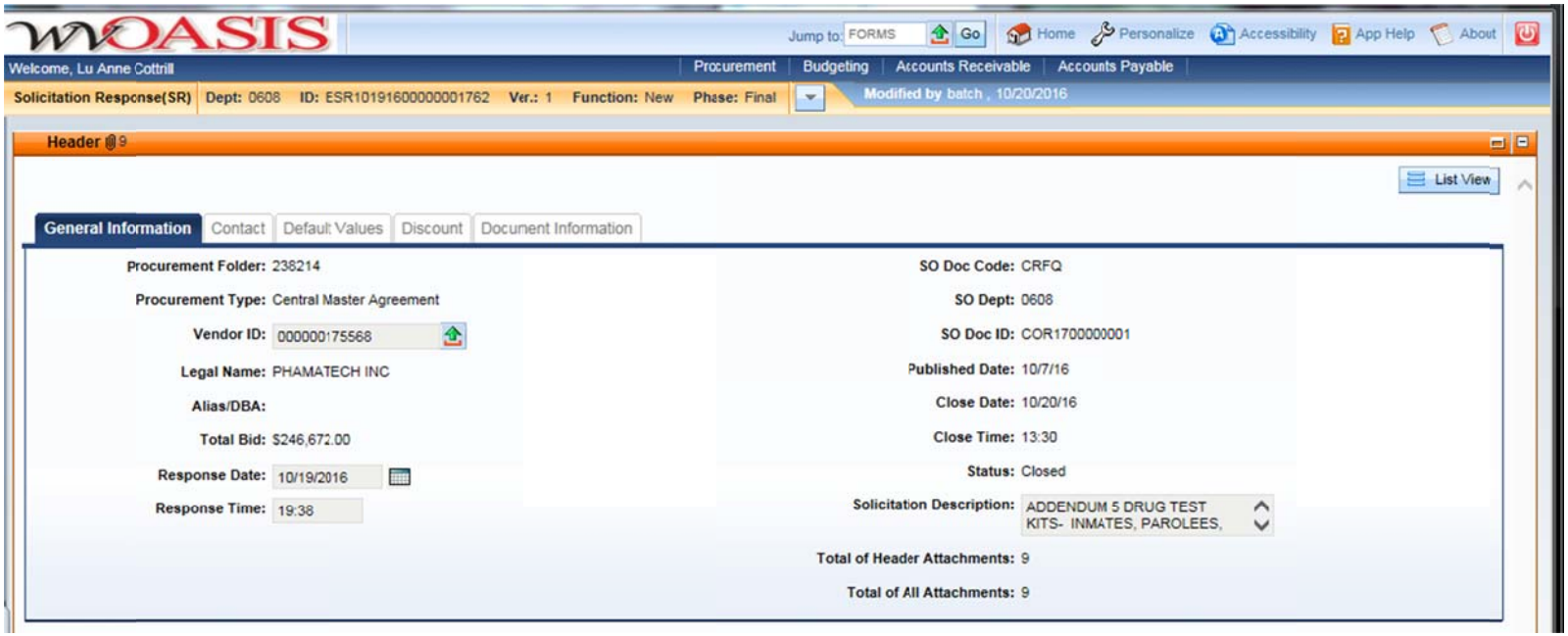
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.


WVOASIS
Jump to: FORMS Go
Home
Personalize
Accessibility
App Help
About
Welcome, Lu Anne Cottrill
Procurement
Budgeting
Accounts Receivable
Accounts Payable
Solicitation Response(SR) Dept: 0608 ID: ESR10191600000001762 Ver.: 1 Function: New Phase: Final
Modified by batch , 10/20/2016
Header 9
List View
General Information
Contact
Default Values
Discount
Document Information
Procurement Folder: 238214
Procurement Type: Central Master Agreement
Vendor ID: 000000175568
Legal Name: PHAMATECH INC
Alias/DBA:
Total Bid: $246,672.00
Response Date: 10/19/2016
Response Time: 19:38
SO Doc Code: CRFQ
SO Dept: 0608
SO Doc ID: COR1700000001
Published Date: 10/7/16
Close Date: 10/20/16
Close Time: 13:30
Status: Closed
Solicitation Description: ADDENDUM 5 DRUG TEST KITS- INMATES, PAROLEES,
Total of Header Attachments: 9
Total of All Attachments: 9

Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Solicitation Response

Proc Folder : 238214

Solicitation Description : ADDENDUM 5 DRUG TEST KITS- INMATES, PAROLEES, AND EMPLOYEE

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation Response	Version
	2016-10-20 13:30:00	SR 0608 ESR10191600000001762	1

VENDOR

000000175568

PHAMATECH INC

Solicitation Number: CRFQ 0608 COR1700000001

Total Bid : $246,672.00 **Response Date:** 2016-10-19 **Response Time:** 19:38:47

Comments:

FOR INFORMATION CONTACT THE BUYER

Crystal Rink

(304) 558-2402
crystal.g.rink@wv.gov

Signature on File **FEIN #** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Narcotic test kits - Inmate and Parolees	2000.00000	EA	$2.800000	$5,600.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Narcotic test kits - Inmate and Parolees	30000.00000	EA	$3.450000	$103,500.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 10-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Narcotic test kits - Inmate and Parolees	13000.00000	EA	$3.700000	$48,100.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 13-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Manual swab test kits - Inmate and Parolees	5000.00000	EA	$4.950000	$24,750.00

Comm Code	Manufacturer	Specification	Model #
41112601			

Extended Description : Manual swab test kits - Inmate and Parolees

Comments: Oral Cube 6panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	Narcotic test kits - Employees	100.00000	EA	$2.800000	$280.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	Narcotic test kits - Employees	100.00000	EA	$3.450000	$345.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 10-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	Narcotic test kits - Employees	100.00000	EA	$3.700000	$370.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 13-panel

Comments: QuickScreen Cup

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	Manual swab test kits - Employees	100.00000	EA	$4.950000	$495.00

Comm Code	Manufacturer	Specification	Model #
41112601			

Extended Description : Manual swab test kits - Employees

Comments: Oral Cube 6panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	Urinalysis laboratory services	100.00000	EA	$11.000000	$1,100.00

Comm Code	Manufacturer	Specification	Model #
85121805			

Extended Description : 6-panel confirmation testing

Comments: Per Drug Price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
10	Urinalysis laboratory services	100.00000	EA	$11.000000	$1,100.00

Comm Code	Manufacturer	Specification	Model #
85121805			

Extended Description : 10-panel confirmation testing

Comments: Per Drug Price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
11	Narcotic test kits - Inmate and Parolees	2000.00000	EA	$25.000000	$50,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Comments: $500.00 flat fee for MRO, OR LAB REPRESENTATIVE AS EXPERT WITNESS PRICING @ quantity of 100 = $50,000.00 total price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
12	Training	1.00000	EA	$0.000000	$0.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : In person training course for DOC employees

Comments: Training at no charge

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
13	Emergency Delivery Order	1.00000	EA	$20.000000	$20.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Emergency Delivery Order

Comments: per 25 test box & supplies / delivery for 2 working days or less

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
14	Shipping Charge	1.00000	EA	$12.000000	$12.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Shipping charge (less than 5 specimens per delivery)

Comments: overnight delivery w/less than 5 samples

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
15	EtG and EtS Testing	1000.00000	EA	$11.000000	$11,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : EtG and EtS Testing

COVER PAGE

SEALED BID – ELECTRONIC SUBMISSION

RFQ Title:	Buyer: Crystal Rink Drug Test Kits for Inmates, Parolees, and Employees Drug Testing Kits and Confirmation Services State of West Virginia – Division of Corrections
Solicitation No.:	CRFQ COR1700000001 – COR238214
Due Date:	**October 20**, 2016 at 1:30 p.m. (EDT)

Business Type:	California based Corporation
Legal name of firm:	Phamatech, Inc.
Federal Tax ID:	330836229
Corporate Address:	15175 Innovation Drive San Diego, CA 92128

Submitted by/Contact Person:	Dana Conde
Title:	Contract Manager
Toll free number:	888-635-5840 extension 276
Fax number:	858-635-5843
Email Address:	dconde@phamatech.com

Name, signature and title of person (s) authorized to sign for firm/agency:

Dana M Conde / Contract Manager

Signature of President/CEO, identifying Dana M Conde as authorized to bind Phamatech, Inc. to this RFQ/contract with the State of West Virginia, Division of Corrections.

Tuan Pham, President/CEO

TABLE OF CONTENTS

Submitted by: Dana M. Conde / Contract Manager
Contact Information: 15175 Innovation Drive, San Diego, CA 92128
Phone: 888 635 5840 X 276 / Fax: 858 635 5843
dconde@phamatech.com / www.phamatech.com

PHAMATECH Laboratories & Diagnostics

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

1. REVIEW DOCUMENTS THOROUGHLY: The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.

2. MANDATORY TERMS: The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

3. PREBID MEETING: The item identified below shall apply to this Solicitation.

☑ A pre-bid meeting will not be held prior to bid opening

☐ A **NON-MANDATORY PRE-BID** meeting will be held at the following place and time:

☐ A **MANDATORY PRE-BID** meeting will be held at the following place and time:

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing.

Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. VENDOR QUESTION DEADLINE: Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are nonbinding.

Submitted e-mails should have solicitation number in the subject line.

Question Submission Deadline: August 29, 2016 at 4:00 PM EST

Submit Questions to: Crystal Rink
2019 Washington Street, East
Charleston, WV 25305
Fax: (304) 558-4115 (Vendors should not use this fax number for bid submission)
Email: Crystal.G.Rink@wv.gov

5. VERBAL COMMUNICATION: Any verbal communication between the Vendor and any State personnel is not binding, including verbal communication at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.

6. BID SUBMISSION: All bids must be submitted electronically through wvOASIS or signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via e-mail. Acceptable delivery methods include electronic submission via wvOASIS, hand delivery, delivery by courier, or facsimile.

The bid delivery address is:
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

A bid that is not submitted electronically through wvOASIS should contain the information listed below on the face of the envelope or the bid may be rejected by the Purchasing Division.:

SEALED BID:
BUYER: Crystal Rink
SOLICITATION NO.: CRFQ COR1700000001
BID OPENING DATE: September 15, 2016
BID OPENING TIME: 1:30 PM EST
FAX NUMBER: 304-558-3970

The Purchasing Division may prohibit the submission of bids electronically through wvOASIS at its sole discretion. Such a prohibition will be contained and communicated in the wvOASIS system resulting in the Vendor's inability to submit bids through wvOASIS. Submission of a response to an Expression or Interest or Request for Proposal is not permitted in wvOASIS.

For Request For Proposal ("RFP") Responses Only: In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus ___n/a___ convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: (This only applies to CRFP)
☐ Technical
☐ Cost

7. BID OPENING: Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when confirmation of delivery is provided by wvOASIS (in the case of electronic submission) or when the bid is time stamped by the official Purchasing Division time clock (in the case of hand delivery).

Bid Opening Date and Time: September 15, 2016 at 1:30 PM EST

Bid Opening Location: Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

8. ADDENDUM ACKNOWLEDGEMENT: Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

9. BID FORMATTING: Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

10. ALTERNATES: Any model, brand, or specification listed in this Solicitation establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.

11. EXCEPTIONS AND CLARIFICATIONS: The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. COMMUNICATION LIMITATIONS: In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.

13. REGISTRATION: Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the $125 fee, if applicable.

14. UNIT PRICE: Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.

15. PREFERENCE: Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Vendor Preference Certificate form has been attached hereto to allow Vendor to apply for the preference. Vendor's failure to submit the Vendor Preference Certificate form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

16. SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES: For any solicitations publicly advertised for bid, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to contract award to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.

17. WAIVER OF MINOR IRREGULARITIES: The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.

18. ELECTRONIC FILE ACCESS RESTRICTIONS: Vendor must ensure that its submission in wvOASIS can be accessed by the Purchasing Division staff immediately upon bid opening. The Purchasing Division will consider any file that cannot be immediately opened and/or viewed at the time of the bid opening (such as, encrypted files, password protected files, or incompatible files) to be blank or incomplete as context requires, and are therefore unacceptable. A vendor will not be permitted to unencrypt files, remove password protections, or resubmit documents after bid opening if those documents are required with the bid.

19. NON-RESPONSIBLE: The Purchasing Division Director reserves the right to reject the bid of any vendor as Non-Responsible in accordance with W. Va. Code of State Rules § 148-1-5.3, when the Director determines that the vendor submitting the bid does not have the capability to fully perform, or lacks the integrity and reliability to assure good-faith performance."

20. ACCEPTANCE/REJECTION: The State may accept or reject any bid in whole, or in part in accordance with W. Va. Code of State Rules § 148-1-4.5. and § 148-1-6.4.b."

21. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of a Award Document signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. DEFINITIONS: As used in this Solicitation/Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation/Contract.

2.1. "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

2.2. "Bid" or **"Proposal"** means the vendors submitted response to this solicitation.

2.3. "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods or services requested in the Solicitation.

2.4. "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

2.5. "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

2.6. "Award Document" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the contract holder.

2.7. "Solicitation" means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

2.8. "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

2.9. "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. CONTRACT TERM; RENEWAL; EXTENSION: The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: This Contract becomes effective on award and extends for a period of one (1) year(s).
Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal should be submitted to the Purchasing Division thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to three (3) successive one (1) year periods or multiple renewal periods of less than one year, provided that the multiple renewal periods do not exceed thirty-six (36) months in total. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

Delivery Order Limitations: In the event that this contract permits delivery orders, a delivery order may only be issued during the time this Contract is in effect. Any delivery order issued within one year of the expiration of this Contract shall be effective for one year from the date the delivery order is issued. No delivery order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within _____ days.

☐ **Fixed Period Contract with Renewals:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and part of the Contract more fully described in the attached specifications must be completed within _____ days.

Upon completion, the vendor agrees that maintenance, monitoring, or warranty services will be provided for one year thereafter with an additional _____ successive one year renewal periods or multiple renewal periods of less than one year provided that the multiple renewal periods do not exceed _____ months in total. Automatic renewal of this Contract is prohibited.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Award Document until all of the goods contracted for have been delivered, but in no event will this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. NOTICE TO PROCEED: Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Award Document will be considered notice to proceed.

5. QUANTITIES: The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☑ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☐ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☐ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. EMERGENCY PURCHASES: The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

7. REQUIRED DOCUMENTS: All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☐ **BID BOND (Construction Only):** Pursuant to the requirements contained in W. Va. Code § 5-22-1(c), All Vendors submitting a bid on a construction project shall furnish a valid bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of _____. The performance bond must be received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be delivered to the Purchasing Division prior to Contract award.
In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☐ **INSURANCE:** The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:

☐ **Commercial General Liability Insurance:** In the amount of _____ _____ or more.

☐ **Builders Risk Insurance:** In an amount equal to 100% of the amount of the Contract.

☐

☐

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

☐ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

☐

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

8. WORKERS' COMPENSATION INSURANCE: The apparent successful Vendor shall comply with laws relating to workers compensation, shall maintain workers' compensation insurance when required, and shall furnish proof of workers' compensation insurance upon request.

9. LITIGATION BOND: The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or $5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.

10. LIQUIDATED DAMAGES: Vendor shall pay liquidated damages in the amount of n/a for n/a. This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

11. ACCEPTANCE: Vendor's signature on its bid, or on the certification and signature page, constitutes an offer to the State that cannot be unilaterally withdrawn, signifies that the product or service proposed by vendor meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise indicated, and signifies acceptance of the terms and conditions contained in the Solicitation unless otherwise indicated.

12. PRICING: The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.

13. PAYMENT: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears.

14. PURCHASING CARD ACCEPTANCE: The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.

☐ Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

15. TAXES: The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

16. ADDITIONAL FEES: Vendor is not permitted to charge additional fees or assess additional charges that were not either expressly provided for in the solicitation published by the State of West Virginia or included in the unit price or lump sum bid amount that Vendor is required by the solicitation to provide. Including such fees or charges as notes to the solicitation may result in rejection of vendor's bid. Requesting such fees or charges be paid after the contract has been awarded may result in cancellation of the contract.

17. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

18. CANCELLATION: The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may also cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-6.1.e.

19. TIME: Time is of the essence with regard to all matters of time and performance in this Contract.

20. APPLICABLE LAW: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

21. COMPLIANCE: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendor acknowledges that it has reviewed, understands, and will comply with all applicable laws, regulations, and ordinances.

22. ARBITRATION: Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

23. MODIFICATIONS: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any change to existing contracts that adds work or changes contract cost, and were not included in the original contract, must be approved by the Purchasing Division and the Attorney General's Office (as to form) prior to the implementation of the change or commencement of work affected by the change.

24. WAIVER: The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

25. SUBSEQUENT FORMS: The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

26. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

27. WARRANTY: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

28. STATE EMPLOYEES: State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

29. BANKRUPTCY: In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

30. PRIVACY, SECURITY, AND CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

31. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

32. LICENSING: In accordance with West Virginia Code of State Rules § 148-1-6.1.e, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

33. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Award Document from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to Vendor.

34. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid or offer was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services; (2) that its bid or offer is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this Solicitation in its entirety; understands the requirements, terms and conditions, and other information contained herein.

Vendor's signature on its bid or offer also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency. The individual signing this bid or offer on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or offer or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

35. VENDOR RELATIONSHIP: The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting, supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, etc. and the filing of all necessary documents, forms, and returns pertinent to all of the foregoing.

Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

36. INDEMNIFICATION: The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

37. PURCHASING AFFIDAVIT: In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of $1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

38. ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE: This Contract may be utilized by other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). Any extension of this Contract to the aforementioned Other Government Entities must be on the same prices, terms, and conditions as those offered and agreed to in this Contract, provided that such extension is in compliance with the applicable laws, rules, and ordinances of the Other Government Entity. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

39. CONFLICT OF INTEREST: Vendor, its officers or members or employees, shall not presently have or acquire an interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

40. REPORTS: Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☐ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

41. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision. The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

42. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.
b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:
c. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or
d. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

43. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products. This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

Dana M. Conde

(Name, Title)
Dana M Conde / Contract Manager

(Printed Name and Title)
15175 Innovation Drive, San Diego, CA 92128

(Address)
888.635.5840 X 276 / 858.635.5843

(Phone Number) / (Fax Number)
dconde@phamatech.com

(email address)

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Phamatech, Inc.

(Company)

Dana M. Conde

(Authorized Signature) (Representative Name, Title)

Dana M Conde / Contract Manager

(Printed Name and Title of Authorized Representative)

10-14-16

(Date)

888.635.5840 X 276 / 858.635.5843

(Phone Number) (Fax Number)

Qualifications & Experience:

MISSION - PHAMATECH's mission and commitment is to provide a solid turnkey drug testing program that is legally defensible in court, comply with court ordered drug testing requirements, and work with Juvenile and Adult Probation in assisting to monitor drug usage. PHAMATECH's drug testing program will parallel with the COUNTY's goal in providing all services necessary to perform a cost effective and timely drug testing program. PHAMATECH concurs and understands that vendor compliance is of the utmost importance because delayed and inaccurate drug test results may adversely affect conditions of incarceration or probation and PHAMATECH fully supports the COUNTY's mission of building a safer community through rehabilitation.

HISTORY: PHAMATECH is a leading expert in providing DRUG AND SUBSTANCE TESTING SERVICES. PHAMATECH was founded in 1991 by a small group of dedicated scientists and business executives. Combining clinical experience, technical expertise and sound business strategies, we have grown steadily over the years to become a major provider of rapid medical diagnostic devices for home healthcare and clinical settings worldwide. In addition, PHAMATECH is a SAMHSA Certified Laboratory, PHAMATECH is also certified by CLIA and CAP - FUDT. Currently, PHAMATECH performs laboratory-based drug of abuse testing for more than 100,000 specimens per month. PHAMATECH has the capacity, equipment and resources to accommodate testing for more than 200,000 specimens per month. The estimated amount of tests and services anticipated for this contract is understood and acknowledged and is well within our capacity. Relying on sophisticated, a state-of-the-art technology, PHAMATECH provides valuable, reliable results at truly affordable prices.

PHAMATECH has deep knowledge in providing clinical and forensic drug testing services to numerous corporations, third party administrators, and professional health clinics, federal, state, county and local governments all over the United States since 2004. In 1998, PHAMATECH revolutionized drug testing with the announcement that we received FDA-clearance on the United States first over-the-counter drug test. PHAMATECH is the only company in the United States that is federally licensed by the Substance Abuse and Mental Health Services Administration, (SAMHSA), with its own manufacturing facility of medical diagnostic screening devices (drug test kits, pregnancy, ovulation, etc.).

SIMILAR SERVICES PROVIDED SINCE 2004: Our drug testing services include random donor selection, urine specimen collection and storage, breath alcohol testing, courier services, laboratory analysis with or without expert witness testimony, Medical Review Officer (MRO) services and statistical reporting. PHAMATECH specializes in high volume screening and confirmation testing.

Phamatech has over 25 years of experience in helping employers and agencies design and manage their testing programs, monitoring their professionals, making their employees more productive and, reducing operating expenses and risks. All our programs are in accordance with requirements of the governing body and or with federal, state, and municipal regulations. PHAMATECH staff are experts on compliance and monitoring issues and we help our clients become experts, too. We pass on our expertise by offering legal services, expert consultation, and training, in addition to our substance abuse testing.

CUSTOMER MAKEUP: Since our founding, PHAMATECH has provided drug and alcohol testing services continuously evolving to meet the needs of our diverse client base, which includes Fortune 500 companies, law enforcement agencies, state and municipal governments both domestically and internationally. Today, we offer a full range of services related to managing substance abuse testing programs.

EXPERIENCE: PHAMATECH has and is currently providing drug testing products and services to a large number of CORRECTIONAL INSTITUTIONS who are monitoring incarcerated individuals, persons on probation or parole as well as court ordered monitoring through Drug Courts. These institutions Include but are not limited to the following:

- **United States Federal Bureau of Prisons, Nationwide (2007 – current)**
- **Broward County Sheriff's Office, Florida, (2008 – current)**
- **First Judicial District of Pennsylvania, (2010 –2015)**
- **Commonwealth of Kentucky, DOC, Justice and Public Safety Cabinet (2009 – 2014)**
- **Maryland, Department of Public Safety and Corrections (2010 – current)**
- **County of Fresno, CA Department of Probation & Parole (2010 – current)**
- **Contra Costa County, California – Children and Family Services (2015-current)**
- **El Paso Probation, Texas – (2012-current)**
- **State of New Jersey Probation and Parole – (2015-current)**

PHAMATECH believes teamwork is the key to success. Providing unparalleled service and support to our distributors and partners, we achieve and maintain loyal alliances unmatched in the industry. Our objective is to be the best in the industry.

LICENSES & CERTIFICATIONS: Please see end of this SECTION for copies of Licenses and Certifications

Substance Abuse and Mental Health Services Administration (SAMHSA) – SAMHSA certification allows PHAMATECH to perform workplace testing under the US Federal Government regulations, US Department of Transportation (DOT), and other federal agencies and employees. SAMHSA certification involves detailed procedures, onsite inspection, and proficiency testing.

Forensic Urine Drug Testing Laboratory certified by the College of American Pathologists (CAP – FUDT) – PHAMATECH subscribes to and participates in the College of American Pathologists (CAP) proficiency testing programs. The Certification of Participation in surveys proficiency testing results is reported to California and CLIA.

Clinical Laboratory Improvement Act – The Centers for Medicare and Medical Services (CMS) US Department of Health and Human Services enforces the US Federal Clinical Laboratories Improvement Act (CLIA) regulations. PHAMATECH has a certification of Compliance and a Certificate of Registration as a laboratory to analyze human specimens. Certification includes an on-site inspection for compliance with the CLIA regulations, personnel and Laboratory regulations, and ongoing proficiency testing (PT).

US Departments of Justice Drug Enforcement Administration Controlled Substance Registration Certification – PHAMATECH, Inc. is certified by the US DEA for possession of controlled substances by and within the laboratory for all scheduled drugs.

After meeting stringent criteria, Phamatech also holds many state licenses that enable our facility to provide laboratory drug testing services; these states include FLORIDA, TEXAS, OKLAHOMA, PENNSYLVANIA, COLORADO, HAWAII AND MARYLAND to name a few.

Certificate of Accreditation

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

The Substance Abuse and Mental Health Services Administration

certifies that

Phamatech, Inc.

San Diego, CA

NLCP Laboratory Number: 0437

has successfully completed the requirements
of the National Laboratory Certification Program for urine laboratories in accordance
with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Effective June 7, 2007

Pamela S. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Frances M. Harding
Director
Center for Substance Abuse Prevention

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
PHAMATECH, INC
15175 INNOVATION DR
SAN DIEGO, CA 92128-3401

CLIA ID NUMBER
05D1078844

EFFECTIVE DATE
10/09/2016

LABORATORY DIRECTOR
NOEMI AMITINA MD DIRECTOR

EXPIRATION DATE
10/08/2018

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

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

308 Certs2_091316

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DEVICE MANUFACTURING LICENSE

Phamatech Inc.
15175 Innovation Drive
San Diego, CA 92128

LICENSE NUMBER: 75904
EXPIRATION DATE: 3/27/2018

The person named herein is licensed to manufacture devices through the expiration date of this license. This annual license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 3/17/2016

PHAMAT1 OP ID: AL

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 06/09/2016

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Wateridge Insurance Services 10717 Sorrento Valley Rd. San Diego, CA 92121 George J. Sports	CONTACT NAME: George J. Sports PHONE (A/C, No, Ext): 858-452-2200 FAX (A/C, No): 858-452-6004 E-MAIL ADDRESS:
INSURED Phamatech, Inc. 15175 Innovation Drive San Diego, CA 92128	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Hartford Casualty Insurance Co — 29424 INSURER B : Twin City Fire Insurance Co. — 29459 INSURER C : Medmarc Casualty Ins. Company INSURER D : Evanston Insurance Company — 35378 INSURER E : Axis Insurance Company — 37273 INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			72UUNTR9588	06/01/2016	06/01/2017	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
C	X PRODUCTS(1)			16CA380065	06/01/2016	06/01/2017	MED EXP (Any one person)	$ 10,000
	CLAIMSMADE/10KSIR						PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO			72UUNTR9588	06/01/2016	06/01/2017	BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
	X Comp/Coll X $1,000 Ded							$
A	UMBRELLA LIAB X OCCUR			72RHUTR9385	06/01/2016	06/01/2017	EACH OCCURRENCE	$ 10,000,000
	EXCESS LIAB / CLAIMS-MADE						AGGREGATE	$ 10,000,000
	DED X RETENTION $ 10,000							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			72WEFO4109	03/15/2016	03/15/2017	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
D	Professional Liab			SM912783	03/17/2016	03/17/2017	Claim/Agg	$1M/$3M
E	Cyber Liability			ELN793059012016	03/28/2016	03/28/2017	Claim/Agg	2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

PROOFOF

PROOF OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

George J Sports

REQUEST FOR QUOTATION CRFQ CORI700000001

COR238214 Drug Test Kits and Supplies

Note: Any reference to THE AGENCY, or AGENCY refers to the *West Virginia Division of Corrections and its respective agents or departments included in this RFQ/project/RFQ.*

SPECIFICATIONS

1. PURPOSE AND SCOPE: **Phamatech understands the purpose and scope as indicated. As the U.S. manufacturer of its own devices, Phamatech has the capability and infrastructure to provide all necessary materials, on-site devices in requested formats and drugs of abuse combinations. Phamatech is also a SAMHSA certified lab and can provide laboratory GC/MS confirmation testing. The AGENCY will not need to source any of this project out to any other vendor. Phamatech understands the quantity needs of the AGENCY and believes we are the best fit to provide the requested services.**

PHAMATECH will provide each site listed in the RFQ (currently 32 sites) with QuickScreen Cup on-site testing devices (these are the same devices currently being used nationwide by the Federal Bureau of Prisons) and Oral Cube salvia tests for both inmate and employee testing. In addition, PHAMATECH will provide all supplies necessary to maintain chain of custody requirements such as: chain of custody forms, security seals, packing and shipping materials (lab packs), collection containers/bottles and labels. Shipping will be included in the pricing cost.

Phamatech understands that there may be new facilities added by the AGENCY during the term of this agreement and will provide all services/supplies to additional facilities at the same contract price.

2. DEFINITIONS: **Phamatech understands the definitions being used in this RFQ.**

3. QUALIFICATIONS: **Since 2007, Phamatech provided U.S. manufactured QuickScreen Cups (on-site drugs testing devices) to the U.S. Bureau of Prisons servicing over 180 locations and over 250,000 inmates nationwide. At this time, Phamatech in supplying approximately 20,000 units of on-site devices per month and providing SAMHSA certified laboratory confirmations on over 1,500 specimen samples per month.**

In addition, since June 2016 Phamatech has provided West Virginia Division of Juvenile Services with SAMHSA certified laboratory screening and confirmation services on approximately 300 specimens per month.

For further detail of past experience, please see QUALIFICATIONS & EXPERIENCE – SECTION 2 and REFERENCES – SECTION 4.

3.2 Please see SECTION 4 – REFERENCES

3.3 Please see SECTION 5 – KEY PERSONNEL

3.4 Please see SECTION 2 – QUALIFICATIONS & EXPERIENCE for Licenses and Certifications.

Phamatech would like to propose the U.S. manufactured QuickScreen™ Integrated Cup with built-in temperature and adulteration strip for the AGENCY'S on-site urine-based drug testing needs – please see the end of this section for Features and Benefits of this product as well as a directional insert for complete instructions for use.

Phamatech would like to propose the Oral Cube One Step Drug Test for the AGENCY'S on-site saliva-based (oral) drug testing needs – please see the end of this section for Features and Benefits of this product as well as a directional insert for complete instructions for use.

4. GENERAL REQUIREMENTS:

4.1 Contract Items and Mandatory Requirements: Vendor shall provide Agency with the Contract Items listed below on an open-end and continuing basis. Contract Items must meet or exceed the mandatory requirements as shown below.

4.1.1 Inmate and Parolee drug testing kits

4.1.1.1 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.1.1.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.1.1.3 Customizable All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 13 panel or equivalent

Phamatech has read and can meet or exceed the requirements for the All-Inclusive On-Site Urine Screening Devices and would like to propose the QuickSreen Drug Test 6-10-13 panel cups with built in temperature strip for this purpose.

As the manufacturer of product, Phamatech will be able to easily provide the on-site devices with the required combinations of drugs of abuse and desired cut-off levels.

QUICKSCREEN™ Cup - Please see Features and Benefits Flyer along with Directional Insert at the end of this section.

4.1.1.4 Panel Saliva Test for oral fluids 6 panel

Phamatech has read and can meet or exceed the requirements for the Panel Saliva Test for oral fluids 6 panel and would like to propose the Oral Cube Oral One Step Drug Test for this purpose.

4.1.1.4.12 **Our SAMHSA certified laboratory can provide the requested fast turnaround time from receipt of specimen for result reporting – maximum of 48hours for negative result reporting and 72 hours for positive confirmation reporting.**

Oral Cube Drug Screen - Please see Features and Benefits Flyer along with Directional Insert at the end of this section.

4.2 Employment/Employee drug testing kits

4.2.1. All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.2.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.2.3 Customizable All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 13 panel or equivalent

Phamatech has read and can meet or exceed the requirements for the All-Inclusive On-Site Urine Screening Devices and would like to propose the QuickSreen Drug Test 6-10-13 panel cups with built in temperature strip for this purpose.

As the manufacturer of product, Phamatech will be able to provide the on-site devices with the required combinations of drugs of abuse and desired cut-off levels.

QUICKSCREEN™ Cup - Please see Features and Benefits Flyer along with Directional Insert at the end of this section.

4.2.4 Panel Saliva Test for oral fluids 6 panel

Phamatech has read and can meet or exceed the requirements for the Panel Saliva Test for oral fluids 6 panel and would like to propose the Oral Cube Oral Fluid Drug Screen Device for this purpose. Our SAMHSA certified laboratory will provide the requested fast turnaround time from receipt of specimen for result reporting – maximum of 48hours for negative result reporting and 72 hours for positive confirmation reporting.

Oral Cube Drug Screen- Please see Features and Benefits Flyer along with Directional Insert at the end of this section.

Phamatech has read, understands and can meet or exceed all requirements in SECTION 4. GENERAL REQUIREMENTS in its entirety; however, we would like to expand on the following HIGHLIGHTS:

4.3 TRAINING: **At no additional cost, PHAMATECH will provide initial (and additional when necessary) in-person training course(s) to the AGENCY, as requested, to ensure effective drug screening practices are consistent with the manufacturer recommendations. PHAMATECH will also provide a certification "train the trainers" program as requested.**

According to AGENCY needs, the in-person training sessions could include any combination of the following areas or include but not be limited to following:

- Different types of drug screening available; urine, saliva, hair, etc. with advantages and disadvantages of each
- Drug screening versus drug confirmation (EMIT, GC/MS, LC/MS/MS)
- Drug of abuse trends; locally and nationally
- How to spot the drug abuser
- Drug chart handouts
- Drug cross reaction sheet handout
- Minimum and maximum detection periods for drug of abuse
- Adulterants/Substitution in urine and saliva
- Types of different adulterants purchase over the internet. Urine substitution using the "whizzinator" as an example.
- Explain what a chain of custody form is and how to complete chain of custody form that is defensible in a court of law (samples provided)
- How to perform a specimen collection; either observed or unobserved
- Live demonstration of using specimen collection kits (samples provided)
- How to read drug test results with interpretation
- THC creatinine ration

4.4 Validity Testing: All QuickScreen cups will have a built in specimen validity testing strip for at least three of the following adulterants: Oxidants, Specific Gravity, pH, Nitrite, Glutaraldehyde, and Creatinine.

4.5.17 Confirmation Testing: Phamatech will confirm necessary tests by GC/MS Gas Chromatography Mass Spectrometry. Our pricing is all inclusive and will include all charges/costs necessary to provide results. Furthermore, Inmate and Parolee Offender confirmation testing will be done to test to LOD and Civilian Pre-employment and Staff "For Cause" Drug Testing will be conducted in compliance with the Guidelines for Federal Workplace Drug Testing Programs.

4.5.18 Alcohol Testing: Phamatech will test and report EtS, in conjunction with EtG, to confirm recent ethanol ingestion; cutoff level 100 ng/mL.

4.6 Phamatech will secure the services of an MRO that is a licensed physician who will provide services on an as needed basis as required, but will work completely independent from Phamatech and there will be no conflict of interest.

For court appearances PHAMATECH offers: in person expert witness, teleconferencing, and pretrial litigation packages to defend any legally challenged drug test results. PHAMATECH will provide to the Agency, top notch *in person* expert witness testimony upon request. Additionally, PHAMATECH will provide, at no cost to The Agency, testimony by telephone, video conferencing, or through sworn affidavit. At all times the following expert witnesses will be available to the Agency: Dr. Thomas Aucoin (VP of laboratory) and Justin Pham (Laboratory Manager). PHAMATECH currently and regularly provides expert witness testimony services by in house personnel for several of our current contractual clients; unlike our competitors that hire outside help to provide expert witness testimony. Our *in house expert witnesses* will defend the verity

of PHAMATECH's laboratory procedures and certified accurate drug test results for any court challenged drug test. To date PHAMATECH has not lost one case in defending the integrity of any confirmed positive drug test results. PHAMATECH also offers comprehensive litigation packages that are rarely challenged in a court of law.

5. Contract Award: Items 5.1 through 5.2.2 understood and agreed.

6. Performance: understood and agreed.

7. Ordering and Payment: Items 7.1 through 7.2 understood and agreed.

On a monthly basis, PHAMATECH will submit hard copies of all drug test results presented in a comprehensive report form that includes the following information: Donor name and DOB, case number, agency name/location, collection date, testing date, received date, drug panel tested, drug cut-offs, negative or positive result, confirmation drug levels, testing method, adulteration findings, and certifying scientist comments where applicable.

8. Travel: understood and agreed.

9. Facilities Access: Items 9.1 through 9.5 not applicable.

10. Delivery and Return: Items 10.1 through 10.5 understood and agreed.

11. Vendor Default: Items 11.1 through 11.2.3 understood and agreed.

12. Miscellaneous: Phamatech will not make any product substitution unless a contract modification is first approved by the AGENCY. As the product manufacturer, Phamatech will carry sufficient inventory to supply the contract items requested under this contract.

12.3 Reports: PHAMATECH will provide and maintain a secured web based system for the Agency and other authorized COUNTY personnel to obtain drug test results 24/7. Negative drug test results will be available within 12 to 24 hours from the time the specimen arrives at our laboratory. Positive drug test results (GC/MS confirmations) for both alcohol and/or drugs will be available 36 to 48 hours also from the time the specimen arrives at the laboratory. All results are transmitted via secured, HIPAA compliant, web-based application system. In the event of an outage to the web-based application management system, a secured fax copy shall be submitted to the approved sites to DCFS dedicated fax telephone numbers and/or delivery via courier service as a temporary measure to get the results to the Agency.

PHAMATECH utilizes the Laboratory Information Management System (LIMS) for faxed results (automated fax server). All negative results are automatically released (within 12 to 24 hours) and all confirmation results are released after a quality control review and acceptance by certifying scientist (within 24 to 48 hours). PHAMATECH has double firewall levels protecting all client data from electronic hackers. PHAMATECH abides by all SAMHSA guidelines and requires that physical access to the testing area must be secured. Only authorized laboratory personnel are allowed in the testing area with their own electronic security code.

PHAMATECH meets or exceeds all SAMHSA *and* CAP-FUDT guidelines for client confidentiality and protection of vital sensitive data.

The Agency has the option to view all drug test results 24/7, 365 via secure internet service. If The Agency decides to use this option; all authorized Agency staff will be assigned a user name and password by facility. Online services are provided by PHAMATECH's via 256 bit SSL encryption, similar to what the banking industry currently uses. All drug test results are immediately posted to the website and are instantaneously available to The Agency.

PHAMATECH's comprehensive monthly statistical reports will include the following:

- **Number of actual tests performed for the current and prior months for all participants with percentage breakdown for both negative and positive drug/alcohol test results.**
- **Number of actual tests performed for- (alcohol only) and (drug and alcohol).**
- **Monthly reports of each test performed by site in alphabetical order.**
- **Monthly reports summarizing each type of test performed.**
- **Annual report in alphabetical order listing total number of each test type by site**
- **Assign an account manager to visit The Agency to personally discuss any additional report needs.**

12.4 Contract Manager/KEY ACCOUNT MANAGER:

Contract Manager: Dana Conde 888.635.5840 X 276 dconde@phamatech.com

Key Account Manager if awarded: Krystina Blas

Telephone Number: 888.635.5840 X 290

Fax Number: 858.635.5843

Email Address: kblas@phamatech.com

PHAMATECH QUICKSCREEN® CUP FEATURES AND BENEFITS

FEATURES	BENEFITS
1. Built-in Timing Device	- Results ready indicator
2. Two-wall design	- Prevents donor tampering
3. Temperature strip insulated on the internal wall	- Prevents donor tampering
4. Adulteration strip insulated on the internal wall	- Detects donor tampering – tests for Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity Bleach, Pyridinium Chlorochromate
4. Waterproof, screen-printed label	- No condensation or slippery cup
5. Room to individually mark donor I.D. and initials	- For easy tracking and monitoring
6. No moving parts, and no tipping, no shaking, and no valves or plungers to operate in order to activate the test.	- Simple, effective, saves time, and easy to use.
7. Inner cup & components are not removable	- Cup cannot be tampered with
8. Made in the U.S.A.	- Our product is American made and upholds the highest standards in accuracy. Overseas product, namely China, does not uphold the same strict standards of Quality control and accuracy.
9. Manufactured by Phamatech	- We are the manufacturer and supplier. This means that you are buying product directly from the manufacturer and not a repackager /relabeler.
10. FDA Cleared	- Product is cleared by the Food and Drug Administration.

Phamatech, Inc. / 15175 Innovation Drive / San Diego, CA 92121 USA
Phone: +1 858 643 5555 Fax: +1 858 635 5843
www.phamatech.com

PHAMATECH
Laboratories & Diagnostics

QuickScreen™ Cup Multi Drug Screening Test

With "Timer + Adulteration" / Catalog # 930

8ZA-25 /

Test Instructions

Intended Use

The QuickScreen™ Cup Multi Drug Screening Test is a rapid, self-timed, qualitative immunoassay for the detection of drugs of abuse in urine. The cutoff concentrations for the test are Barbiturates at 200 ng/mL, Benzodiazepines at 200 ng/mL, Methadone at 300 ng/mL, Amphetamine at 1000 ng/mL, Methamphetamine at 500 ng/mL, Cocaine metabolite (Benzoylecgonine) at 300 ng/mL, THC metabolite (THCA) at 50 ng/mL, Opiates at 300 ng/mL, Oxycodone at 100 ng/mL, and PCP at 25 ng/mL. This assay is intended for professional use.

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

Summary & Explanation of the Test

Barbiturates (BAR) are a large class of abused pharmaceuticals that are anxiolytic, sedative-/hypnotic, anticonvulsant and anesthetic drugs. As CNS depressants, barbiturates affect excitatory and inhibitory synaptic neurotransmission. Ultra short-acting barbiturates used for anesthesia, such as Pentobarbital, depress excitatory neuronal transmission to a greater extent than anti-convulsant barbiturates such as Phenobarbital. Barbiturates are rapidly and completely absorbed with nearly 100% bioavailability. Short-acting barbiturates are primarily excreted in urine as metabolites, while long-acting barbiturates are primarily excreted unchanged. Ratios of drugs to metabolites excreted vary, dependent upon duration of action.

Benzodiazepines (BZD) are another large class of abused pharmaceuticals that are sedative-/hypnotics and anti-anxiety drugs that produce calming effects; thus are often prescribed as tranquilizers. Frequently abused Benzodiazepines include Alprazolam (Xanax®), Diazepam (Valium®), Lorazepam (Ativan®), Triazolam (Halcion®), Chlordiazepoxide (Librium®), Flurazepam (Dalmane®) and Temazepam (Restoril®). A trend has been observed in recent years of abuse of these legitimate pharmaceuticals in conjunction with illicit controlled substances such as methadone and heroin. Benzodiazepines may be detected for up to 2 weeks in urine.

Methadone (MTD) is a long-acting synthetic opiate agonist clinically available in the U.S. since 1947. Acting on the central nervous and cardiovascular systems, producing respiratory and circulatory depression, Methadone also produces meiosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions.

Amphetamine (AMP), Methamphetamine (MET), ***MDA and MDMA*** and their metabolites are central nervous system stimulants whose pharmacological properties include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well being. Large doses and extended usage can result in higher tolerance levels and physiological dependency. Both *d* and *l* forms of Amphetamine and the (+) form of Methamphetamine are controlled substances.

Cocaine (COC) is an alkaloid present in coca leaves (*Erythroxine coca*) whose pharmacological properties include alertness, wakefulness, increased energy and an overall feeling of euphoria. Cocaine has been used medicinally as a local anesthetic; however, its addictive properties have minimized its modern value as an anesthetic. Elimination of Cocaine is predominantly controlled by its biotransformation to Benzoylecgonine. Very low concentrations of Cocaine may be detected in urine during the initial several hours, but Benzoylecgonine persists in urine at detectable concentrations for 48 hours.

Δ^9-Tetrahydrocannabinol (THC) is generally accepted as the principle active component in marijuana and hashish, although other cannabinoids contribute to their physiological activity. THC is rapidly absorbed by inhalation and through the gastrointestinal tract, and is almost completely metabolized. Its predominant metabolite, 11-Nor-Δ^9-Tetrahydrocannabinol-9-Carboxylic Acid, or **THCA**, is found in the plasma, feces and urine along with other compounds. Very low concentrations of THC may be detected in urine during the initial several hours after smoking, but THCA persists in urine at a detectable concentration for many days.

Opiates (OPI) are addictive, pain-relieving narcotic drugs derived from the opium poppy (*Papaver somniferum*). An opiate is any natural or synthetic drug, derived from this plant, that has morphine-like pharmacological actions. Natural opiates include Morphine, Codeine and Thebaine. Synthetic opiates include Heroin, Hydrocodone and Levorphanol.

Oxycodone (OXY) is an effective analgesic for mild to moderate pain control, chronic pain syndromes, and for the treatment of terminal cancer pain. Five mg of Oxycodone is equivalent to 30 mg of codeine when administered orally. Oxycodone and morphine are equipotent for pain control in the normal population. Oxycodone is considered to be similar to morphine, in all respects, including its abuse & dependence liabilities.

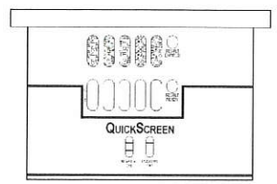
Phencyclidine, also known as **PCP** or "angel dust," is used primarily as a recreational drug for its hallucinogenic effects. Commonly taken orally, by inhalation, by sufflation or intravenously, it is well-absorbed by all routes of administration, concentrating fastest in fatty tissues and the brain. Unchanged PCP is excreted in the urine in moderate amounts (10% of the dose). Terminal half-life varies considerably, ranging from 8 to 55 hours, though averaging 18. Effects of this drug are unpredictable and variable. Users may exhibit signs of euphoria, anxiety, relaxation, increased strength, time and space distortions, panic and hallucination.

Urine based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of immunoassays have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large number of negative specimens and focus on the smaller number of initially positive samples.

Principle of the Procedure

The QuickScreen™ Cup Multi-Drug Screening Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample compete with drug / protein conjugate immobilized on a porous membrane for a limited number of antibody / dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify drugs of abuse in urine with a high degree of confidence. The test device also contains a self-timer that indicates when test results are ready to be interpreted.

In the procedure, a fresh urine sample is collected directly into the cup. The urine is absorbed into each test panel by capillary action, mixes with the antibody / dye conjugate, and flows across the pre-coated membrane.



When sample drug levels are 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 Band that, *regardless of its intensity*, indicates a negative result.

Reagents & Materials Supplied

1. 25 Self-Timed Test Devices (Cat. # 9308ZA); separate panels for each target drug contain:
   a. Monoclonal anti-drug antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
   b. Drug derivative / protein conjugate immobilized as a line in the Test Region (**T**)
   c. Goat anti-mouse antibody immobilized as a line in the Control Region (**C**)
2. Directional Insert (Cat. # 9308ZA-DI)
3. Adulteration Directional Insert (Cat. # 9093)
4. (*Optional*) Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –
5. (*Optional*) Split Specimen Collection Kit (Cat. # 9502 or equivalent)

Warnings & Precautions

1. FOR *IN VITRO* DIAGNOSTIC USE ONLY.
2. For Professional use only.
3. Urine samples have the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
4. Do not use this kit beyond its expiration date.
5. This method is established using urine only. No other fluid has been evaluated.
6. Do not reuse the Test Device.

Storage & Handling Requirements

Store at room temperature (15 – 28 °C). Do not freeze. Refer to expiration date for stability.

Sample Collection & Preparation

A fresh urine sample should be collected in the cup device immediately prior to testing. The urine should be collected to the recommended volume indicated by the "FILL TO HERE" mark on the outside of the cup.

Samples may be tested immediately or stored for up to 48 hours at 2 – 8 °C. For longer storage, freeze samples at –20 °C or below.

Assay Procedure

Preparation

1. Confirm that the cup device is at room temperature (15 – 28 °C) before testing.
2. Do not open the foil pouch until you are ready to perform the test.

Testing

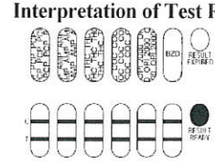
1. Open the pouch at the tear notch, remove the cap from the test device and discard the desiccant packets.
2. Have the donor collect his or her urine specimen in the cup to the recommended volume. Make sure that the urine level is at least at the "**FILL TO HERE**" mark printed on the front of the cup. Replace the cap and check the temperature strip to ensure that the temperature of the specimen is between 90° and 100° F.
3. Read the test results when indicated (see When to Read Test Results Using the "Timer.")

When to Read Test Results Using the "Timer"

When the "RESULT READY" window is completely filled with red color, or is almost completely covered with red color that reaches the top of the window, the test results are ready to interpret.

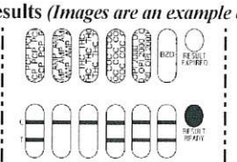
When red color becomes clearly visible at the bottom of the "RESULT EXPIRED" window, test results should no longer be interpreted and should not be considered as conclusive. Test results stable for 60 minutes.

Interpretation of Test Results *(Images are an example of this type of test)*



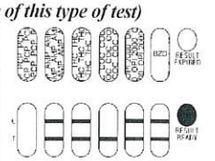
Negative Test Results for all drugs tested

Negative – A negative result is indicated when two (**2**) colored bands appear, one in the Control Region (**C**) and one in the Test Region (**T**), ***before*** any red color appears at the bottom of the "RESULT EXPIRED" window. This result indicates that the target drug is not present or its concentration is below the detection sensitivity of the test panel. Some negative results may appear in as little as 1 minute, and can be safely interpreted as soon as 2 colored bands are visible.



Positive Test Results for Amphetamine & THC

Positive – A positive result is indicated when only one (**1**) colored band appears in the Control Region (**C**) and no band appears in the Test Region (**T**), ***after*** a red spot appears in the "RESULT READY" window. This result indicates that the target drug concentration is at or above the detection sensitivity of the panel. More than one panel may be positive. Potentially positive results can only be reported when a red spot appears in the timer's "RESULT READY" window, and ***before*** any red color appears at the bottom of the timer's "RESULT EXPIRED" window.



Invalid Test Results for PCP & Cocaine

Invalid – A test must be considered invalid if, ***after*** a red spot appears in the "RESULT READY" window, no bands appear or if a band appears in the Test Region without a Control Band. The presence of a Control Band is necessary to confirm assay performance.

Quality Control

An internal procedural control line has been incorporated into the test device to help ensure proper kit performance and reliability. However, the use of external controls is recommended. Positive and negative controls within 25% of the cutoff concentration should produce the expected results. For positive controls, only one (**1**) colored band will appear in the Control Region (**C**), and no band will appear in the Test Region (**T**). For negative controls, two (**2**) colored bands will appear, one in the Control Region (**C**) and one in the Test Region (**T**).

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Limitations of the Procedure

1. It is possible that substances and factors not described in this directional insert may interfere with the test, causing false results (*e.g.* technical or procedural error).
2. This test has been developed for testing urine samples only. Its performance using other specimens has not been substantiated.
3. Adulterated urine samples may produce erroneous results.
4. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, a new sample must be obtained.
5. All preliminary positive results must be confirmed by another method. Gas chromatography/mass spectrometry (GC/MS) is the method of choice to confirm the presence and concentration of a drug in urine.
6. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of target drugs or the level of intoxication.
7. Because QuickScreen™ is a competitive assay no prozone effect is present.
8. Occasionally, samples containing target drugs below the target drug's cutoff sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity - The sensitivity of the Phamatech QuickScreen™ was evaluated on urine samples and compared with a commercially available immunoassay at the cutoff concentrations by two independent laboratories. The results, comparing Phamatech QuickScreen™ to GC/MS are reported as % (agreement) in the following table.

Specificity - The specificity of the Phamatech QuickScreen™ was evaluated on urine samples and compared with a commercially available immunoassay at the cutoff concentrations by two independent laboratories. The results, comparing Phamatech QuickScreen™ to GC/MS are reported as % (agreement) in the following table.

Accuracy – The accuracy of the Phamatech QuickScreen™ was evaluated on urine samples and compared with a commercially available immunoassay at the cutoff concentrations by two independent laboratories. The results, comparing Phamatech QuickScreen™ to GC/MS are reported as % (agreement) in the following table:

EQUIVALENCY DATA

Target Drug	AMP	BAR	BZD	COC	MET	MTD	OPI	OXY	THC	PCP
***n* =**	**189**	**104**	**290**	**164**	**189**	**109**	**176**	**192**	**143**	**167**
Sensitivity	97.6	>99	>99	>99	95.9	97.5[3]	>99	>99	>99	99
Specificity	>99	>99	95.4[1]	95.9[2]	>99	>99	>99	>99	>99	99
Accuracy	99.4	>99	97.9	98.1	97.3	98.1	>99	>99	>98	>99

[1]Six samples at concentrations 3.5 to 9.2% below cutoff gave positive results in the Benzodiazepines Clinical study at site 2

[2]Five discrepant results were observed in the Cocaine Clinical Study. The samples were from 3 to 10% below the assay cutoff concentration (271 to 293 ng/mL) and subsequently tested positive by GC/MS.

[3] 2 samples of 324 and 336 ng/mL (8% and 12% above cut-off, respectively) gave negative result in the MTD Clinical study.

Precision – Eight urine pools, ranging in concentration from 0 to 200% of cutoff, were assayed twice a day for 20 days. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were determined to be less than 2%.

Cross-Reactivity – The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen Pro Multi Drug Screening Test. The results, in µg/mL, are expressed as that amount of compound capable of giving a result equivalent to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates no cross-reactivity was observed when the compound was tested at 100 µg/mL to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates the compounds were tested to 100 µg/mL with no cross-reactivity observed.

Compound	BAR	BZD	MTD	AMP	MET	COC	THC	OPI	OXY	PCP
Amobarbital	0.15									
Aprobarbital	0.05									
Barbital • Butabarbital • Pentobarbital	0.025									
Butalbital	0.3									
Butethal	0.075									
5,5-Diallylbarbituric Acid	0.1									
Phenobarbital • Secobarbital	0.2									
(±)-Thiopental	9.5									
Alprazolam[A] • Clonazepam		0.5								
Bromazepam		0.6								
Chlordiazepoxide		0.3								
Desmethyldiazepam		0.75								
Diazepam • Flunitrazepam		0.4								
Flurazepam • Medazepam • Prazepam		1.0								
(±)-Lorazepam • Triazolam[B]		0.5								
Lormetazepam		0.4								
Nitrazepam • Oxazepam		0.2								
Temazepam		0.25								
(−)-α-Acetylmethadol (LAAM)			1							
(−)-α-Methadol			0.8							
(±)-Methadone			0.3							
d-Amphetamine				1						
dl-Amphetamine • 3-Hydroxytyramine				10						
l-Amphetamine • (R)-(+)-α-Phenylethylamine				100						
Mephentermine				100	10					
(±)-3,4-Methylenedioxyamphetamine (MDA)				4.5						
(±)-α-Phenylethylamine • β-Phenylethylamine				10						
Tyramine				12.5	62.5					
(−)-Deoxyephedrine					1					
Nylidrin					5					
(+)-Methamphetamine					0.5					
(±)-3,4-Methylenedioxymethamphetamine (MDMA)					3.5					
Benzoylecgonine • Cocaine						0.3				
Metoclopramide						25				
Procaine • Pyrilamine						100				
11-Hydroxy-Δ^9-THC[C]							1			
11-Nor-Δ^8-THC-9-Carboxylic Acid[C]							0.1			
11-Nor-Δ^9-THC-9-Carboxylic Acid[C]							0.05			
Δ^8-Tetrahydrocannabinol							100			
Δ^9-Tetrahydrocannabinol							0.05			
Codeine								0.3	[D]	
Heroin[B]								0.3		
Dextromethorphan								50	[D]	
Ethylmorphine[B]								0.35	[D]	
Hydrocodone								0.4		
Hydromorphone								0.4		
Nalorphine								0.5		
Morphine								0.3	0.3	
Morphine-3-β-D-Glucuronide								0.3	0.3	
Naloxone								0.4	0.4	
Naltrexone								5	5	
Normorphine[B]								10	10	
Oxycodone								0.6	0.1	
EDDP (Primary Methadone Metabolite)										25
Phencyclidine										0.025

[A] A blank space indicates that no cross-reactivity was observed when the compound was tested to 25 µg/mL.
[B] A blank space indicates that no cross-reactivity was observed when the compound was tested to 10 µg/mL.
[C] A blank space indicates that no cross-reactivity was observed when the compound was tested to 5 µg/mL.
[D] Level Not been Determined

Interfering Substances – The following compounds were spiked into normal human urine and tested for interference with the QuickScreen™ Pro Multi Drug Screening Test. The compounds were tested to 100 µg/mL, except as noted, with no interference observed.

Acetaminophen • Acetoacetic Acid • Acetone • *N*-Acetylprocainamide • Acetylsalicylic Acid (Aspirin) • Albumin • Alphenal • Amantadine • (+)-Amethopterin • Amikacin • *dl*-Aminoglutethimide • Aminopyrine • Amitriptyline • Amoxicillin • Ampicillin • Apomorphine • (−)-Arterenol • *l*-Ascorbic Acid (Vitamin C) • Aspartame • *d*-Aspartic Acid • *dl*-Aspartic Acid • *l*-Aspartic Acid • Atropine • Barbituric Acid • Benzoic Acid • Benzphetamine • Benztropine Methane Sulfonate • Bilirubin • Bromocriptine Mesylate • (+)-Brompheniramine • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalexin • Chloramphenicol • Chloroquine • (+)-Chlorpheniramine • (±)-Chlorpheniramine • Chlorpromazine • Chlorpropa-mide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonidine • (−)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • Desipramine • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Diphenylhydantoin • Disopyramide • Doxepin • Doxylamine • (+)-ψ-Ephedrine • (−)-ψ-Ephedrine • (+)-Ephedrine • (±)-Ephedrine • (−)-Ephedrine • (±)-Epinephrine • (−)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • Ethylenediaminetetraacetic Acid • EMDP (Secondary Methadone Metabolite) • Fenfluramine • Fenoprofen • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hexobarbital • Human Hemoglobin • Hydrochlorothiazide • *dl*-β-Hydroxybutyric Acid • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyindole-2-Carboxylic Acid • Hydroxyzine • Ibuprofen • Imipramine • Indole-3-Acetic Acid • Indole-3-Butyric Acid • Indomethacin • (+)-Isoproterenol • (±)-Isoproterenol • (−)-Isoproterenol • Doxsuprine • Kanamycin • Ketamine • Ketoprofen • Labetalol • Lidocaine • Lithium Carbonate • Melanin • Meperidine • Meprobamate • Mescaline • *dl*-Metanephrine • Methaqualone • (S)-6-Methoxy-α-Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl*-Alanine • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*l*-Alanine • Methylphenidate • Methyprylon • (±)-Metoprolol • Nafcillin • Naphazoline • α-Naphthaleneacetic Acid • β-Naphtha-leneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nicotinic Acid • Nifedipine • Nomifensine • Nordoxepin[D] • Norethindrone • Nortriptyline • Noscapine • Orphenadrine • Oxalic Acid • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Phenelzine • Pheniramine • Phenothiazine • Phentermine • Phenylacetone • *l*-Phenylalanine • Phenylbutazone • *trans*-2-Phenylcyclopropylamine • *l*-Phenylephrine • (±)-Phenylpropanolamine • Piroxicam • Potassium Chloride • Prednisolone • Primidone • Procainamide • Prochlorperazine • Promazine • Promethazine • (+)-Propoxyphene • 2-Propyl-pentanoic Acid • Protriptyline • Quinidine • Quinine • Ranitidine • Riboflavin • Salicylic Acid • (−)-Scopolamine • Sodium Chloride • Sulindac • Terbutaline • Tetracycline • Tetraethylthiuram Disulfide (Antabuse) • Tetrahydrozoline • Theophylline • Thioridazine • *cis*-Thiothixene • Tobramycin • Triamterene • Trifluoperazine • Triflupromazine • *dl*-Trihexyphenidyl • Trimethobenzamide • Trimethoprim • Trimipramine • Triprolidine • Urea • Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

[D] No interference was observed when the compound was tested to 10 µg/mL.
[E] No interference was observed when the compound was tested to 2.5 µg/mL.

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QuickScreen™ Pro Multi Drug Screening Test

With "Timer and Adulteration" / Catalog # 9308ZA

FOR IN VITRO DIAGNOSTIC USE ONLY

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9308ZA-DI, Rev. A, GD1 Eff. 2/18/2015

QUICKSCREEN Adulteration Test

For in-vitro use only. Read all instructions, precautions, and limitations below **and** the instruction booklet of the ***QuickScreen drug test*** before performing this test.

Intended Use

QuickScreen Adulteration Test is a quick visual test for the determination of diluted or adulterated urine specimens. It is an important part of any drug-testing program.

Summary and Explanation

QuickScreen Adulteration Test contains seven different reagent areas. Results are read visually by comparing the colors in your test results against the color chart provided. No equipment is required.

QuickScreen Adulteration Test provides testing for Creatinine, Nitrite, pH, Specific Gravity, Glutaraldehyde, Bleach, and Pyridinium Chlorochromate in urine. Test results may be useful for assessing the integrity of the urine sample submitted for Drugs-of-Abuse testing. *QuickScreen Adulteration Test* detects if the sample is possibly diluted with water or other liquids as indicated by the creatinine and specific gravity tests. It also detects whether the sample contains commercially available adulterants including nitrite, glutaraldehyde, bleach, pyridinium chlorochromate and other oxidizing agents. *QuickScreen Adulteration Test* can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

Test Principle

In general, all seven tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color change. ***Results are obtained by comparing the color on each test pad with the corresponding color chart label below.***

Creatinine: Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

Specific Gravity: Testing for sample dilution. The test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the color rangse from dark blue or blue green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

pH: Testing for the presence of acidic or alkaline adulterant. The test is based on the well-known double pH indicator method that gives distinguishable colors over a wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Nitrite: Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine of form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In the assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green, brown, orange color complex.

Pyridinium Chlorochromate: Testing for the presence of Pyridinium chlorochromate in urine. In this test, the presence of chromate forms a blue-green color complex.

Specimen Collection

Collect urine sample as instructed in the ***QuickScreen drug test*** booklet.

Procedure for Reading Test Results

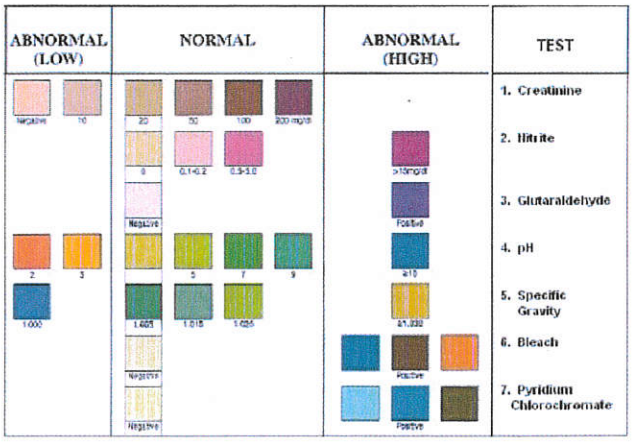
1. You can read the results of the *QuickScreen Adulteration Test* immediately after collection.
2. Visually compare the color of each reagent area to its corresponding color blocks on the color chart.
3. Obtain results by direct color chart comparison.

Note: All reagent areas may be read immediately after collection up to 10 minutes. Do not read after 10 minutes.

Interpretation of Results

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding test color chart below.

Color Chart



Limitations

Comparison to the color chart is dependent on the visual interpretation of the individual. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method. Some compounds or physical properties that may affect the test result are listed below. Medications that discolor the urine may also cause abnormal results due to masking of the reactions of the reagents on the test pads.

Expected Values

Creatinine: Daily Creatinine excretion related to muscle mass of the human body is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, samples with a creatinine level of lower than 20mg/dl should be considered adulterated.

Specific Gravity: Random urine may vary in specific gravity from 1.003-1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016-1.022. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with a specific gravity level less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

PH: Normal urine ranges from 4.5 to 8.0. Values below pH 4.0 or above 9.0 are indicative of adulteration.

Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections or bacterial contamination. In the *QuickScreen Adulteration Test*, nitrite levels above 7.5mg/dl are considered abnormal.

Glutaraldehyde: Glutaraldehyde is not a natural component of the human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, a false positive may result when ketone bodies are present in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Bleach: The presence of any bleach in urine is indicative of adulteration, as bleach is not a normal constituent of urine.

Pyridinium Chlorochromate: The presence of any Pyridinium Chlorochromate in urine is indicative of adulteration, as this is not a normal constituent of urine. Presence of a blue or grey color indicates tampering with an oxidative adulterant.

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9092-v.1-02182008

ORAL CUBE FEATURES

Product Description

- Easy to Administer Anywhere, Anytime
  - Quick and Accurate Results
  - Easy to Use and Premium Quality
  - Forensic and Research Use Only
  - Not for Home Use

In drug use analysis, oral fluid drug screening has certain advantages over the screening of other biological fluids such as urine and blood. Oral fluid is readily accessible, and is less likely to be adulterated. With the OralCube Saliva Test Kit, drugs may be detected immediately after ingestion, even before they are metabolized and would show up in urine.

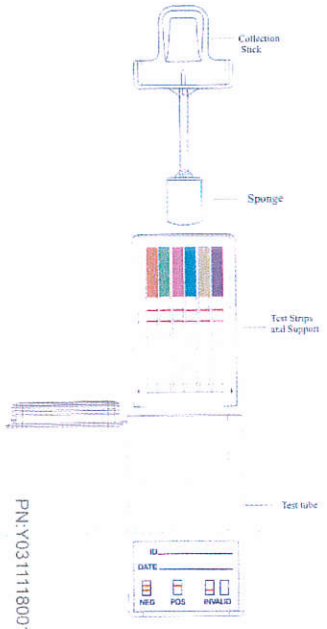
The ORAL CUBE Saliva Test Kit is designed to work at a lower detection level for all test drugs than those detected in urine samples. Oral Cube screening for drugs of abuse detects the presence of parent compounds and drug metabolites.

Oral Cube is a rapid drug screening test for the simultaneous detection of drugs in human This Oral Cube One-step Drug Test Oral Fluid Drug Screen Device is so easy and convenient to use. It eliminates cross-gender collection issues, is non-invasive, no instrumentation, and best part of all is it is a ONE STEP collection and testing drug test! It is convenient to administer anywhere and anytime with results in 10 minutes.

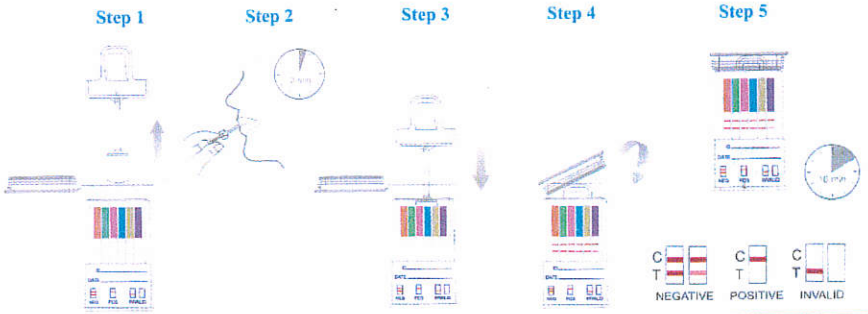
- Saliva Drug Test
- No Restroom Needed
- Fast Results
- Accurate
- Transport Ready
- For Forensic Use Only
- Results in 10 Minutes
- Able to Photocopy Results
- Test for Alcohol as Low as 0.02% BAC

Oral Cube One-step Drug Test *Procedure Card*

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.



1. Remove the collection stick and test tube from the sealed pouch.
2. Tear off the package of the collection stick. (Step 1)
3. Insert the sponge end of the collection stick into mouth and soak sponge into saliva for 3 minutes. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.). (Step 2)
4. Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step 4)
6. **Read results at 10 minutes.**(If there is a label over reading window, peel off the label to read test results.). Do not read results after 1 hour. (Step 5)



PN:Y0311118001

Oral Fluid Drug Screen Device Oral Fluid Drug Screen Device Oral Fluid Drug Screen Device

Oral Cube™

Oral Fluid Drug and Alcohol Screen Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/ACL Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Alcohol and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/ACL is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Alcohol and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12 ng/mL
	Δ^9-THC	75 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL
Oxycodone (OXY)	Oxycodone	50 ng/mL
Methadone (MTD)	Methadone	75 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Alcohol (ACL)	Alcohol	> 0.02 % B.A.C

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

"For Forensic Use Only" does not apply to any workplace testing or other non law enforcement testing, regardless of whether or not that testing is conducted under other federal agency (e.g., Department of Transportation) authority.

SUMMARY AND EXPLANATION OF THE TEST

The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/ACL and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

AMPHETAMINE (AMP)
Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, Amphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use[1].

The Amphetamine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

METHAMPHETAMINE (mAMP)
Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use[1].

The Methamphetamine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Methamphetamine concentration in oral fluid exceeds 50 ng/mL.

COCAINE (COC)
Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].
The Cocaine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the cocaine metabolite in oral fluid exceeds 20 ng/mL.

OPIATE (OPI)
The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose[2]. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiates assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the concentration of Morphine in oral fluid exceeds the 40 ng/mL cut-off level.

MARIJUANA (THC)
Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in saliva shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

The Marijuana assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the 11-nor-Δ^9-THC-9 COOH concentration exceeds 12 ng/mL.

The Marijuana assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Δ^9-THC concentration exceeds 75 ng/mL.

PHENCYCLIDINE (PCP)
Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL[4].

The Phencyclidine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Phencyclidine concentration in oral fluids exceeds 10 ng/mL.

BENZODIAZEPINES (BZO)
Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

The Benzodiazepines assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the concentration of Oxazepam in oral fluids exceeds 50 ng/mL.

OXYCODONE (OXY)
Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

The Oxycodone assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the concentration of oxycodone in oral fluid exceeds 50 ng/mL.

METHADONE (MTD)
Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists[5].

The Methadone assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Methadone concentration in oral fluids exceeds 75 ng/mL.

BARBITURATES (BAR)
Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.
Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.
Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.
The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days[5]

The Barbiturates assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Barbiturates concentration in oral fluid exceeds 300 ng/mL.

BUPRENORPHINE (BUP)
Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.
Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The Buprenorphine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Buprenorphine concentration in oral fluid exceeds 10 ng/mL.

ALCOHOL (ACL)
Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

PRINCIPLE

(1)The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of

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the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3C{=}O + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_2O$$

H

Blue

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidaze to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

REAGENT

(1)The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, Marijuana, Phencyclidine, Oxazepam, Oxycodone, Methadone, Barbiturates and Buprenorphine.

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol Oxidaze, Peroxidase, Buffer and Stabilizing Proteins.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The Oral Fluid Drug Screen Device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The test device is for single use.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

• Test devices • Package insert • Procedure card

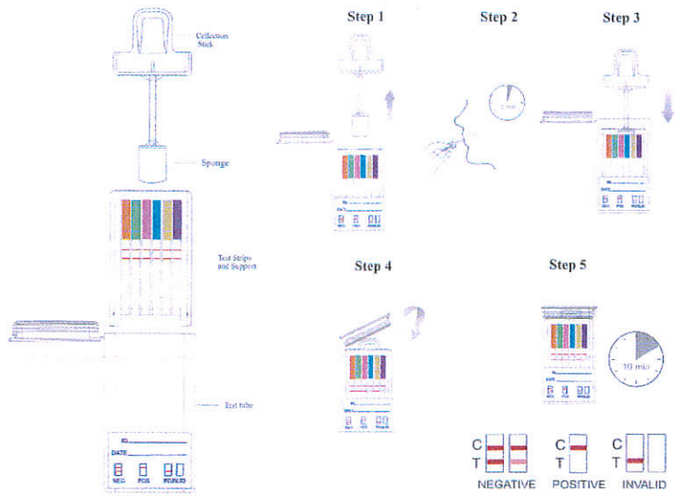
Materials Required But Not Provided

• Timer

DIRECTIONS FOR USE

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

1. Remove the collection stick and test tube from the sealed pouch.
2. Tear off the package of the collection stick. (Step 1)
3. Insert the sponge end of the collection stick into mouth and soak sponge into saliva for 3 minutes. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.). (Step 2)
4. Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step 4)
6. Read results of alcohol test at 2 minutes and drug tests at 10 miuntes.(If there is a label over reading window, peel off the label to read test results.)Do not read alcohol test result after 5 minutes and drug test results after 1 hour.(Step 5)
7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:

Two lines appear. * One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

POSITIVE:

One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

(Please refer to the alcohol color chart)

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream colored); it should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

Alcohol Presumptive Positive Result: The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02 % B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device***. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		mAMP		COC		OPI		THC		PCP		BZO		OXY		MTD		BAR		BUP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	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	30	0	30	0	30	0
-25% Cut-off	30	28	2	29	1	30	0	27	3	27	3	30	0	28	2	28	2	29	1	29	1	27	3
Cut-off	30	13	17	16	14	19	11	18	12	14	16	20	10	13	17	12	18	10	20	12	18	16	14
+25% Cut-off	30	4	26	7	23	5	25	3	27	1	29	7	23	4	26	3	27	2	28	3	27	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02%, 0.08%, 0.15%, 0.30%,). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** are summarized below:

Test	Total # of Test/ Concentration	B.A.C.									
		0.00%		0.02%		0.08%		0.15%		0.30%	
		-	+	-	+	-	+	-	+	-	+
Alcohol	15	15	0	1	14	0	15	0	15	0	15

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
ß-Phenylethylamine	4,000
(+)3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000

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Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE (COC)	
Benzoylecogonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphine	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-ß-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
BENZODIAZEPINES (BZO)	
a-Hydroxyalprazolam	1,260
Alprazalam	40
Bromazepam	400
Chlordiazepoxide	780
Chlordiazepoxide HCl	390
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	50
Temazepam	20
Triazolam	2,500
OXYCODONE (OXY)	
Oxycodone	50

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Codeine	25,000
Dihydrocodeine	6,250
Ethylmorphine	12,500
Hydrocodone	1,000
Hydromorphone	6,250
Oxymorphone	1,000
Thebaine	25,000
MARIJUANA (THC)	
11-nor-Δ9 -THC-9 COOH	12
Cannabinol	3,000
Δ8 -THC	75
Δ9 -THC	75
METHADONE (MTD)	
Methadone	75
Doxylamine	12,500
BARBITURATES (BAR)	
Alphenol	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Secobarbital	300
BUPRENORPHINE (BUP)	
Norbuprenorphine	10
Buprenorphine	20
3-D-glucuronide	15
Norbuprenglucuronide	200

Alcohol Test
The Alcohol test will react with methyl, ethyl,and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

NON CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** when tested with concentrations up to 100 µg/mL.

Acetaminophen	Benzoic acid	Creatinine
Acetophenetidin	Benzphetamine	Deoxycorticosterone
N-Acetylprocainamide	D/L-Brompheniramine	Dextromethorphan
Acetylsalicylic acid	Caffeine	Diclofenac
Aminopyrine	Cannabidol	Diflunisal
Amoxicillin	Chloralhydrate	Digoxin
Ampicillin	Chloramphenicol	Diphenhydramine
L-Ascorbic acid	Chlorothiazide	L-Y-Ephedrine
Apomorphine	D/L-Chloropheniramine	ß-Estradiol
Aspartame	Chlorpromazine	Estrone-3-sulfate
Atropine	Chloroquine	Ethyl-p-aminobenzoate
Cholesterol	Norethindrone	L(-)-Epinephrine
Clonidine	D-Norpropoxyphene	Erythromycin
Cortisone	Noscapine	Fenoprofen
L-Cotinine	D/L-Octopamine	Furosemide
Gentisic acid	Naproxen	Ranitidine
Hemoglobin	Niacinamide	Salicylic acid
Hydralazine	NifedipineOxalic acid	Serotonin
Hydrochlorothiazide	Oxolinic acid	Sulfamethazine
Hydrocortisone	Oxymetazoline	Sulindac
O-Hydroxyhippuric acid	Papaverine	Tetracycline
p-Hydroxytyramine	Penicillin-G	Tetrahydrocortisone 3-acetate
Ibuprofen	Pentazocine hydrochloride	Tetrahydrocortisone 3 (ß-D-glucuronide)
Iproniazid	Perphenazine	Thiamine
D/L-Isoproterenol	Phenelzine	Thioridazine
Isoxsuprine	Trans-2-phenylcyclopropylamine	D/L-Tyrosine
Ketamine	hydrochloride	Tolbutamide
Ketoprofen	Phenylpropanolamine	Triamterene
Labetalol	Prednisolone	Trifluoperazine
Loperamide	Prednisone	Trimethoprim
Meperidine	D/L-Propranolol	D/L-Tryptophan
Meprobamate	D-Propoxyphene	Tyramine
Methylphenidate	D-Pseudoephedrine	Uric acid
Nalidixic acid	Quinacrine	Verapamil
Naloxone	Quinine	Zomepirac
Naltrexone	Quindine	

Alcohol Test
The following substances may interfere with the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** when using samples other than oral fluid:
(1) Agents which enhance color development: Peroxides and strong oxidizers
(2) Agents which inhibit color development:
Reducing Agents: such as Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanalics and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyldopa, L-dopa, L-methyldopa, and Methampyrone, etc.
The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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REQUEST FOR QUOTATION
CRFQ COR1700000001
COR238214 Drug Test Kits and Supplies

SPECIFICATIONS

1. **PURPOSE AND SCOPE:** The West Virginia Purchasing Division is soliciting bids on behalf of the Division of Corrections to establish a contract for I Cup Panel Drug Test kits (including standard and customizable), mouth swabs, other supplies and Confirmation Laboratory Services as specified in this RFQ.

   Agency has over 5,000 inmates housed in multiple correctional sites throughout the State of West Virginia. The Agency has more than 2,500 parolee offenders located throughout the state.

   In addition to drug testing of WVDOC inmates and parolee offenders, the specified drug testing kits and confirmation laboratory services may be utilized for civilian pre-employment drug testing as well as "for cause" testing on employees of the Agency.

   Drug testing kits and associated supplies shall be shipped to the facilities listed on Attachment A. In addition, Vendor agrees to provide drug testing kits and associated supplies to all new facilities added by the Agency during the term of this agreement at the same contract price.

2. **DEFINITIONS:** The terms listed below shall have the meanings assigned to them below. Additional definitions can be found in section 2 of the General Terms and Conditions.

   2.1 **"Contract Item"** or **"Contract Items"** means the list of items identified in Section 3.1 below and on the Pricing Pages.

   2.2 **"Contract Services"** means Laboratory confirmation testing as more fully described in these specifications.

   2.3

   2.4 **"Pricing Pages"** means the schedule of prices, estimated order quantity, and totals contained in wvOASIS or attached hereto as Exhibit A, and used to evaluate the Solicitation responses.

   2.5 **"Solicitation"** means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

   2.6 **"ALL INCLUSIVE"** means self-contained to prevent exposure to contamination.

   2.7 **"RFQ"** means the official request for quotation published by the Purchasing Division and identified as COR238214.

2.8 **"STATEWIDE"** means that the vendor must provide services and commodities to all DOC facilities in the state in 55 counties.

The following acronyms will correspond with the type of drug being specified going further in this RFQ:

AMP – Amphetamines
BAR – Barbiturates
BUP - Buprenorphine
BZO – Benzodiazepines
COC – Cocaine
MAMP – Methamphetamines
MDMA - Ecstasy
MTD – Methadone
OPI – Opiates
OXY – Oxycodone
PCP – Phencyclidine
PPX – Propoxyphene
SynCANN – Synthetic Cannabinoids
TCA – Tricyclic antidepressants
THC – Tetrahydrocannabinol/Marijuana

2.9 **"FDA 510 K"** refers to the notification to FDA of vendors intent to market a medical device.

3. **QUALIFICATIONS:** Vendor shall have the following minimum qualifications.

3.1 For laboratory confirmation services, a minimum of five (5) years' experience, to include state and/or county correctional facility. Inmate population must be a minimum of 5,000 inmates to qualify for consideration.

3.2 For laboratory confirmation services, Vendor shall provide a minimum of three (3) professional references which should include at least one state or county correctional facility. Vendor references should be submitted with bid.

3.3 For laboratory services, Vendor shall provide curriculum vitae of Laboratory Director with bid.

3.4 For laboratory services, Vendor shall be certified by the Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) for employment and parole revocations for drug testing confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate drug testing confirmations.

Vendor shall provide proof of such certifications with its bid.

4. GENERAL REQUIREMENTS:

4.1 Contract Items and Mandatory Requirements: Vendor shall provide Agency with the Contract Items listed below on an open-end and continuing basis. Contract Items must meet or exceed the mandatory requirements as shown below.

4.1.1 Inmate and Parolee drug testing kits

4.1.1.1 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.1.1.1.1 The Product shall be a 6 panel test including AMP, BARB, COC, MAMP, OPI, and THC.

4.1.1.1.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

4.1.1.1.3 The product shall have built in adulteration detection to aid in the prevention of sample tampering.

4.1.1.1.4 The product shall be all inclusive without a separate testing device.

4.1.1.1.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample

4.1.1.1.6 The product shall be able to detect drugs indicated on the panel simultaneously.

4.1.1.1.7 The product shall not leak during air/ground shipping.

4.1.1.1.8 The cup shall have a minimum fill line clearly displayed on the outside of the cup.

4.1.1.1.9 The Agency reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.

4.1.1.1.10	The Product shall have a minimum 18 month shelf life.
4.1.1.1.11	The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.
4.1.1.1.12	The product shall be FDA approved for commercial distribution with an active 510K notification document.
4.1.1.1.13	Vendor shall provide, at their expense, the following samples upon request:
4.1.1.1.13.1	Shipping Bag
4.1.1.1.13.2	Shipping container that will hold a minimum of two (2) specimen cups
4.1.1.1.13.3	Chain of custody form
4.1.1.1.14	Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.1.1.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.1.1.2.1	The Product shall be a 10 panel test including AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC.
4.1.1.2.2	The product shall render accurate results (rate of 97% or higher) in under a minute.
4.1.1.2.3	The product shall have built in adulteration detection to aid in the prevention of sample tampering.
4.1.1.2.4	The product shall be all inclusive without a separate testing device.
4.1.1.2.5	The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample

4.1.1.2.6	The product shall be able to detect drugs indicated on the panel simultaneously.
4.1.1.2.7	The product shall not leak during air/ground shipping.
4.1.1.2.8	The cup shall have a minimum fill line clearly displayed on the outside of the cup.
4.1.1.2.9	The Agency reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.
4.1.1.2.10	The Product shall have a minimum 18 month shelf life.
4.1.1.2.11	The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.
4.1.1.2.12	The product shall be FDA approved for commercial distribution with an active 510K notification document.
4.1.1.2.13	Vendor shall provide, at their expense, the following samples upon request:
4.1.1.2.13.1	Shipping Bag
4.1.1.2.13.2	Shipping container that will hold a minimum of two (2) specimen cups
4.1.1.2.13.3	Chain of custody form
4.1.1.2.14	Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.1.1.3 Customizable All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 13 panel or equivalent

4.1.1.3.1	The Product shall be a 13 panel test including (at a minimum) AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC, and shall also be customizable at any time at no additional cost.

4.1.1.3.2	The product shall render accurate results (rate of 97% or higher) in under a minute.
4.1.1.3.3	The product shall have built in adulteration detection to aid in the prevention of sample tampering.
4.1.1.3.4	The product shall be all inclusive without a separate testing device.
4.1.1.3.5	The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample
4.1.1.3.6	The product shall be able to detect drugs indicated on the panel simultaneously.
4.1.1.3.7	The product shall not leak during air/ground shipping.
4.1.1.3.8	The cup shall have a minimum fill line clearly displayed on the outside of the cup.
4.1.1.3.9	The Agency reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.
4.1.1.3.10	The Product shall have a minimum 18 month shelf life.
4.1.1.3.11	The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.
4.1.1.3.12	The product shall be FDA approved for commercial distribution with an active 510K notification document.
4.1.1.3.13	Vendor shall provide, at their expense, the following samples upon request:
4.1.1.3.13.1	Shipping Bag
4.1.1.3.13.2	Shipping container that will hold a minimum of two (2) specimen cups

4.1.1.3.13.3 Chain of custody form

4.1.1.3.14 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.1.1.4 Panel Saliva Test for oral fluids 6 panel

4.1.1.4.1 The product shall be a 6 panel test including AMP, BAR, COC, MAMP, OPI, and THC.

4.1.1.4.2 Product shall be non-invasive, gender neutral collections with no exposure to specimen.

4.1.1.4.3 The product shall render accurate results (rate of 97% or higher) in under a minute.

4.1.1.4.4 The product shall be a packaged all-inclusive without a separate testing device, with the ability to detect multiple drugs.

4.1.1.4.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample

4.1.1.4.6 The product shall be able to detect drugs indicated on the panel simultaneously.

4.1.1.4.7 The Product shall have a minimum 18 month shelf life.

4.1.1.4.8 The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.1.1.4.9 The product shall be FDA approved for commercial distribution with an active 510K notification document.

4.1.1.4.10 Vendor shall provide, at their expense, the following samples upon request:

4.1.1.4.10.1 Shipping Bag

4.1.1.4.10.2	Shipping container that will hold a minimum of two (2) specimen cups
4.1.1.4.10.3	Chain of custody form
4.1.1.4.11	Each test shall be provided in a seal bag with lot number, expiration date, and drug cut-off levels.
4.1.1.4.12	The product shall have fast turn-around time from receipt of specimen (48 hours 2 negative, 72 hours positive).
4.1.1.4.13	Each oral swab kit shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.2 Employment/Employee drug testing kits

4.2.1 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.2.1.1	The Product shall be a 6 panel test including AMP, BARB, COC, MAMP, OPI, and THC.
4.2.1.2	The product shall render accurate results (rate of 97% or higher) in under a minute.
4.2.1.3	The product shall have built in adulteration detection to aid in the prevention of sample tampering.
4.2.1.4	The product shall be all inclusive without a separate testing device.
4.2.1.5	The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample
4.2.1.6	The product shall be able to detect drugs indicated on the panel simultaneously.
4.2.1.7	The product shall not leak during air/ground shipping.
4.2.1.8	The cup shall have a minimum fill line clearly displayed on the outside of the cup.

4.2.1.9 The Agency reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.

4.2.1.10 The Product shall have a minimum 18 month shelf life.

4.2.1.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.1.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

4.2.1.13 Vendor shall provide, at their expense, the following samples upon request:

4.2.1.13.1 Shipping Bag

4.2.1.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.1.13.3 Chain of custody form

4.2.1.14 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.2.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.2.2.1 The Product shall be a 10 panel test including AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC.

4.2.2.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

4.2.2.3 The product shall have built in adulteration detection to aid in the prevention of sample tampering.

4.2.2.4 The product shall be all inclusive without a separate testing device.

4.2.2.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which

indicates test is valid, and indication of presence of drug in sample

4.2.2.6 The product shall be able to detect drugs indicated on the panel simultaneously.

4.2.2.7 The product shall not leak during air/ground shipping.

4.2.2.8 The cup shall have a minimum fill line clearly displayed on the outside of the cup.

4.2.2.9 The state reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.

4.2.2.10 The Product shall have a minimum 18 month shelf life.

4.2.2.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing..

4.2.2.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

4.2.2.13 Vendor shall provide, at their expense, the following samples upon request:

4.2.2.13.1 Shipping Bag

4.2.2.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.2.13.3 Chain of custody form

4.2.2.14 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.2.3 Customizable All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 13 panel or equivalent

4.2.3.1 The Product shall be a 13 panel test including (at a minimum) AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC, and shall also be

customizable at any time at no additional cost.

4.2.3.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

4.2.3.3 The product shall have built in adulteration detection to aid in the prevention of sample tampering.

4.2.3.4 The product shall be all inclusive without a separate testing device.

4.2.3.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample

4.2.3.6 The product shall be able to detect drugs indicated on the panel simultaneously.

4.2.3.7 The product shall not leak during air/ground shipping.

4.2.3.8 The cup shall have a minimum fill line clearly displayed on the outside of the cup.

4.2.3.9 The state reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.

4.2.3.10 The Product shall have a minimum 18 month shelf life.

4.2.3.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.3.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

4.2.3.13 Vendor shall provide, at their expense, the following samples upon request:

4.2.3.13.1 Shipping Bag

4.2.3.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.3.13.3 Chain of custody form

4.2.3.14 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.2.4 Panel Saliva Test for oral fluids 6 panel

4.2.4.1 The Product shall be a 6 panel test including AMP, BAR, COC, MAMP, OPI, and THC.

4.2.4.2 Product shall be non-invasive, gender neutral collections with no exposure to specimen.

4.2.4.3 The product shall render accurate results (rate of 97% or higher) in under a minute.

4.2.4.4 The product shall be a packaged all-inclusive without a separate testing device, with the ability to detect multiple drugs.

4.2.4.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample

4.2.4.6 The product shall be able to detect drugs indicated on the panel simultaneously.

4.2.4.7 The Product shall have a minimum 18 month shelf life.

4.2.4.8 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.4.9 The product shall be FDA approved for commercial distribution with an active 510K notification document.

4.2.4.10 Vendor shall provide, at their expense, the following samples upon request:

4.2.4.10.1 Shipping Bag

4.2.4.10.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.4.11 Chain of custody form

4.2.4.12 Each test shall be provided in a seal bag with lot number, expiration date, and drug cut-off levels.

4.2.4.13 The product shall have fast turn-around time from receipt of specimen (48 hours 2 negative, 72 hours positive).

4.2.4.14 Each oral swab kit shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

4.3 Vendor shall provide initial in-person training course(s) at no additional cost to the Agency to ensure that the Agency performs effective drug screens in a manner consistent with manufacturer recommendations. In addition, vendor will provide in-depth and interactive training procedures for additional staff training. Vendor will provide additional training should changes in product warrant such supplemental training. Vendor will provide a certification process in which, train the trainers are able to certify other users and provide a "certificate" upon successful completion of the competency.

4.4 The kits shall have a built-in specimen validity testing for three or more of the following: Oxidants, Specific Gravity, pH, Nitrite, Glutaraldehyde, and Creatinine.

4.5 Urinalysis screening drug testing kit shall be convenient and ready to use at any location.

4.5.1 Drug testing kits shall not require any mixing of reagents or pretreatments/special handling of urine samples.

4.5.2 Drug testing kits shall be capable of producing results within five (5) minutes and results shall be stable for a minimum of one hour.

4.5.3 Vendor shall provide kits that are easy to determine the result clearly and concisely.

4.5.4 Drug testing kit shall not require refrigeration.

4.5.5 Drug testing kit must utilize colloidal gold technology.

4.5.6 Drug testing kit shall have a built-in temperature strip to indicate validity of specimen.

4.5.7 Vendor shall provide a drug testing kit wherein the screening results can be photocopied as a permanent record.

4.5.8 Drug testing kits shall include a built-in procedural control that confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

4.5.9 Vendor shall provide for each single donor cup a preprinted chain of custody with specimen ID not to exceed 15 characters and a self-adhesive peel off label with matching specimen ID number.

4.5.10 The label shall provide a place to enter collection time, date, and client initials.

4.5.11 Packaging

4.5.11.1 The Drug Test Kits shall be provided in a seal bag with lot number, expiration date, drugs cut- off levels.

4.5.11.2 Vendor shall to supply clear sealable shipping bags and sturdy cardboard shipping containers for shipping positive results for lab confirmation.

4.5.11.3 The name and location of each Division of Corrections facility is listed in Exhibit A. The Vendor shall provide the contract items, at contract price, to any additional DOC facility(s) that may open, or require equipment and supplies during the course of the contract.

4.5.12 Upon award, the successful laboratory confirmation services Vendor shall provide the following ancillary supplies to all Agency facilities listed on Attachment A:

Specimen collection containers/bottles
Specimen baggies with absorbent material
Chain of Custody forms
Labels of various configurations
Security Seals
Pre-paid mailers
Overnight shipping service lab packs

4.5.13 Gas Chromatography/Mass Spectrometry (GC/MS) and/or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) shall be the testing confirmation method.

4.5.14 The confirmation laboratory shall be currently certified and maintain certification by the US Department of Health and Human Services (HHS) for all confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate confirmations, and Substance Abuse Mental Health Administration (SAMSHA), to meet the standards for federal workplace drug testing programs for employment and parolee offender

revocations. A copy of the certification should be provided with the bid.

4.5.15 The confirmation laboratory may, for inmate testing, be performed by certified Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories; however, the Agency retains the requirement for SAMSHA lab testing for employee and pre-employment screenings. In addition, Agency will utilize SAMSHA lab testing for all parole revocations.

4.5.16 If the SAMSHA, and/or CLIA certification of the confirmation laboratory is suspended or revoked, Vendor shall notify Agency within ten (10) business days.

4.5.17 Vendor shall provide GC/MS confirmation testing of all positive screens or specimens that Agency requests to be confirmed. The methodology must 1) apply a theory or technique that can be, and has been, tested; 2) the theory or technique must have been subjected to peer review and publication; 3) it must have a known, or potential, error rate; 4) there must be an existence and maintenance of standards controlling its operation.; and 5) it must have attracted widespread acceptance within a relevant scientific community. See Daubert v. Merrell Dow Pharmaceuticals, Inc. 509 US 579 (1993).

Inmates and Parolee Offenders: The purpose of this testing is for criminal justice purposes and the Agency does not use administrative cutoffs for workplace testing. As such, the Agency requires that the confirmation lab test to limit of detection (LOD), which are consistent with the methodology specified above. The LOD shall reflect the concentrations at which the specific drug can be detected to a reasonable degree of scientific certainty and upon which admissible opinion testimony can be given therefrom for both institutional discipline and probation revocation proceeding.

Civilian Pre-employment and Staff "For Cause" Drug Testing: The confirmation testing for this category shall be conducted in compliance with the Guidelines for Federal Workplace Drug Testing Programs. These Guidelines can be located at: https://www.federalregister.gov/articles/2016/06/30/2016-15469/mandatory-guidelines-for-federal-workplace-drug-testing-programs

4.5.18 Ethyl glucuronide (EtG) tests shall be used for alcohol (ethanol) screens. In addition to EtG, Ethyl Sulfate (EtS) shall be used as secondary testing for specific metabolite or biomarker of ethanol. Vendor must test and report EtS, in conjunction with EtG, to confirm recent ethanol ingestion.

4.5.19 The cutoff level for use in the EtG/EtS testing shall be 100 ng/mL. Any EtG level over 100 ng/mL must indicate exposure to ethanol.

4.5.20 The successful Vendor for laboratory confirmation services shall provide overnight delivery services to its laboratory for all samples and specimens for both drug and alcohol testing. All alcohol specimens and all positive drug specimens may be shipped to the laboratory for confirmation services.

4.5.21 All urine specimens that test positive for drugs, alcohol, and/or metabolites shall be stored at a secure warehouse for a minimum of six (6) months. Negative alcohol specimens will be stored for two (2) days. Additionally, chain of custody records, documentation, and analytical records shall be securely stored for a minimum of three (3) years.

4.6 Vendor shall provide services of a Medical Review Officer (MRO on an as needed basis. Said MRO shall review, analyze, and report on confirmed positive test results. When required, MRO shall conduct medical interviews with the donor for any confirmed positive, adulterated, substituted, invalid test results, and if necessary, review donor's medical history. Agency may request expert testimony from MRO in court or grievance proceedings regarding verified positive findings. This must be a per hour bid to include any travel.

4.7 Vendor must provide the agency with the most up to date version of each drug testing kit

5. CONTRACT AWARD:

5.1 **Contract Award:** The Contract is intended to provide Agencies with a purchase price on all Contract Items. The Contract shall be awarded to the Vendor that provides the Contract Items meeting the required specifications for the lowest overall total cost as shown on the Pricing Pages.

5.2 **Pricing Pages:** Vendor should complete the Pricing Pages by indicating unit price, and extended price. Vendor should complete the Pricing Pages in their entirety as failure to do so may result in Vendor's bids being disqualified.

5.2.1 The Pricing Pages contain a list of the Contract Items and estimated purchase volume. The estimated purchase volume for each item represents the approximate volume of anticipated purchases only. No future use of the Contract or any individual item is guaranteed or implied.

5.2.2 Vendor should electronically enter the information into the Pricing Pages through wvOASIS, if available, or as an electronic document. In most cases, the Vendor can request an electronic copy of the Pricing Pages for bid purposes by sending an email request to the following address: Crystal.G.Rink@wv.gov.

6. **PERFORMANCE:** Vendor and Agency shall agree upon a schedule for performance of contract Services and Contract Services Deliverables, unless such a schedule is already included herein by Agency. In the event that this Contract is designated as an open-end contract, Vendor shall perform in accordance with the release orders that may be issued against this Contract.

7. **ORDERING AND PAYMENT:**

   7.1 **Ordering:** Vendor shall accept orders through wvOASIS, regular mail, facsimile, e-mail, or any other written form of communication. Vendor may, but is not required to, accept on-line orders through a secure internet ordering portal/website. If Vendor has the ability to accept on-line orders, it should include in its response a brief description of how Agencies may utilize the on-line ordering system. Vendor shall ensure that its on-line ordering system is properly secured prior to processing Agency orders on-line.

   7.2 **Payment:** Agency shall pay flat fee for confirmation services, and as shown on the Pricing Pages, for all Contract Services performed and accepted under this Contract. Vendor shall accept payment in accordance with the payment procedures of the State of West Virginia.

8. **TRAVEL:** Vendor shall be responsible for all mileage and travel costs, including travel time, associated with performance of this Contract. Any anticipated mileage or travel costs may be included in the flat fee or hourly rate listed on Vendor's bid, but such costs will not be paid by the Agency separately.

9. **FACILITIES ACCESS:** Performance of Contract Services may require access cards and/or keys to gain entrance to Agency's facilities. In the event that access cards and/or keys are required:

   9.1 Vendor must identify principal service personnel which will be issued access cards and/or keys to perform service.

   9.2 Vendor will be responsible for controlling cards and keys and will pay replacement fee, if the cards or keys become lost or stolen.

   9.3 Vendor shall notify Agency immediately of any lost, stolen, or missing card or key.

   9.4 Anyone performing under this Contract will be subject to Agency's security protocol and procedures.

9.5 Vendor shall inform all staff of Agency's security protocol and procedures

10. DELIVERY AND RETURN:

10.1 **Delivery Time:** Vendor shall deliver standard orders within five (5) working days after orders are received. Vendor shall deliver emergency orders within two (2) working day(s) after orders are received. Vendor shall ship all orders in accordance with the above schedule and shall not hold orders until a minimum delivery quantity is met.

10.2 **Late Delivery:** The Agency placing the order under this Contract must be notified in writing if orders will be delayed for any reason. Any delay in delivery that could cause harm to an Agency will be grounds for cancellation of the delayed order, and/or obtaining the items ordered from a third party.

Any Agency seeking to obtain items from a third party under this provision must first obtain approval of the Purchasing Division.

10.3 **Delivery Payment/Risk of Loss:** Standard order delivery shall be F.O.B. destination to the Agency's location. Vendor shall include the cost of standard order delivery charges in its bid pricing/discount and is not permitted to charge the Agency separately for such delivery. The Agency will pay delivery charges on all emergency orders provided that Vendor invoices those delivery costs as a separate charge with the original freight bill attached to the invoice.

10.4 **Return of Unacceptable Items:** If the Agency deems the Contract Items to be unacceptable, the Contract Items shall be returned to Vendor at Vendor's expense and with no restocking charge. Vendor shall either make arrangements for the return within five (5) days of being notified that items are unacceptable, or permit the Agency to arrange for the return and reimburse Agency for delivery expenses. If the original packaging cannot be utilized for the return, Vendor will supply the Agency with appropriate return packaging upon request. All returns of unacceptable items shall be F.O.B. the Agency's location. The returned product shall either be replaced, or the Agency shall receive a full credit or refund for the purchase price, at the Agency's discretion.

10.5 **Return Due to Agency Error:** Items ordered in error by the Agency will be returned for credit within 30 days of receipt, F.O.B. Vendor's location. Vendor shall not charge a restocking fee if returned products are in a resalable condition. Items shall be deemed to be in a resalable condition if they are unused and in the original packaging. Any restocking fee for items not in a resalable condition shall be the lower of the Vendor's customary restocking fee or 5% of the total invoiced value of the returned items.

11. VENDOR DEFAULT:

11.1 The following shall be considered a vendor default under this Contract.

11.1.1 Failure to provide Contract Items in accordance with the requirements contained herein.

11.1.2 Failure to comply with other specifications and requirements contained herein.

11.1.3 Failure to comply with any laws, rules, and ordinances applicable to the Contract Services provided under this Contract.

11.1.4 Failure to remedy deficient performance upon request.

11.2 The following remedies shall be available to Agency upon default.

11.2.1 Immediate cancellation of the Contract.

11.2.2 Immediate cancellation of one or more release orders issued under this Contract.

11.2.3 Any other remedies available in law or equity.

12. MISCELLANEOUS:

12.1 **No Substitutions:** Vendor shall supply only Contract Items submitted in response to the Solicitation unless a contract modification is approved in accordance with the provisions contained in this Contract.

12.2 **Vendor Supply:** Vendor must carry sufficient inventory of the Contract Items being offered to fulfill its obligations under this Contract. By signing its bid, Vendor certifies that it can supply the Contract Items contained in its bid response.

References

Reference #1:
U.S. Federal Bureau of Prisons
320 First Street, NW STE 300
Washington, D.C. 20534
Contact Person: Michael Drake
Telephone: 202 359 4219
Email: mdrake@bop.gov
Services Provided / Term of Service: Phamatech provides customized on-site drug screening devices to over 180 correctional facilities nationwide, confirmation laboratory services and statistical reporting / January 2009-present

Reference #2:
The Sheriff of Broward County Department of Community Control
4200 NW 16 ST, STE 607
Lauderhill, FL 33313
Contact Person: Dwight Stephens
Telephone: 954 935 6786
Email: Dwight_stephens@sheriff.org
Services Provided / Term of Service: Phamatech provides drug screening & confirmation laboratory services, provides center for specimen collection including staff, transportation of specimen and statistical reporting / January 2009-present

Reference #3:
Los Angeles County Probation
9150 E Imperial Highway
Downey, CA 90242
Contact Person: Michael Exparza
Telephone: 562 940 3694
Email: michael.esparza@probation.lacounty.gov
Services Provided / Term of Service: Phamatech provides onsite drug screening devices, lab screening and confirmation services, specimen pickup and transportation, statistical reporting / March 2009-present

Reference #4:
Commonwealth of Pennsylvania, Department of Corrections
555 Walnut Street
Harrisburg, PA 17101
Contact Person: Michelle Quigley
Telephone: 717 728 4061
Email: miquigley@pa.gov
Services Provided / Term of Service: Phamatech provides lab screening and confirmation services, specimen pickup and transportation, statistical reporting / January 2009-present

Reference #5:

Luzerne County Probation
20 N Pennsylvania AVE
Wilkes-Barre, PA 18701
Contact Person: Carmen Lopresto
Telephone: 570 825 1730
Email: carmenlopresto@luzcoadultprobation.com
Services Provided / Term of Service: Phamatech provides onsite drug screening devices, lab screening and confirmation services, specimen pickup and transportation, statistical reporting / August 2009-present

Reference #6:
Fort Bend County CSCD
4520 Reading Road, Suite B
Rosenberg, TX 77471
Contact Person: Robert Goodwin
Telephone: 281 633 7239
Email: Robert.goodwin@fortbendcountx.gov
Services Provided / Term of Service: Phamatech provides onsite drug screening devices, lab screening and confirmation services, specimen pickup and transportation, statistical reporting / September 2002-August 2016.

Reference #7:
West Virginia Division of Juvenile Services
1200 Quarrier Street
Charleston, West Viriginia 25301
Contact Person: Jason Wright
Telephone: 304-558-9800
Email: Jason.r.wright@wv.gov
Services Provided / Term of Service: Phamatech provides lab screening and confirmation services, specimen pickup and transportation, statistical reporting / June 2016 –present.

KEY PERSONNEL:

CUSTOMER SERVICE PHONE: 858 635 5840

CUSTOMER SERVICE OFFICE HOURS: 5:00am – 5:00pm (PST)

Phone: 888 643 5840

Fax: 858 635 5843

The following individuals will be responsible for account supervision in their respective areas of expertise:

- Tuan Pham, PhD, CEO/President
- Tom Aucoin, PhD, Vice President of Laboratory
- Justin Pham, Laboratory Manager
- Krystina Blas, Executive Account Manager/Supervisor
- John Polanco, Vice President Sales
- Bonnie Filosa, Customer Service Manager
- Souk Sounakhene – IT LIMS Specialist/Systems Administrator
- Jodee Callaghan – Finance Manager

Laboratory Scientist

Thomas Aucoin, PhD – Vice President of Laboratory

Dr. Aucoin is currently responsible for the overall operation of PHAMATECH Laboratory drug testing services. He has been in the drug testing industry for more than 25 years, the last 11 years with PHAMATECH. Prior to joining PHAMATECH, Dr. Aucoin served as Vice President of Laboratory at LabCorp for more than 15 years. He is a certifying scientist and qualifies as an expert witness in the field of Toxicology. Dr. Aucoin holds a Ph.D. degree and is an inventor of numerous patents. Dr. Aucoin is responsible for ongoing consultation with the Laboratory Department regarding technical issues, changes in testing processes or regulations, and special test requests.

X 224 email: tgaucoin@aol.com - Please see complete curriculum vitae at the end of this section.

Certifying Scientist

Justin Pham – Laboratory Director

Justin Pham manages all of PHAMATECH laboratory day-to-day functions. He has more than 15 years of laboratory experience, the last 10 years with PHAMATECH. He has previously worked in managerial positions in the Toxicology department at LabCorp of America. Justin Pham is also qualified as a certifying Scientist and holds a B.S. degree. Mr. Pham will be responsible for certifying all laboratory results and answering client's questions regarding interpretation of results.

X 244 email: jpham@phamatech.com

Executive Account Manager/Supervisor

Kystina Blas – Executive Account Manager

Krystina has been in account management with Phamatech for over 3 years and interfaces with clients on a daily basis. Her duties include: updating client profiles; setting up clients' accounts and testing parameters; random selection; preparing statistical reports; verify invoices; communicate with clients regarding both new accounts and modifications to existing accounts. Krystina majored in business administration and will serve as the KEY ACCOUNT MANAGER for this contract; she will be accessible 24/7.

X 290 email: kblas@phamatech.com mobile: to be provided if awarded

Sales Director

John Polanco – Vice President Sales

John Polanco has been involved in the drug testing industry for more than 20 years and under PHAMATECH employment for 15 years. He currently serves as Vice President of Sales at PHAMATECH, responsible for some of the company's largest customers including the U.S. Federal Bureau of Prisons, the Salvation Army and numerous Probation Departments in Texas and throughout the country. Before merging his company Elite Health Services with PHAMATECH, he won several competitive bids; Harris County CSCD, Travis County Juvenile, El Paso Juvenile, El Paso CSCD, Angelina County, Smith County, Jefferson County, Tarrant County, Fort Bend County, American Airlines etc. He also operated his own collection site in Dallas, Texas. Additionally, Mr. Polanco holds B.S. and M.A. graduate degrees. Mr. Polanco will be responsible for ongoing consultation on issues concerning testing, reports, customer services, complaints and any other contractual matters.

X 227 email: john@phamatech.com

Customer Service Manager

Bonnie Filosa – Customer Service Manager

Bonnie holds a B.S. degree and has been with PHAMATECH for more than 18 years. She manages a team of customer service representatives that interact with clients daily. Prior to working at PHAMATECH, Bonnie worked in the customer service department at American Airlines. Bonnie and her team is responsible for coordinating all daily functions related to supplies, logistics, specimen collection, courier schedule, laboratory analysis, and reporting of results to the MRO or clients. They can be reached 24/7 by contacting our toll-free telephone.

X 229 email: bonnie@phamatech.com

IT / LIMS Specialist/System Administrator

Souk Sounakhene - Systems Administrator

Souk is a Systems Administrator with more than 15 years of experience in system analysis, laboratory LIMS management and support. He has extensive knowledge on lab functionality and workflow from start to finish. He also has extensive knowledge of the lab system and administration, enabling him to

perform tasks as an effective member of the information systems and laboratory support team. Souk is responsible for programming testing parameters, results and reporting format, as well as all web related functions.

X 268 email: ssounakhene@phamatech.com

Finance Manager

Jodee Callaghan – Finance Manager

Jodee has more than 20 years of experience in different accounting responsibilities, including purchasing, receivables, payables, billing, inventory control, and financing. She has been with Phamatech for more than 17 years and holds a B.S. degree. Jodee is responsible for all issues related to billing, payments, and credits.

X 240 email: jodee@phamatech.com

All key project team members that will be assigned to this contract have between 3-25+ years of experiences in providing drug testing services.

Through many years of experience and successful business relationships PHAMATECH has established a strong network. This network includes designated account representatives, substance abuse professionals and employees.

IN SUMMARY: PHAMATECH is extremely familiar with the requirements of this solicitation and is very capable of performing the services as described. PHAMATECH has current and past clients that require similar services to this RFP. With each of these contracts, Phamatech provides a customized turnkey drug testing program that follows strict chain of custody regulations and is defensible in court.

Thomas G. Aucoin Ph.D.

[redacted]

Education

Doctor of Philosophy Degree (1990)
Biomedical Science
Specialization in Toxicology
College of Pharmacy and Allied Health Professions
Northeastern University
Boston, MA

Master of Science Degree (1986)
Forensic Chemistry
College of Criminal Justice
College of Arts and Sciences
Northeastern University
Boston, MA

Bachelors of Art Degree (1983)
Biology / Chemistry
Point Loma College,
San Diego, CA

Non-Degree Student Status (1982)
University of California
Riverside, CA.

Professional Experience

Vice President of Laboratory Operations (2005-Present)
Phamatech, Inc
San Diego, CA
Initiation and development of a forensic toxicology laboratory to support company goals and objectives.

Vice President (1990-2005)
Laboratory Corporation of America
Research Triangle Park, NC.
Responsible for operations, profitability and performance of seven strategically located certified drug testing laboratories.

Associated Vice President
Laboratory Corporation of America
Research Triangle Park, NC.
Responsible for operations, profitability and performance of six strategically located certified drug testing laboratories.

Laboratory Director
Laboratory Corporation of America/National Health Laboratories
La Jolla, CA.
Responsible for the integration, standardization and acquisition of multiple forensic drug testing laboratories.

Operations Manager
Laboratory Corporation of America/ National Health Laboratories
La Jolla, CA.
Responsible for cost savings management, review and approval of capital expenditures, approval of laboratory personnel, insure scientific integrity, standardization of laboratory policies and procedures.

Associate Laboratory Director
Laboratory Corporation of America/National Health Laboratories/National Reference Laboratory
Nashville, TN.
Responsible for the establishment of a SAMHSA certified laboratory. Creation and maintenance of a positive operational income while maintaining the highest quality standards and client services in the Health care industry. Responsible for daily laboratory personnel management, client interaction, development and standardization of methodologies and to provide expert testimonies.

Supervisor
Laboratory Corporation of America/National Health Laboratories
San Diego, CA.
Responsible for the establishment of a SAMHSA certified laboratory. Creation and maintenance of a positive operational income while maintaining the highest quality standards and client services in the Health care industry. Responsible for daily laboratory personnel management, client interaction, development and standardization of methodologies and to provide expert testimonies.

Research Assistant (1988-1990)
Toxicology Department
College of Pharmacy and Allied Health Professions
Northeastern University
Boston, MA
Conducting independent research on NIH-NCI grant # CA47671

Forensic Scientist (1986-1987)
K-Chem Laboratories
Boston, MA
Consulted for several drug-related investigations and analyses.

Graduate Teaching Assistant (1986-1987)
Criminal Investigations and Forensic Science
College of Criminal Justice
Northeastern University
Boston, MA
Classroom and laboratory instruction for undergraduates focusing on forensic science, forensic toxicology and laboratory instrumentation.

Graduate Teaching Assistant (1985-1986)
Department of Pharmacology
College of Pharmacy and Allied Health Professions
Northeastern University
Boston, MA
Classroom and laboratory instruction in pharmacology and physiology for undergraduates on classical pharmacological actions and interactions.

Graduate Teaching Assistant (1985)
Department of Pharmacology
College of Pharmacy and Allied Health Professions
Northeastern University
Boston, MA
Classroom and laboratory instruction in pharmacology and physiology for undergraduates on classical pharmacological. actions and interactions.

Forensic Chemistry Internship (1985)
State Health Laboratories
State of Rhode Island and Providence Plantations
Observed and studied toxicological investigations of drugs, human autopsy specimens and animal specimens.

Chemist (1983-1984)
Deutsch Electronics
Oceanside, CA.
Chemist for electroplating facility and related plant operations.

Teaching Assistant (1981- 1983)
Dept. of Biology and Chemistry
Point Loma College
San Diego, CA
Laboratory instruction for undergraduates in biology and chemistry.

Publications

T. AuCoin and R. Schatz. Effects of o-xylene on glutathione synthesis and utilization. (abstract) Toxicologist 10(1) 1990.

T. AuCoin and R. Schatz. The effects of xylene isomers on glutathione metabolism (Abstract) . Toxicologist 9 (1) 1989.

T. AuCoin, G. Furman, C. LeBel, A. Roberts and R. Schatz. Effect of xylene isomers on rat brain microsomal membranes and glutathione levels (Abstract) . Toxicologist 8 (1) 1988.

L. King, T. AuCoin and R. Schatz. Effects of p-xylene on cerebral membranes (Abstract). Toxicologist 7 (1) 1987.

T. AuCoin and R. Schatz. The effects of L-methionine-d, 1-sulfoximine on cerebral sulfur-containing compounds (Abstract). Toxicologist 7 (1) 1987.

V. Heasley, K. Wade, T. AuCoin, O. Gipe, D. Shellhamer and G. Heasley. A study of the acid-catalyzed reaction of N-bromosuccinimide in methanol with some unsaturated carbonyl compounds. J. Org. Chem., Vol. 48, No 8, 1983.

Abstracts:

T. AuCoin and R. Schatz. Effect of o-xylene on glutathione synthesis and utilization. Northeast Regional Society of Toxicology, Sturbridge, MA , October 1989

T. AuCoin and R. Schatz. Xylene inhibits glutathione biosynthesis in rat liver. Northeast Regional Society of Toxicology, Boston , June, 1989

T. AuCoin and R. Schatz. Ortho-xylene inhibits glutathione synthesis in rat liver. New England Pharmacologists Eighteenth Annual meeting, Boston, MA, February 1989

T. AuCoin and R. Schatz. The effects of xylene isomers on glutathione metabolism. Northeast Regional Society of Toxicology, Sturbridge, MA, October 1988.

T. AuCoin, D. Silverman and R. Schatz. Effects of toluene and xylene on rat hepatic glutathione as related to lipid peroxidation. Northeast Regional Society of Toxicology, Boston, MA, June 1988.

G. Furman, T. AuCoin, C. LeBel, A. Roberts and R. Schatz. Alteration in rat brain microsomal membranes and glutathione levels in response to xylene isomers. New England Pharmacologists Seventeenth Annual meeting, Providence, RI, January 1988.

G. Furman, T. AuCoin, C. LeBel, A. Roberts and R. Schatz. Effect of xylene isomers on rat brain microsomal membranes and glutathione levels. Northeast Regional Society of Toxicology, Cambridge, MA, October 1987

T. AuCoin, D. Brown and R. Schatz. Effects of p-xylene on reduced and oxidized glutathione in rat liver and lung tissue. Northeast Regional Society of Toxicology, Pittsfield, MA, May 1987

T. AuCoin and R. Schatz. Effects of L-methionine-d, 1-sulfoximine on cerebral sulfur-containing compounds. New England, Phamacologists Sixteenth Annual meeting, Westborough, MA, January 1986

L. King, A. Roberts, T. AuCoin, and R. Schatz. Effect of p-xylene on cerebral and pulmonary membranes. Seventh Annual Undergraduate Research Service, West Virginia University, November 1986

C. LeBel, T. AuCoin, M. Gill and R. Schatz. Preconvulsant and anticonvulsant membrane fluidity effects. Northeast Regional Society of Toxicology, Groton, CT, October 1986.

Invited Seminars and Presentations:

T. AuCoin. "Smoking, drinking and solvent exposure". Chemistry/Biology Seminar Series. Eastern Nazarene College, Wollaston, MA, November 1988

T. AuCoin. "Forensic Toxicology ". New England Association of Chemistry Teachers. Museum of Science, Boston, MA, October 1989

T. AuCoin. "Toxicology". Occupational Safety and Health Fall Academy-Harvard School of Public Health. Wellesley, MA, October 1989

T. AuCoin. "Effects of organic solvents on glutathione metabolism". Massachusetts College of Pharmacy & Allied Health Sciences, Boston, MA January 1990.

Memberships

Society of Forensic Toxicologists
Student Member (1989)

Research Associates
Point Loma College
Past President
(1983-Present)

Society of Toxicology
Student Member (1988)

Society of Toxicology, Northeast Regional Chapter
Member (1985)

Rho Chi, Pharmacy Honor Society, Beta Tau Chapter
Member (1986)

New England Phamacologist
Member (1985)

American Academy of Forensic Scientist
Provisional Member (1988)

American Academy of Forensic Science
Trainee affiliate (1985- 1988)

Point Loma College Alumni Association
Member 2000

Organization of Forensic Scientists at
Northeastern University
Member (1984- 1986)
Treasurer (1985- 1986)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ COR1700000001

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[X]	Addendum No. 1	[ ]	Addendum No. 6
[X]	Addendum No. 2	[ ]	Addendum No. 7
[X]	Addendum No. 3	[ ]	Addendum No. 8
[X]	Addendum No. 4	[ ]	Addendum No. 9
[X]	Addendum No. 5	[ ]	Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Phamatech, Inc.

Company

Dana M. Conde

Authorized Signature

Dana M Conde / Contract Manager 10-17-16

Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.

Rev. 04/14

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. **Application is made for 2.5% vendor preference for the reason checked:**
   ____ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
   ____ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**
   ____ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% vendor preference for the reason checked:**
   ____ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% vendor preference for the reason checked:**
   ____ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% vendor preference for the reason checked:**
   ____ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**
   ____ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**
   ____ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. **Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules*.**
   XX Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: Phamatech, Inc. Signed: Dana M. Conde

Date: 10-12-16 Title: Dana M Conde / Contract Manager

THIS CERTIFIES THAT

Phamatech, Incorporated

NMSDC
National Minority Supplier Development Council

* Nationally certified by the: **PACIFIC SOUTHWEST MINORITY SUPPLIER DEVELOPMENT COUNCIL**

*NAICS Code(s): 325413; 424210; 541380; 621511

* Description of their product/services as defined by the North American Industry Classification System (NAICS)

05/12/2016

Issued Date

AZ01422

Certificate Number

Joset B. Wright-Lacy

05/31/2017

Expiration Date

Scott Gregory, President & CEO

By using your password (NMSDC issued only), authorized users may log into NMSDC Central to view the entire profile: http://nmsdc.org

Certify, Develop, Connect, Advocate.

* MBEs certified by an Affiliate of the National Minority Supplier Development Council, Inc.®

RFQ No. CRFQ COR1700000071

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Phamatech, Inc. / Dana M Conde / Contract Manager

Authorized Signature: Dana M. Conde Date: 10-18-16

State of California

County of San Diego, to-wit:

Taken, subscribed, and sworn to before me this 18th day of October, 20 16

My Commission expires Feb. 13, 2019.

AFFIX SEAL HERE

NOTARY PUBLIC Jodee Callaghan

JODEE CALLAGHAN
COMM. #2100011
NOTARY PUBLIC • CALIFORNIA
SAN DIEGO COUNTY
Commission Expires Feb. 13, 2019

Purchasing Affidavit (Revised 07/01/2012)

Exhibit A	CRFQ COR1700000001

COR238214 - Drug Testing Kits & Confirmation Services

Item No.	Description	Estimated Quantity	Unit Price	Extended Price	
1	6-Panel Urine Test Kit (Inmate/Parolee)	2000	$ 2.80	$ 5,600.00	
2	10-Panel Urine Test Kit (Inmate/Parolee)	30000	$ 3.45	$ 103,500.00	
3	13-Panel Urine Test Kit (Inmate/Parolee)	13000	$ 3.70	$ 48,100.00	
4	Oral Swab Test Kit (Inmate/Parolee) - 6panel	5000	$ 4.95	$ 24,750.00	
5	6-Panel Urine Test Kit (Employee)	100	$ 2.80	$ 280.00	
6	10-Panel Urine Test Kit (Employee)	100	$ 3.45	$ 345.00	
7	13-Panel Urine Test Kit (Employee)	100	$ 3.70	$ 370.00	
8	Oral Swab Test Kit (Employee) - 6panel	100	$ 4.95	$ 495.00	
9	Laboratory confirmation (Inmate/Parolee)	100	$ 11.00	$ 1,100.00	
10	Laboratory confirmation (Employee)	100	$ 11.00	$ 1,100.00	
11	MRO, or Lab Representative, as Expert Witness	100	$ 500.00	$ 50,000.00	
12	Training	1	NO CHARGE	NO CHARGE	
13	Emergency Delivery Order - PER 25test BOX&SUPPLIES	1	$ 20.00	$ 20.00	2 working days or less
14	Shipping Charge (less than 5 specimens per delivery)	1	$ 12.00	$ 12.00	
15	EtG and EtS testing	1000	$ 11.00	$ 11,000.00	
			Total Bid Amount	$ 246,672.00	

Bidder/Vendor Information

Name	Phamatech, Inc.
Address	15175 Innovation DR, San Diego, CA 92128
Phone Number	888.635.5840
Fax Number	858.635.5843
Email	dconde@phamtech.com
Authorized Signature	

Actual Quantities ordered may be more or less than noted on bid form Exhibit A