



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

(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>[Signature]</i>		DATE Feb 10, 2011
PRINTED NAME Zeynep Igot		TITLE President
COMPANY NAME Coform Biosciences		
MAILING ADDRESS 6310 Nancy Lodge Rd, #103		
CITY, STATE, ZIP San Diego CA 9121		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 261 78 1862
PHONE NO. 888 526 6347 ext 703	FAX NO. 973-807-5575	E-MAIL ADDRESS z.igot@coformbiosciences.com

NOTICE OF AWARD (OSCA USE ONLY)

ACCEPTED BY OFFICE OF STATE COURTS ADMINISTRATOR AS FOLLOWS: <i>IN ITS ENTIRETY AS SUBMITTED</i>		
CONTRACT NO. OSCA 11-029-04	CONTRACT PERIOD July 1, 2011 through June 30, 2012	
CONTACTS COORDINATOR <i>[Signature]</i>	DATE 2-23-2011	STATE COURTS ADMINISTRATOR <i>[Signature]</i>

February 22, 2011

RFP NO. OSCA 11-029-00
TITLE: Drug/Alcohol Testing

CONTACT: Russell Rottmann
PHONE NO.: (573) 522-6766
ISSUE DATE: January 6, 2011

RE: RFP NO. OSCA 11-029-00

Dear Mr Rottmann

Enclosed please find Confirm BioSciences' proposal in response to the subject solicitation.

We are a women owned small business and would be honored to have the opportunity to serve your needs.

Also enclosed are the 510(K) notification document approved by the US Food and Drug Administration (FDA) and, as requested, our applicable past performance information and other exhibits that were required for the RFP

Confirm Biosciences agrees to all terms, conditions and provisions of the subject solicitation. Thank you in advance for your time and consideration. We look forward to the possibility of supporting you for this requirement.

Sincerely

Zeynep

Zeynep Ilgaz
Confirm BioSciences

Nancy Ridge Technology Center
6310 Nancy Ridge Drive #103
San Diego CA 92121

888-526-6347 ext 703
973-807-5575 fax
www.confirmbiosciences.com
www.hairconfirm.com



ConfirmBiosciences

info@confirmbiosciences.com
www.confirmbiosciences.com

5663 Balboa Ave, #430
San Diego, CA 92111

t: 858.430.2800
f: 630.566.0708



Confirm BioSciences

Bid Proposal For:

Solicitation: N0018911QZ032

Non Instrumental Drug Testing Kits

Bid Due Date: Feb 23, 2011

Issuing Officer: Erin Kiran

FISC Norfolk Contracting Dept., Philadelphia

United States Navy

700 Robbins Avenue, Bldg 2B

Philadelphia, PA 19111-5083

Phone (215) 697-9617

Fax (215) 697-9569

Respectfully Submitted By:

Confirm BioSciences Inc

6310 Nancy Ridge Road, # 103

San Diego, CA, 92121

Zeynep Ilgaz- President



1	Signed Documentation
2	Pricing
3	Bidder Information Exhibit A
4	Prior Experience Exhibit B
5	Personal Expertise Exhibit C
6	Method of Performance Exhibit
7	Product Inserts



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: osea.contracts@courts.mo.gov

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(U.S. Mail)	(Courier Service)
Office of State Courts Administrator	Office of State Courts Administrator
Contracts Unit	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

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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>[Signature]</i>		DATE Feb 10, 2011
PRINTED NAME Zhang 1982		TITLE President
COMPANY NAME Lantern Biosciences		
MAILING ADDRESS 1010 Nancy Ridge Road, #103		
CITY, STATE, ZIP San Diego, CA 92121		
VENDOR NO. (IF KNOWN)		FEDERAL EMPLOYER ID NO. 261791862 261781862
PHONE NO. 898-526-6347	FAX NO. 973-807-5575	E-MAIL ADDRESS zhang@lanternbiosciences.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

PRODUCT PRICING		
SKU	Item Description	PRICE
Drug Tests Urine Cup Kit		
Picture of Cup		
WDOA-254C2	5-Panel Key Cup; COC,THC,OPI,AMP,mAMP	\$2.61
WDOA-255C2	5-Panel Key Cup; COC,THC,MOP,AMP,mAMP	\$2.61
WDOA-3104C2	10- Panel Key Cup ; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,MDMA	\$4.31
WDOA-7104C2	10-Panel Key Cup; COC,THC,OPI,BZO,mAMP,TCA,OXY,BUP,BAR,MTD	\$4.31
Drug Tests Dip Card Kit		
Picture of Cards		
WDAM-114	1-Panel Card; AMP Amphetamines	\$0.60
WDBA-114	1-Panel Card; BAR	\$0.60
WDBZ-114	1-Panel Card; Benzodiazepines BZO	\$0.60
WDBU-114	1-Panel Card; Buprenorphine BUP	\$0.60
WDCO-114	1-Panel Card; COC	\$0.60
WDMD-114	1-Panel Card; Ecstasy-MDMA	\$0.60
WDMA-114	1-Panel Card; mAMP	\$0.60
WDMO-114	1-Panel Card; MOP	\$0.60
WDMT-114	1-Panel Card; MTD	\$0.60
WDOP-114	1-Panel Card; OPI	\$0.60
WDOX-114	1-Panel Card; OXY	\$0.60
WDPC-114	1-Panel Card; PCP Phencyclidine	\$0.60
WDPP-114	1-Panel Card; PPX Propoxyphene	\$0.60
WDTC-114	1-Panel Card; TCA Tricyclic Antidepressants	\$0.60
WDTH-114	1-Panel Card; THC	\$0.60
WDOA-124	2-Panel Card; COC,THC	\$1.14
WDOA-424	2-Panel Card; THC,mAMP	\$1.14
WDOA-234	3-Panel Card; COC,mAMP,THC	\$1.45

WDOA-134	3-Panel Card; COC,THC,OPI	\$1.45
WDOA-244	4-Panel Card; COC,AMP,THC,OPI	\$1.55
WDOA-144	4-Panel Card; COC,THC,OPI,mAMP	\$1.55
WDOA-155	5-Panel Card; COC,THC,MOP,AMP,PCP	\$1.61
WDOA-254	5-Panel Card; COC,THC,OPI,AMP,mAMP	\$1.61
WDOA-255	5-Panel Card; THC,COC,MOP,AMP,mAMP	\$1.61
WDOA-354	5-Panel Card; COC,THC,OPI,mAMP,OXY	\$1.61
WDOA-554	5-Panel Card; COC,THC,OPI,mAMP,MDMA	\$1.61
WDOA-654	5-Panel Card; COC,THC,OPI,mAMP,BZO	\$1.61
WDOA-655	5-Panel Card; COC,THC,MOP,mAMP,BZO	\$1.61
WDOA-754	5-Panel Card; COC,THC,OPI,AMP,BZO	\$1.61
WDOA-855	5-Panel Card;COC,OXY,MOP,BUP,BZO	\$1.61
WDOA-954	5-Panel Card;THC,mAMP,AMP,MTD,BAR	\$1.61
WDOA-164	6-Panel Card; COC,THC,OPI,AMP,mAMP,PCP	\$1.89
WDOA-264	6-Panel Card; COC,THC,OPI,AMP,mAMP,BZO	\$1.89
WDOA-364	6-Panel Card; COC,AMP,mAMP,THC,OPI,MDMA	\$1.89
WDOA-465	6-Panel Card; THC,COC,MOP,AMP,BZO,MTD	\$1.89
WDOA-564	6-Panel Card; COC,THC,OPI,mAMP,BZO,OXY	\$1.89
WDOA-664	6-Panel Card;COC, AMP, mAMP, THC, OPI, OXY	\$1.89
WDOA-764	6-Panel Card; COC,mAMP,THC,OPI,PCP,BZO	\$1.89
WDOA-865	6-Panel Card; COC,BUP,MTD,OXY,MOP,BZO	\$1.89
WDOA-274	7-Panel Card; COC,THC,OPI,AMP,mAMP,BZO,OXY	\$2.58
WDOA-184	8-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR	\$2.76
WDOA-194	9-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD	\$2.89
WDOA-295	9-Panel Dip Card;THC,COC,MOP,AMP,BZO,MTD,OXY,PPX,BUP	\$2.95
WDOA-1104	10-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,TCA	\$3.10
WDOA-1105	10-Panel Card; COC,THC,MOP,AMP,mAMP,PCP,BZO,BAR,MTD,TCA	\$3.10
WDOA-2105	10-Panel Card; COC,THC,MOP,AMP,mAMP,OXY,BZO,BAR,MTD,TCA	\$3.10
WDOA-3104	10-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,MDMA	\$3.10
WDOA-4104	10-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,OXY	\$3.10
WDOA-5104	10-Panel Card; COC,THC,BAR,BZO,mAMP,AMP,MDMA,PPX,MTD,OPI	\$3.10
WDOA-6104	10-Panel Card; COC,THC,OPI,BZO,AMP,TCA,OXY,BUP,BAR,MTD	\$3.10
WDOA-7104	10-Panel Card; COC,THC,OPI,BZO,mAMP,TCA,OXY,BUP,BAR,MTD	\$3.10
WDOA-1114	11-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,TCA,OXY	\$3.26
WDOA-1124	12-Panel Card; COC,THC,OPI,AMP,mAMP,PCP,BZO,BAR,MTD,MDMA,OXY,PPX	\$3.51
WDOA-2125	12-Panel Card; COC,THC,MOP,AMP,MAMP,TCA,BZO,BAR,MTD,MDMA,OXY,PPX	\$3.51
Drug Tests Strip Kit		
WDTH-101	1-Strip; THC	\$0.73
WDCO-101	1-Strip; COC	\$0.73
WDOP-101	1-Strip; OPI	\$0.73
WDMA-101	1-Strip; mAMP	\$0.73
SALIVA- ORAL BASED DRUG TEST--INSTANT		



SVC 5	5 Panel Saliva- COC, THC, AMP, OPI, BZO	\$6.00
SAV 6	6 Panel Saliva - COC,THC,AMP,MET, OPI, BZO	\$6.50
LAB TESTING		
	Hair Drug Testing- 5 Panel	\$42.99
	Testing supplies, specimen transport, GC/MS Confirmation, Medical Review Officer Review Included	

OSCA 11- 029

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.

Confirm Biosciences was incorporated in January 2008. Confirm Biosciences© is a leading provider of point-of-care medical diagnostic products as well as lab based drug testing services. We offer a full range of drug and alcohol on-site test kits for use in workplace, occupational health, government, school, and public safety settings. An extensive line of forensic field test kits are available for law enforcement and public safety. Confirm Biosciences© brings both laboratory testing and point of care testing to the consumer through innovation and product development

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

Confirm Biosciences is a nationally recognized, full service provider of all methods of drug detection technologies and laboratory services.

Services include instant drug testing kits and supplies. Lab based hair and urine drug and steroid testing services.

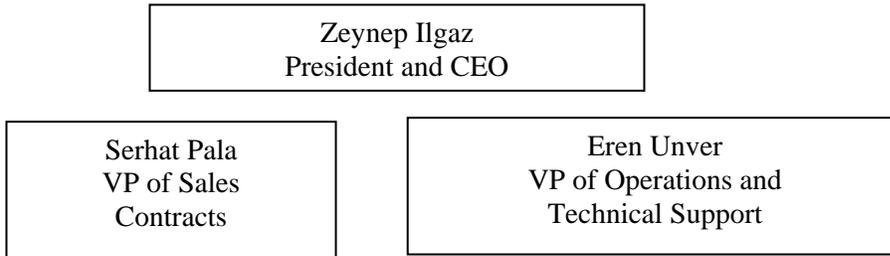
- c. Provide a list of and a short summary of information regarding the vendor’s current contracts/clients. List, identify, and provide reasons for each contract/client gained and lost in the past 2 years.

Confirm BioSciences currently holds a contract with XE Services (former Blackwater) to perform their lab based steroid testing as well as instant oral drug testing needs. Other clients include constructions, manufacturing, staffing agencies that require workplace drug testing solutions.

Confirm Biosciences also provides hair drug testing services to schools and educational facilities that are funded by the government to provide student drug testing programs.

- b. 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.

Organizational Structure:



Kim Lee
Administrative Coordinator

President and CEO: Zeynep Ilgaz
zilgaz@confirmbiosciences.com 888 526 6347 ext 703

Zeynep Ilgaz is the co-founder and President of Confirm BioSciences. As the global leader in the field of lab testing for drugs of abuse, Confirm BioSciences is committed to being on the cutting edge of offering new, service-oriented drug testing technologies.

Ilgaz is an advisor to the National Institutes of Health commercialization assistance program and is a dedicated participant in the educational and entrepreneurial programs of San Diego State University, UCSD, High Tech High and the San Diego Unified School District. She has initiated a corporate giving program whose beneficiaries include The Alpha Project for the Homeless, The McAlister Institute, San Diego Youth and Community Services, Teen Challenge International and Volunteers of America's Alcohol and Drug Services Center.

Ilgaz received her MBA from San Diego State University in 2000. She earned her bachelor's degree in Economics and Finance from Bosphorus University, Istanbul, Turkey.

Ilgaz was a recipient of the 2008 YWCA TWIN (Tribute to Women in Industry) awards and a recipient of 40 under 40 in from San Diego Metropolitan Magazine in September 2008. In 2009, SDSU presented her with the Charles Lamden Rising Star in Business award. In 2010, Ms Ilgaz has been recognized as one of San Diego's Top Young Influentials by the SDDT.

Zeynep will be the primary point of contact for this contract.

VP of Sales: Serhat Pala
spala@confirmbiosciences.com

Serhat Pala is the VP of Sales for Confirm Biosciences where he oversees all major contracts, negotiations and sales activities.

Prior to working in San Diego, Serhat worked in banking industry first as a credit card product manager and as the director of strategic planning at Interbank Turkey where he oversaw product and strategic management of retail consumer financial products. In his early career, Serhat has participated in various consulting projects and assignments regarding technology commercialization, Internet marketing and medical devices. As a serial entrepreneur, Serhat found three successful Internet businesses that each grossed over \$1 million in annual revenue.

Serhat holds a bachelor of Economics from Bogazici University Istanbul, Turkey and a Masters in Business from San Diego State University, where he both graduated with honors. In 2006 Serhat was nominated by the San Diego Business Journal as one of the top influencers in San Diego.

In 2008, he was awarded by Turkish American Council with prestigious Commercial Leadership Award of the year. At the age of 35 he was the youngest recipient of the award.

VP of Operations and Technical Support: Eren Unver
eunver@confirmbiosciences.com

Eren has an MBA from Southern States University San Diego. He has extensive experience in operations, warehouse managements and coordination. His Role will be the assistant coordinator for this contract.

Administrative Coordinator: Kim Lee
klee@confirmbiosciences.com

- 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.

Confirm Biosciences has never missed a deadline for product or service delivery and had never any complaints in regards to its reporting system. All supplies are delivered on time. Customer service is available 24 hours.

At no time had Confirm biosciences had contractual terminated for any reason

At no time have any damages or penalties been assessed or awarded against Confirm Biosciences

At no time has Confirm Biosciences been involved in any matters of litigation. No officer of the firm has ever been convicted or charged with any crime

- 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.

Please see attached

EXHIBIT B

PRIOR EXPERIENCE

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

Vendor Name or Subcontractor Name: <u>Confirm Biosciences</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Employee Screening Management
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	Employee Screening Management 98 E. Sunbridge Dr Fayetteville AR 72703
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Gary Graves, Account Manager gary@pre-screen.com 1.888.371.4615
Dates of Prior Services:	2 years
Dollar Value of Prior Services:	\$40,000
Description of Prior Services Performed:	Providing Point of Collection Drug Testing Products

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

Signature of Reference Contact Person

Date of Signature

EXHIBIT B- 2

PRIOR EXPERIENCE

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

Vendor Name or Subcontractor Name: <u>Confirm Biosciences</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Test Medical
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	Test Medical 6633 Ashman Road Maria Stein OH 45860
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Jeremy Carlson, Purchasing Manager (419) 586-9462 jeremy@testsymptomsathome.com
Dates of Prior Services:	3 years
Dollar Value of Prior Services:	\$60,000
Description of Prior Services Performed:	Confirm BioSciences has been supplying Test Medical with lab based urine and hair testing services as well as instant drug testing cups.. Products have been provided under individual purchase orders issued to Confirm BioSciences as needed by Test Medical. Confirm Biosciences has provided full support, technical assistance and warranty on all products and services provided.

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

Signature of Reference Contact Person

Date of Signature

EXHIBIT B-

PRIOR EXPERIENCE

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

Vendor Name or Subcontractor Name: <u>Confirm Biosciences</u>	
Reference Information (Prior Services Performed For:)	
Name of Reference Company:	Uritox Medical
Address of Reference Company: ✓ Street Address ✓ City, State, Zip	Uritox Medical 3060 W. Sylvania Ave STE B Toledo, OH 43613
Reference Contact Person Information: ✓ Name ✓ Phone # ✓ E-mail Address	Jehad Awada, President 877-487-4869 jawada@uritox.com
Dates of Prior Services:	3 years
Dollar Value of Prior Services:	\$250,000
Description of Prior Services Performed:	Confirm BioSciences has been supplying Uritox with lab based urine and hair testing services as well as instant drug testing cups.. Products have been provided under individual purchase orders issued to Confirm BioSciences as needed by Uritox. Last year we also provided Uritox with lab based steroid testing services.

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

OSCA 11- 029

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. Zeynep Ilgaz (Name) President and CEO (Title) Primary Contact (Proposed Role/Function)	Zeynep is a graduate of SDSU and a founder of Confirm Biosciences. She has extensive experience in working with the government, contracts as well as commercial customers. The company has established a well functioning web reporting system for results delivery. Ilgaz was a recipient of the 2008 YWCA TWIN (Tribute to Women in Industry) awards and a recipient of 40 under 40 in from San Diego Metropolitan Magazine in September 2008. In 2009, SDSU presented her with the Charles Lamden Rising Star in Business award. In 2010, Ms Ilgaz has been recognized as one of San Diego's Top Young Influentials by the SDDT.
2. Serhat Pala VP of Sales (Title) Support (Proposed Role/Function)	Serhat is a graduate of SDSU and has been a key In identifying client need and increasing the companies national accounts. His experience in contracts and commercial clients is at a similar level. In 2006 Serhat was nominated by the San Diego Business Journal as one of the top influencers in San Diego. In 2008, he was awarded by Turkish American Council with prestigious Commercial Leadership Award of the year. At the age of 35 he was the youngest recipient of the award
3. Eren Unver (Name) VP of Operations (Title) Technical Support (Proposed Role/Function)	Eren is a graduate of Southern States University where he received his MBA. He has been key in building the technical infrastructure and operational side of Confirm Biosciences.
4. Kim Lee (Name) Administrative Coordinator (Title) Support (Proposed Role/Function)	Kim's extensive background in office management and coordination within the government field allows her to develop standards and procedures for our clients as well as for our in house needs.
5. _____ (Name) _____ (Title) _____ (Proposed Role/Function)	

OSCA 11- 029
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)
All instant drug test devices come the product requested, instructions on how to use, product insert, chain of custody forms and mailing packets (upon request)
Lab based services include collection kit, prepaid mailer, reporting, online reporting, as part of the price as explained in the pricing proposal.
2. Describe the instruction or training provided to treatment court staff pertaining to properly collecting a sample and completing necessary documentation.
All necessary training can be provided over the phone or online. We have CD;s and videos of instructions.
3. Describe how the sample is transported to the testing laboratory (U S Postal, Fed Ex, UPS, etc.).
Our tests can be transported into where ever the staff member needs to be. All tests come individually sealed so they remain steroid and protected until they are needed.
4. Describe the methods of testing which are employed (LC/MS/MS, GS/MS, LC/MS, and/or Immunoassay methods).
5. All test results are highly accurate (enclosed package insert) and compare directly to GC/MS testing.
Gc/MS confirmation is used for all lab based services.
6. **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?
All tests are manufactured fresh and come with a min of 18 months shelf life. All urine tests are FDA 510K cleared

All test cards have a required build in control indicator which tell the operator that the tests are valid to run.

	<u>ng/mL</u>	
AMP	Amphetamine	1000 ng/mL and 300 ng/mL
BAR	Barbiturates	200 ng/mL
BZD	Benzodiazepine	300 ng/mL
COC	Cocaine	300 ng/mL
MET	Methamphetamine	1000 ng/mL
MOR/OPI	Morphine/Opiates	2000 ng/mL
MOR/OPI300	Morphine/Opiates	300 ng/mL
MTD	Methadone	300 ng/mL
OXY100	Oxycodone	100 ng/mL
OXY300	Oxycodone	300 ng/mL
PCP	Phencyclidine	25 ng/mL

TCA	Tricyclic Antidepressants	1000 ng/mL
THC	Marijuana	50 ng/mL

All test

7. Describe the turnaround time for results.

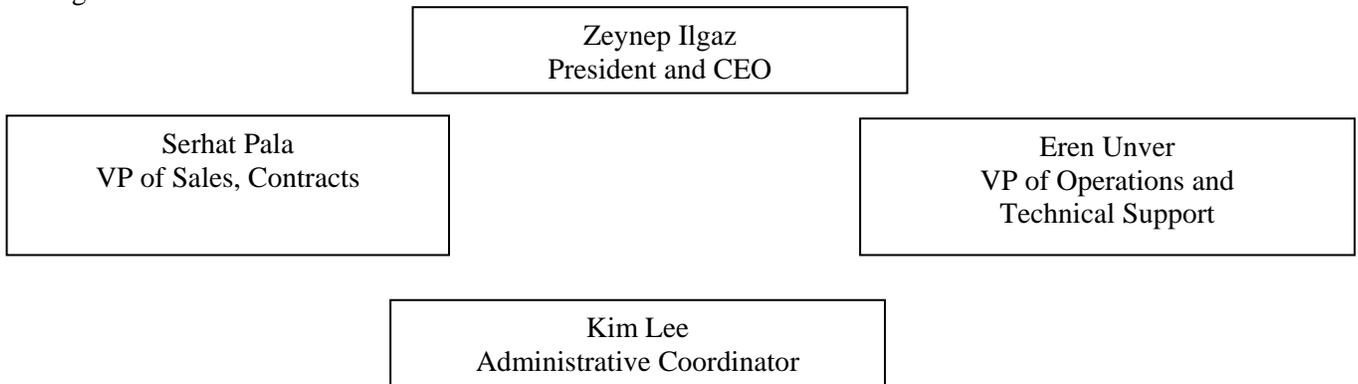
All results are provided to our client, by way of our web based reporting. Negative results are available within 24 hours. Positive results will take an additional 24 hours.

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

All results are provided to our client, by way of our web based reporting. They can also be reported via fax or email if client wishes so.

9. **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.

Organizational Chart:



President and CEO: Zeynep Ilgaz
zilgaz@confirmbiosciences.com 888 526 6347 ext 703

Zeynep Ilgaz is the co-founder and President of Confirm BioSciences. As the global leader in the field of lab testing for drugs of abuse, Confirm BioSciences is committed to being on the cutting edge of offering new, service-oriented drug testing technologies.

Zeynep will be the primary point of contact for this contract.

VP of Sales: Serhat Pala
spala@confirmbiosciences.com

Serhat Pala is the VP of Sales for Confirm Biosciences where he oversees all major contracts, negotiations and sales activities. Serhat Pala will function as a supporting role for this contract.

VP of Operations and Technical Support: Eren Unver
eunver@confirmbiosciences.com

Eren has an MBA From Southern States University San Diego. He has extensive experience in operations, warehouse managements and coordination. His Role will be the assistant coordinator for this contract.

Administrative Coordinator: Kim Lee
 klee@confirmbiosciences.com

Kim’s extensive background in office management and coordination within the government field allows her to develop standards and procedures for our clients as well as for our in house needs.

- 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.

Each team member will have a role in executing the contract. Ms Ilgaz will be the main point of contact. Mr Pala will act as a supporting role in executing the contract. He will also be responsible for support and training purposes. Mr Unver will act as an assistant coordinator, he will process all PO’s and make sure all shipments are made on time. Ms Lee will act as coordinator and support person. She will be responsible in handling all the paperwork, lab processing paperwork and back end reporting.

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.
 The contract will be under main supervision of Ms Ilgaz. Confirm Biosciences administers drug testing for a large variety of clients and has the know how and experience to handle such contracts in a timely and professional manner.
- 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.
 Confirm Biosciences has all the sufficient resources to execute this contract. All products and services are available on an as needed basis. Once a contract has been awarded to u, we maintain adequate supplies at all times for immediate delivery.

10. Outside United States - If any products and/or services offered under this RFP are being manufactured or performed at sites outside the United States, the vendor MUST disclose such fact and provide details in the space below or on an attached page.

Are products and/or services being manufactured or performed at sites outside the United States?	Yes ____	No ____
Describe and provide details: Some of our instant drug testing devices are manufactured in China. Most of our products are manufactured in the USA. All our lab services are done in the USA.		



DRUGS OF ABUSE TESTS

Urine drug testing is one of the most popular methods of random drug testing for recent drug use, as they are easy to use and provide fast and accurate results.

Integrated Test Cup: This is the most preferred method in this category as the cup and test are combined for ease of use. There is no handling of the specimen required.

Dip Card: Dip Card urine drug testing uses test strips which are dipped into the urine sample. Once the strips become saturated, the results can be determined.

Dip Strip: Dip Strip urine drug testing uses a test strip which is dipped into the urine sample. Once the strips become saturated, the results can be determined.

OUR DRUG TESTS ARE:

- FDA APPROVED
- CE CLEARED
- EASY TO USE
- HIGH QUALITY
- FAST AND ACCURATE RESULTS
- CLEAN, HYGIENIC TESTING
- CAN DETECT UP TO 12 DRUGS



Wondfo One Step Multi-Drug Urine Cup

Suitable for the following catalogue number:

W2002-C	W2006-C	W2010-C
W2003-C	W2007-C	W2011-C
W2004-C	W2008-C	W2012-C
W2005-C	W2009-C	

Wondfo One Step Multi-Drug Urine Cup offers any combination from 2 to 12 drugs of abuse tests for 16 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Cannabinoids (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxyamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), , Buprenorphine (BUP), Oxycodone (OXY), Ketamine (KET), Propoxyphene (PPX).

This package insert applies to all combinations of multi-drug tests panel with integrated cup. Therefore, some information on the performance characteristics of the product may not be relevant to your test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test."

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level. For healthcare professional use only. For in vitro diagnostic use.

INTENDED USE

Wondfo One Step Multi-Drug Urine Cup is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Test	Calibrator	Cut off (ng/ml)
Amphetamine	Amphetamine	1,000
Barbiturates	Secobarbital	300
Benzodiazepines	Oxazepam	300
Cocaine	Benzoyllecgonine	300
Marijuana	Marijuana	50
Methadone	Methadone	300
Methamphetamine	Methamphetamine	1,000
Methylenedioxyamphetamine	3,4-Methylenedioxyamphetamine HCl(MDMA)	500
Morphine	Morphine	300
Opiate	Morphine	2000
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Notriptyline	1,000
Buprenorphine	Buprenorphine	10
Oxycodone	Oxycodone	100
Ketamine	Ketamine	1,000
Propoxyphene	Propoxyphene	300

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

PRINCIPLE

One Step Multi-Drug Urine Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiration date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Do not use the cup if the cup is broken.

STORAGE AND STABILITY

- Store at 4 °C ~ 30 °C up to the expiration date.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- One pouch containing a test card and a desiccant.

- One urine cup
- Package insert

Material Required But Not Provided

- Timer
- External controls

SPECIMEN COLLECTION AND PREPARATION

- Wash your hands with soap and warm water.
- Open the pouch and remove the urine cup.
- Open the cap of the cup and urinate directly into the test cup. Replace and seal the cap by pressing down on all the corners. Check the cap for a tight seal. The test just requires 25mL urine.
- Urine specimens may be refrigerated (2°C -8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
- Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (10°C to 30°C). Bring the test to room temperature prior to testing.

1. After the urine has been collected, place the test cup on a flat surface.
2. Open the sealed pouch by tearing along the notch. Remove the test card from the pouch and use it as soon as possible.
3. Uncover the small cap of the cup, then insert the test card.
4. Press the test card slowly until liquid level touch the red line.
5. Release the test card, cover the small cap.
6. Wait for 5 minutes, remove the label and read the result. **Do not read results after 5 minutes.**



INTERPRATATION OF RESULTS

Positive (+)

A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

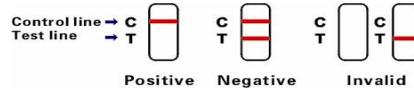
Negative (-)

A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Though there is an internal procedural control line in the test device of control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test result does not distinguish between drugs of abuse and certain medicines.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using each of the tests and commercially available drug rapid test (Acon One Step Multi-Line Screen Test with Integrated E-Z Split Key IM Cup (Urine)). 740 specimens were used in the test. Positive results were confirmed by GC/MS. The results were listed as follows:

Specimen	% Agreement with commercial kit							
	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA
Positive	>99%	97.5%	95%	100%	95%	90%	>99%	95%
Negative	>99%	99%	100%	99%	99%	99%	>99%	99%
Total	>99%	98.6%	97.9%	>99%	97.9%	96.4%	>99%	97.9%

Specimen	MOP	OPI	PCP	TCA	BUP	OXY	KET	PPX
	300	2000						
Positive	97.5%	97.5%	97.5%	95%	97%	>99%	96%	95%
Negative	99%	99%	99%	99%	97%	>99%	99%	100%
Total	98.6%	98.6%	98.6%	97.9%	97%	>99%	97.5%	97.9%

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA
Positive	94%	92%	97%	96%	95%	95%	99%	97%
Negative	99%	98%	97%	99%	96%	99%	99%	99%
Total	97%	95%	97%	98%	96%	97%	99%	98%

Specimen	MOP 300	OPI 2000	PCP	TCA	BUP	OXY	KET	PPX
Positive	98%	99%	91%	95%	90%	92.5%	92.5%	90%
Negative	98%	99%	99%	99%	97.5%	97.5%	95%	97.5%
Total	98%	99%	95%	97%	93.8%	95%	93.8%	93.8%

Analytical Sensitivity

Standard drugs were spiked into urine samples to the concentration of - 50% cut off and ±25% cut off. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		COC		THC		MTD		MET		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
25% Cut-off	30	25	5	26	4	26	4	25	5	23	7	25	5	25	5	23	7
Cut-off	30	12	18	10	20	14	16	15	15	14	16	12	18	13	17	10	20
±25% Cut-off	30	5	25	8	22	5	25	6	24	3	27	6	24	5	25	4	26
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MOP 300		OPI 2000		PCP		TCA		BUP		OXY		KET		PPX	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
25% Cut-off	30	24	6	25	5	26	4	24	6	26	4	26	4	27	3	26	4
Cut-off	30	10	20	14	16	15	15	14	16	1	29	3	27	2	28	1	29
±25% Cut-off	30	3	27	5	25	7	23	6	24	0	30	0	30	0	30	0	30
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.

Amphetamine	Methamphetamine
d-Amphetamine	D(+)-Methamphetamine
d.1-Amphetamine	D-Amphetamine
1-Amphetamine	Chloroquine
(+/-) 3,4-methylenedioxyamphetamine	(+/-)-Ephedrine
Phentermine	(-)-Methamphetamine
Barbiturates	(+/-)3,4-methylenedioxymethamphetamine(MDMA)
Secobarbital	b-Phenylethylamine
Amobarbital	Trimethobenzamide
Alphenol	Methylenedioxymethamphetamine(MDMA)
Aprobarbital	3,4-Methylenedioxyamphetamine HCl(MDMA)
Butabarbital	3,4-Methylenedioxyamphetamine HCl
Butathal	3,4-Methylenedioxyethylamphetamine
Butalbital	Morphine
Cyclopentobarbital	Morphine
Pentobarbital	Codeine
Phenobarbital	Ethyl Morphine
Benzodiazepines	Hydrocodone
Oxazepam	Hydromorphone
Alprazolam	Morphine-3-β-D-glucuronide
α-Hydroxyalprazolam	Thebaine
Bromazepam	Opiate 2000
Chlordiazepoxide	Morphine
Clonazepam HCl	Codeine
Clobazam	Ethylmorphine
Clonazepam	Hydrocodone
Clorazepate dipotassium	Hydromorphone
Delorazepam	Levorphanol
Desalkylflurazepam	σ-Monoacetylmorphine
Diazepam	Morphine 3-β-D-glucuronide
Estazolam	Norcocodeine
Flunitrazepam	Normorphine
D,L-Lorazepam	Oxycodone
	Oxymorphone
Midazolam	Procaine
Nitrazepam	Thebaine
Norchlordiazepoxide	Phencyclidine
Nordiazepam	Phencyclidine
Temazepam	4-Hydroxyphencyclidine
Trazolam	Tricyclic Antidepressants
Cocaine	Notriptyline
Benzoyllecgonine	Nordoxepine
Cocaine HCl	
Cocaeethylene	
Ecgonine	
Marijuana	Trimipramine
11-nor-D9-THC-9-COOH	Amitriptyline
11-nor-D8-THC-9-COOH	Promazine
11-hydroxy-D9-Tetrahydrocannabinol	Desipramine

D8- Tetrahydrocannabinol	7,500	Imipramine	400
D9- Tetrahydrocannabinol	10,000	Clomipramine	12,500
Cannabinol	10,000	Doxepine	2,000
Cannabidiol	100,000	Maprotiline	2,000
Methadone		Promethazine	25,000
Methadone	300	Buprenorphine	
Doxylamine	50,000	Buprenorphine 3-D-Glucuronide	15
Oxycodone		Norbuprenorphine	20
Dihydrocodeine	20,000	Norbuprenorphine 3-D-Glucuronide	200
Codeine	100,000	Ketamine	
Hydromorphone	100,000	Methadone	50,000
Morphine	>100,000	Pethidine	12,500
Acetylmorphine	>100,000	Methylamphetamine	12,500
Buprenorphine	>100,000	Methoxyphenamine	12,500
Ethylmorphine	>100,000	Promethazine	25,000
Propoxyphene		Phencyclidine	25,000
d-Propoxyphene	300		
d-Norpropoxyphene	300		

Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with One Step Multi-Drug Urine Cup at a concentration of 100 μg/ml.

Non Crossing-Reacting Compounds

Acetophenetidin	Creatinine	Loperamide	Quinidine
Nalidixic acid	Deoxycorticosterone	Meprobamate	Quinine
Acetylsalicylic acid	Dextromethorphan	Methoxyphenamine	Ranitidine
Aminopyrine	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diffunisal	Naloxone	Serotonin
Ampicillin	Digoxin	Naltrexone	Sulfamethazine
L-Phenylephrine	Diphenhydramine	Naproxen	Sulindac
Apomorphine	L-ψ-Ephedrine	Niacinamide	Tetracycline
Aspartame	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate
Benzilic acid	β-Estradiol	D-Norpropoxyphene	Tetrahydrocortisone,
Benzoic acid	Estrone-3-sulfate	Noscapine	(β-D-glucuronide)
Benzphetamine	Erythromycin	D,L-Octopamine	Tetrahydrozoline
Bilirubin	Fenoprofen	Oxalic acid	Thiamine
Deoxycorticosterone	Furosemide	Oxolinic acid	Thioridazine
Caffeine	Gentisic acid	Oxymetazoline	D,L-Tyrosine
	Hemoglobin	Papaverine	Tolbutamide
	Hydralazine	Penicillin-G	Triamterene
Chloralhydrate	Hydrochlorothiazide	Perphenazine	Trifluoperazine
Chloramphenicol	Hydrocortisone	Phenelzine	Trimethoprim
Chlorothiazide	O-Hydroxyhippuric acid	L-Phenylephrine	Tyramine
D,L-Chlorpheniramine	3-Hydroxytyramine	β-Phenylethylamine	D,L-Tryptophan
Chlorpromazine	D,L-Isoproterenol	Phenylpropranolamine	Urine acid
Chlorquine	Cholesterol	Prednisone	Verapamil
Cholesterol	Isosuprine	D,L-Propranolol	Zomepirac
Clonidine	Ketoprofen	L-Cotinine	D-Pseudoephedrine
Cortisone	Labeltalol		

From the results above, it is clear that One Step Multi-Drug Urine Cup resists well against interference from these substances.

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- Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elsevier Science Publishing Company, Inc., New York, 1988
- Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
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- McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

MEANING OF SYMBOLS ON PACKAGE

	Keep away from sunlight
	Store between 4°C and 30°C
	Keep dry
	Do not re-use

Guangzhou Wondfo Biotech Co., Ltd.
Wondfo Sciencetech Park
South China Univ. of Technology
Guangzhou 510641
ManufacturerChina



One Step Multi-Drug Urine Test Panel

Catalogue No. See Box label

Suitable for the following catalogue number:

- | | | |
|---------|---------|---------|
| W2002-P | W2006-P | W2010-P |
| W2003-P | W2007-P | W2011-P |
| W2004-P | W2008-P | W2012-P |
| W2005-P | W2009-P | |

Wondfo One Step Multi-Drug Urine Test panel offers any combination from 2 to 12 drugs of abuse tests for 16 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), Buprenorphine (BUP), Oxycodone (OXY), Ketamine (KET), Propoxyphene (PPX).

This package insert applies to all combinations of multi-drug tests panel. Therefore, some information on the performance characteristics of the product may not be relevant to your test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test."

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level.

For professional use only, For in vitro diagnostic use.

INTENDED USE

Wondfo One Step Multi-Drug Urine Test Panel is consisted of twelve individual one-step immunoassays. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Test	Calibrator	Cut off (ng/ml)
Amphetamine	Amphetamine	1,000
Barbiturates	Secobarbital	300
Benzodiazepines	Oxazepam	300
Cocaine	Benzoyllecgonine	300
Marijuana	Marijuana	50
Methadone	Methadone	300
Methamphetamine	Methamphetamine	1,000
Methylenedioxymethamphetamine	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Morphine	Morphine	300
Opiate	Morphine	2000
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Notriptyline	1,000
Buprenorphine	Buprenorphine	10
Oxycodone	Oxycodone	100
Ketamine	Ketamine	1,000
Propoxyphene	Propoxyphene	300

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

PRINCIPLE

Wondfo One Step Multi-Drug Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug /protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

WARNING AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiry date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Do not read after 5 minutes

STORAGE AND STABILITY

- Store at 4 °C ~ 30 °C in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- 25 Tests
- Package insert

Material Required But Not Provided

- Timer
- 25 Urine cup

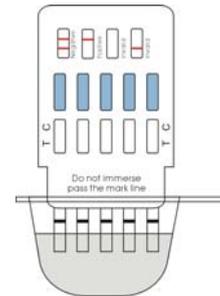
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2 °C -8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (10°C to 30°C)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



INTERPRATATION OF RESULTS

Positive (+)

A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

Negative (-)

A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medicines.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using each of the tests and commercially available drug rapid test (Acon One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key IM Cup (Urine)). 740 specimens were used in the test. Positive results were confirmed by GC/MS. The results were listed as follows:

Specimen	% Agreement with commercial kit							
	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA
Positive	>99%	97.5%	95%	100%	95%	90%	>99%	95%
Negative	>99%	99%	100%	99%	99%	99%	>99%	99%
Total	>99%	98.6%	97.9%	>99%	97.9%	96.4%	>99%	97.9%

Specimen	MOP 300	OPI 2000	PCP	TCA	BUP	OXY	KET	PPX
Positive	97.5%	97.5%	97.5%	95%	97%	>99%	96%	95%
Negative	99%	99%	99%	99%	97%	>99%	99%	100%
Total	98.6%	98.6%	98.6%	97.9%	97%	>99%	97.5%	97.9%

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA
Positive	94%	92%	97%	96%	95%	95%	99%	97%
Negative	99%	98%	97%	99%	96%	99%	99%	99%
Total	97%	95%	97%	98%	96%	97%	99%	98%

Specimen	MOP 300	OPI 2000	PCP	TCA	BUP	OXY	KET	PPX
Positive	98%	99%	91%	95%	90%	92.5%	92.5%	90%
Negative	98%	99%	99%	99%	97.5%	97.5%	95%	97.5%
Total	98%	99%	95%	97%	93.8%	95%	93.8%	93.8%

Analytical Sensitivity

Standard drugs were spiked into negative urine samples to the concentration of -50% cutoff, -25% cutoff, cutoff, +25% cutoff and +50% cutoff. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		COC		THC		MTD		MET		MDMA		
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+25% Cut-off	30	25	5	26	4	26	4	25	5	23	7	25	5	25	5	23	7	7
Cut-off	30	12	18	10	20	14	16	15	15	14	16	12	18	13	17	10	20	20
+25% Cut-off	30	5	25	8	22	5	25	6	24	3	27	6	24	5	25	4	26	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	30

Drug Conc. (Cut-off range)	n	MOP 300		OPI 2000		PCP		TCA		BUP		OXY		KET		PPX		
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
-25% Cut-off	30	24	6	25	5	26	4	24	6	26	4	26	4	27	3	26	4	4
Cut-off	30	10	20	14	16	15	15	14	16	1	29	3	27	2	28	1	29	29
+25% Cut-off	30	3	27	5	25	7	23	6	24	0	30	0	30	0	30	0	30	30
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	30

Analytical Specificity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.

Amphetamine		Methamphetamine	
d-Amphetamine	1,000	D(+)-Methamphetamine	1,000
d,l-Amphetamine	3,000	D-Amphetamine	50,000
l-Amphetamine	50,000	Chloroquine	50,000
(+/-)	5,000	(+/-)-Ephedrine	50,000
3,4-methylenedioxyamphetamine			
Phentermine	3,000	(-)-Methamphetamine	25,000
Barbiturates		(+/-)3,4-methylenedioxymethamphetamine(MDMA)	2,000
Secobarbital	300	b-Phenylethylamine	50,000
Amobarbital	300	Trimethobenzamide	10,000
Alphenol	150		
Aprobarbital	200	Methylenedioxymethamphetamine(MDMA)	
Butobarbital	75	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500
Butathal	100	3,4-Methylenedioxymethamphetamine HCl	3,000
Butibal	2,500	3,4-Methylenedioxyethylamphetamine	300
Cyclopentobarbital	600	Morphine	
Pentobarbital	300	Morphine	300
Phenobarbital	100	Codeine	300
Benzodiazepines		Ethyl Morphine	300
Oxazepam	300	Hydrocodone	5,000
Alprazolam	200	Hydromorphone	5,000
α-Hydroxyalprazolam	1,500	Morphine-3-b-d-glucuronide	1,000
Bromazepam	1,500	Thebaine	30,000
Chlordiazepoxide	1,500	Opiate 2000	
Clonazepam HCl	800	Morphine	2,000
Clobazam	100	Codeine	2,000
Clonazepam	800	Ethylmorphine	5,000
Clorazepate dipotassium	200	Hydrocodone	12,500
Delorazepam	1,500	Hydromorphone	5,000
Desalkylflurazepam	400	Levorphanol	75,000
Diazepam	200	α-Monoacetylmorphine	5,000
Estazolam	2,500	Morphine 3-β-D-glucuronide	2,000
Flunitrazepam	400	Norcodeine	12,500
D,L-Lorazepam	1,500	Normorphine	50,000
		Oxycodone	25,000
Midazolam	12,500	Oxymorphone	25,000
Nitrazepam	100	Procaine	150,000
Norchlordiazepoxide	200	Thebaine	100,000
Nordiazepam	400	Phencyclidine	
Temazepam	100	Phencyclidine	25
Trazolam	2,500	4-Hydroxyphencyclidine	12,500
Cocaine		Tricyclic Antidepressants	
Benzoyllecgonine	300	Notriptyline	1,000
Cocaine HCl	750	Nordoxepine	1,000
Cocaethylene	12,500		
Ecgonine	32,000		
Marijuana		Trimipramine	3,000

11-nor-D9-THC-9-COOH	50	Amitriptyline	1,500
11-nor-D8-THC-9-COOH	30	Promazine	1,500
11-hydroxy-D9-Tetrahydrocannabinol	2,500	Desipramine	200
D8- Tetrahydrocannabinol	7,500	Imipramine	400
D9- Tetrahydrocannabinol	10,000	Clomipramine	12,500
Cannabinol	10,000	Doxepine	2,000
Cannabidiol	100,000	Maprotiline	2,000
Methadone		Promethazine	25,000
Methadone	300	Buprenorphine	
Doxylamine	50,000	Buprenorphine 3-D-Glucuronide	15
Oxycodone		Norbuprenorphine	20
Dihydrocodeine	20,000	Norbuprenorphine 3-D-Glucuronide	200
Codeine	100,000	Ketamine	
Hydromorphone	100,000	Methadone	50,000
Morphine	>100,000	Pethidine	12,500
Acetylmorphine	>100,000	Methylamphetamine	12,500
Buprenorphine	>100,000	Methoxyphenamine	12,500
Ethylmorphine	>100,000	Promethazine	25,000
Propoxyphene		Phencyclidine	25,000
d-Propoxyphene	300		
d-Norpropoxyphene	300		

Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with One Step Multi-Drug Urine Test Panel at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

Acetophenetidin	Creatinine	Loperamide	Quinidine
Nalidixic acid	Deoxycorticosterone	Meprobamate	Quinine
Acetylsalicylic acid	Dextromethorphan	Methoxyphenamine	Ranitidine
Aminopyrine	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diffunisal	Naloxone	Serotonin
Ampicillin	Digoxin	Naltrexone	Sulfamethazine
L-Phenylephrine	Diphenhydramine	Naproxen	Sulindac
Apomorphine	L-γ-Ephedrine	Niacinamide	Tetracycline
Aspartame	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate
Benzilic acid	β-Estradiol	D-Norpropoxyphene	Tetrahydrocortisone,
Benzoic acid	Estrone-3-sulfate	Noscapine	(β-D-glucuronide)
Benzphetamine	Erythromycin	D,L-Octopamine	Tetrahydrozoline
Bilirubin	Fenoprofen	Oxalic acid	Thiamine
Deoxycorticosterone	Furosemide	Oxolinic acid	Thioridazine
Caffeine	Gentisic acid	Oxymetazoline	D,L-Tyrosine
	Hemoglobin	Papaverine	Tolbutamide
	Hydralazine	Penicillin-G	Triamterene
Chloralhydrate	Hydrochlorothiazide	Perphenazine	Trifluoperazine
Chloramphenicol	Hydrocortisone	Phenelzine	Trimethoprim
Chlorothiazide	O-Hydroxyhippuric acid	L-Phenylephrine	Tyramine
D,L-Chlorpheniramine	3-Hydroxytyramine	β-Phenylethylamine	D,L-Tryptophan
Chlorpromazine	D,L-Isoproterenol	Phenylpropanolamine	Urine acid
Chlorquine	Isoxsuprine	Prednisone	Verapamil
Cholesterol	Ketoprofen	D,L-Propranolol	Zomepirac
Clonidine	Labelalol	L-Cotinine	D-Pseudoephedrine

From the results above, it is clear that One Step Multi-Drug Urine Test Panel resists well against interference from these substances.

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- Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring - Verlag, 1977.
- Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
- Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

MEANING OF SYMBOLS ON PACKAGE

-  Keep away from sunlight
-  Store between 4°C and 30°C
-  Keep dry
-  Do not re-use

 Guangzhou Wondfo Biotech Co., Ltd.
Wondfo Sciencetech Park
South China Univ. of Technology
Guangzhou 510641

Manufacturer China
Version 15/04/2008

 Authorized Representative:
Qarad b.v.b.a.
Volmolenheide 13
B-2400 Mol, Belgium

K050024

NOV 17 2005

Premarket Notification - Wondfo Biotech Co. Ltd.

TAB 4

SUMMARY

Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
Address: South China University of Technology
Guangzhou, P.R. China 510641
Phone: 012-86-20-871-12194
Name of contact person: Howard Mann
Sherbo Associates
8903 Spruce Mill Drive
Yardley, PA 19067
Phone: (215) 369-3785
Fax: (215) 369-5246
Date the summary was prepared: September 16, 2004
Name of the device: One Step Multiple Drugs of Abuse Assays
Trade or proprietary name: One Step Multiple Drugs of Abuse Assays
Common or usual name: Immunochromatographic test for the qualitative detection of:

- Amphetamine
- Barbiturate
- Benzodiazepine
- Cocaine
- Marijuana
- Methadone
- Methamphetamine
- Methylenedioxymethamphetamine
- Morphine
- Opiate
- Phencyclidine
- Tricyclic antidepressant drugs

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
DKZ	862.3100
DIS	862.3150
JXM	862.3170
DIO	862.3250
LAF	862.3610
DJG	862.3610
DJG	862.3650
DJR	862.3620
LFG	862.3650
LCM	No regulation number for PCP
DJC	862.3910
LDJ	862.3870

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]: ACON Laboratories, Inc. One Step Drug Screen Test Card, K020771.

Description of the device:

Assay Principle: Immunochromatographic assay for drugs of abuse using a lateral flow, one step system for the qualitative detection of specific drugs in human urine. Each assay uses a monoclonal antibody-dye conjugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

Intended use of the device:

The One Step Multiple Drugs of Abuse Assays is intended for the qualitative determination of drugs and their metabolisms in human urine. They are intended for the healthcare professional use including professionals at point-of-care sites.

Summary of the technological characteristics of our device compared to the predicate device:

The Wondfo Biotech Co., Ltd. One Step Multiple Drugs of Abuse Assays have similar technological characteristics and performance to the predicate and are equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2005

Wondfo Biotech Co. Ltd.
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.

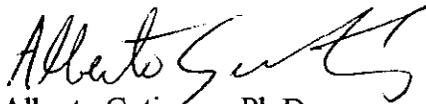
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 --

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

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

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K050024

Device Name: Multiple Drugs of Abuse Assays

Indications For Use:

One Step Multiple Drugs of Abuse Assays is used for the qualitative determination of the following drugs of abuse in urine:

Product Name	Cutoff
Amphetamine (amphetamine)	1000ng/ml
Barbiturate (secobarbital)	300ng/ml
Benzodiazepines (oxazepam)	300ng/ml
Cocaine (benzoylecgonine)	300ng/ml
Methamphetamine (methamphetamine)	1000ng/ml
Morphine (morphine)	300ng/ml
Opiate (morphine)	2000ng/ml
Methadone (methadone)	300ng/ml
Methylenedioxymethamphetamine (methylenedioxymethamphetamine)	500ng/ml
Phencyclidine (phencyclidine)	25ng/ml
Tricyclic antidepressant drugs (nortriptyline)	1000ng/ml
Cannabinoids (tetrahydrocannabinol-COOH)	50ng/ml

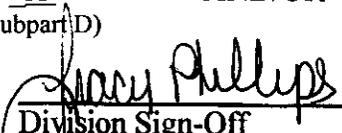
The configurations of the One Step Multiple Drugs of Abuse Assays are available in any combination of the above tests. These devices are intended to be used by healthcare professionals only. For in vitro diagnostic use. Measurements obtained by this device are used in the diagnosis and treatment of use or overdose of the drugs listed above.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

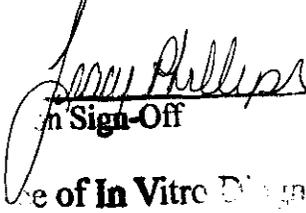
510(k)

K050024

page 1 of 2

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

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



in Sign-Off

Director of In Vitro Diagnostic Device
Evaluation and Safety

Page 2 of 2

(k) K050024