transitions Program (CCTP) Meeting

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a public conference hosted by CMS. This conference will provide a forum for

community-based organizations, hospitals, Quality Improvement Organizations, Administration on Aging grantees, and other healthcare providers to receive useful guidance and ask questions about the upcoming Community-based Care Transitions Program. The meeting is open to the public, but attendance is limited to space and Webinar lines available.

**DATES:** *Meeting Date:* Friday, December 3, 2010, from 8 a.m. to 4 p.m., eastern standard time (e.s.t.).

*Deadline for Webinar or Web-based Registration:* Thursday, December 2, 2010, 8 a.m., e.s.t.

*Deadline for Meeting Registration:* Friday, November 19, 2010, 4 p.m., e.s.t.

Limited walk-in registration may be available the evening prior to the conference and the morning of the conference as space permits.

**ADDRESSES:** *Meeting Location:* Marriott Waterfront Hotel, 700 Aliceanna Street, Baltimore, MD 21202.

*Registration:* The meeting is open to the public, but attendance is limited to space and Webinar lines available. A link to the agenda and registration information will be posted on the CMS Care Transitions Web site at <http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1239313> as soon as it is available. Persons wishing to attend this meeting in person or via Webinar are encouraged to register in advance.

*Special Accommodations:* Individuals who require special accommodations should send an e-mail request to [CareTransitions@cms.hhs.gov](mailto:CareTransitions@cms.hhs.gov) or via regular mail to the address specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials will be posted on the CMS Care Transitions Web site prior to the meeting.

#### FOR FURTHER INFORMATION CONTACT:

Juliana Tiongson, Social Science Research Analyst, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, Mail Stop C4-14-15, telephone 410-786-0342 or e-mail [Juliana.Tiongson@cms.hhs.gov](mailto:Juliana.Tiongson@cms.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Community-based organizations (CBOs) are defined in the statute as community-based organizations that provide care transition services across a continuum of care through arrangements with subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act) and whose governing body includes

sufficient representation of multiple health care stakeholders, including consumers. Experts in the field will present evidence-based care transition models, and lessons learned from participation in the Quality Improvement Organizations' (QIOs) 9th scope of work care transitions sub-national theme and related initiatives. Healthcare leaders will present broader, hospital-based interventions to reduce readmissions, as well as the positive financial implications of successfully reducing readmissions. This conference will also provide an overview of the Community-based Care Transitions Program (CCTP) and provide the opportunity for hospitals to connect with CBOs in their communities. Once a solicitation for the CCTP is published, proposals will be accepted on a rolling quarterly basis beginning in early 2011.

## II. Meeting Agenda

The agenda for the December 3, 2010 meeting will include the following topic areas:

- Overview of the CCTP under section 3026 of the Affordable Care Act.
- The Business Case for Improving Care Transitions.
- Building Community Support and Root Cause Analysis.
- Overview of Care Transition Interventions.
- Implementation of Care Transition Interventions—Successes and Challenges.

**Authority:** Section 3026 of the Affordable Care Act

Dated: October 21, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-27789 Filed 10-29-10; 4:15 pm]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, November 18, 2010, 2 p.m. to November 18, 2010, 4 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 25, 2010, 75 FR 65498-65499.

The meeting title has been changed to "RFA Panel: Translational Research in Pediatric and Obstetric Pharmacology". The meeting is closed to the public.



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### Device Listing Database

**Proprietary Device Name:** PRESTIGE 24I, MGC 240  
**Common/Generic Device Name:** CLINICAL CHEMISTRY ANALYZER  
**Classification Name:** ANALYZER, CHEMISTRY (PHOTOMETRIC, DISCRETE), FOR CLINICAL USE  
**Device Class:** 1  
**Product Code:** JJE  
**Regulation Number:** [862.2160](#)  
**Medical Specialty:** Clinical Chemistry  
**Owner/Operator:** [TOKYO BOEKI MEDICAL SYSTEM LTD.](#)  
**Owner/Operator Number:** 9060135  
**Registered Establishment Name:** [TOKYO BOEKI MEDICAL SYSTEM LTD.](#)  
**Establishment Registration Number:** 3004378326  
**Date of Listing:** 11/28/03  
**Listing Status:** Active  
**Establishment Operations:** Manufacturer

Database Updated 8/08/2005

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Center for Devices and Radiological Health / CDRH

K973628



USA: One Gateway Center, Suite 415 Newton, MA 02158  
1-617-527-9933, Ext. 22 Fax: 1-617-527-8230

NL: van Rensselaerweg 4, Spankeren 6956AV, NL  
-31-313-43500 Fax:31-313-427807

September 19, 1997

### **Premarket Notification [510(k)] Summary**

#### **for the VITALAB FLEXOR Clinical Laboratory Analysis and Reagent System**

**Device Name:**

Vitalab Flexor (In-vitro diagnostic system). The Vitalab Flexor is also tradenamed the Vitalab Selectra 2 and the Vitalab Viva. References in this document submission may use either of the two names interchangeably.

**Common Name:**

Automated chemistry analyzer, micro, for clinical use.

**Classification Name:**

Analyzer, chemistry, micro, for clinical use - has been classified as Class I devices, as per 21 CFR 862.2170. This device is intended for clinical use in conjunction with certain materials to measure a variety of analytes.

**Establishment Registration:**

Vital Scientific NV, a company established under the laws of the Netherlands, with headquarters at van Rensselaerweg 4, Spankeren, 6956 AV, The Netherlands and with a USA branch office located at One Gateway Center, Suite 415, Newton, MA 02158. Vital Scientific is a registered as a medical device manufacturer under files number 8030478. All instruments are manufactured in the Netherlands. Contact person: Israel M. Stein MD.

**Performance Standards:**

There are no performance standards for these devices.

**Labeling:**

This device is labeled in accordance with 21 CFR 809.10.

**Summary description of device:**

A random access, automated Clinical Micro-Chemistry Analyzer with a throughput of up to 180 test per hour which is intended for clinical use in conjunction with certain materials to measure a variety of analytes, including applications in clinical chemistry, monitoring drugs of abuse and in therapeutic drug monitoring.

**Substantial Equivalence:**

The Vitalab Flexor System is substantially equivalent to the Roche Cobas Mira presently in distribution in the United States. The Vitalab Flexor System has the same technological characteristics and intended use as these systems. These systems are automated micro-chemistry analyzers intended for clinical use in conjunction with certain materials to measure a variety of analytes (21 CFR 862.2170).

We are including data on twenty-nine (29) representative Clinical Chemistry analytes manufactured by Trace Scientific Pty. Ltd., seven (7) representative analytes for Drugs of Abuse manufactured by Behring Diagnostics and two (2) representative analytes for therapeutic drug monitoring, manufactured by Behring Diagnostics. All of these analytes are presently 510(k) approved under separate submissions by their respective companies. These analytes were chosen because they are representative of the reaction types to be processed on the analyzer.

Thirty-eight (38) representative methods were selected for evaluation including Acid Phosphatase, Alkaline Phosphatase, Albumin, ALT, Amylase, AST, Bicarbonate, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Creatinine Kinase, Creatinine, Gamma GT, Glucose, Inorganic Phosphate, Iron, LDH, Magnesium, Total Protein, Triglycerides, Urea, Uric Acid, Benzodiazepine, Cocaine, Opiate, Amphetamine, Methadone, THC, Cyclosporin, and Carbamazepine. These include the following analytical modes: endpoint, kinetic with linearity check, bichromatic endpoint, two-point kinetic, and non-linear calibration curve.

The data for precision, accuracy, linearity and drift demonstrate general agreement with levels that are comparable to other systems presently being

marketed commercially in the United States. The data demonstrate positive correlation and substantial equivalence.

The optional Vitalab ISE accessory for the determination of Sodium, Potassium, and Chloride is manufactured by AVL Scientific Corp. This unit is essentially equivalent to other ISE units marketed by AVL in the United States.

Vital Scientific NV, submits that the Vitalab Flexor System has clinically acceptable performance comparable to similar devices currently in commercial distribution. These data provide scientific evidence of equivalency for Vitalab Flexor System. The data indicates a positive correlation, and therefore, is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Israel M. Stein, M.D.  
. Managing Director  
Vital Scientific  
One Gateway Center, Suite 415  
Newton, Massachusetts 02158

MAR 13 1998

Re: K973628  
VITALAB FLEXOR Analyzer  
Regulatory Class: II  
Product Code: JJF, CDN, CEM, CGA, DJC, DKZ, JGS,  
JXO, KLT, LAR, JRE  
Dated: January 30, 1998  
Received: February 2, 1998

Dear Dr. Stein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

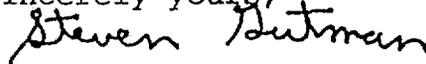
Page 2

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K97 3628

Device Name: VITALAB FLEXOR

Indications For Use:

This notification is for an *in vitro* diagnostic device, which is an automated chemistry analyzer, micro type, intended for clinical use in conjunction with certain materials to measure a variety of analytes, including applications in clinical chemistry, monitoring drugs of abuse and in therapeutic drug monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973628

Prescription Use 2  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

190