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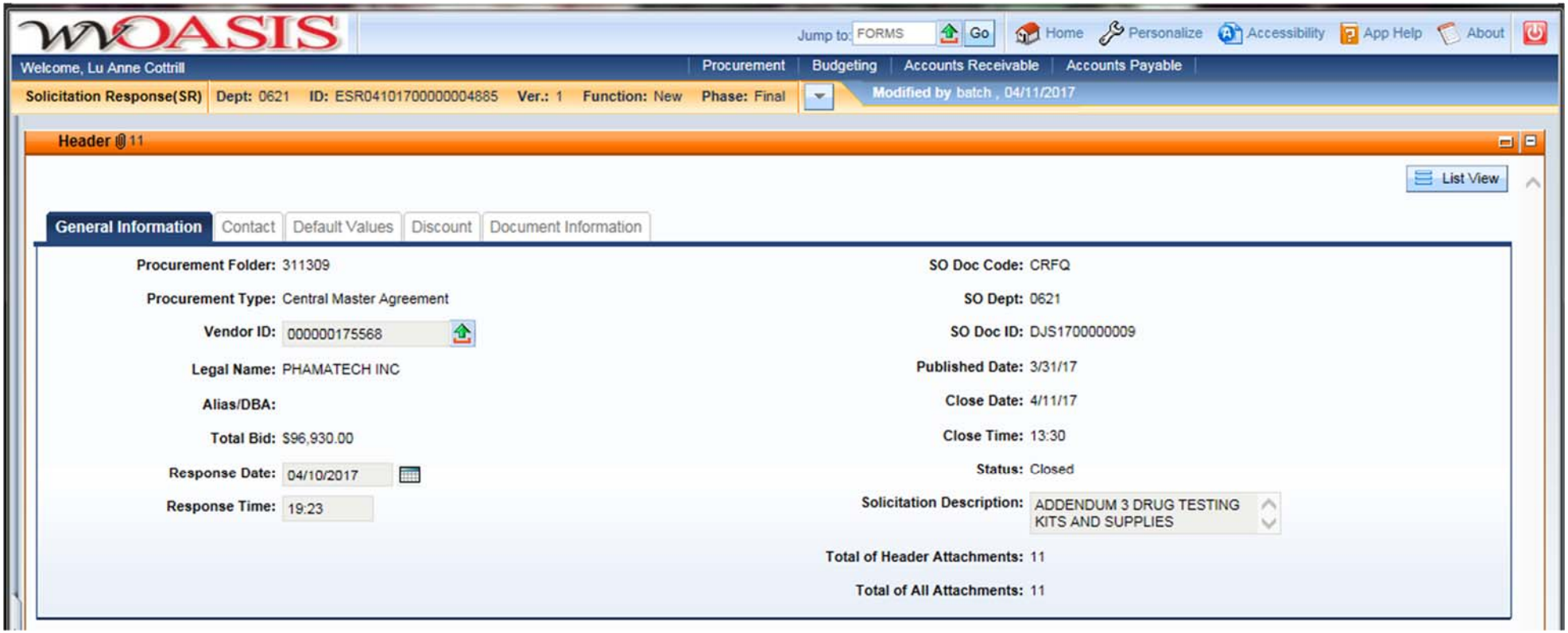
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About
Welcome, Lu Anne Cottrill
Procurement
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Solicitation Response(SR) Dept: 0621 ID: ESR04101700000004885 Ver.: 1 Function: New Phase: Final
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Header 11
List View
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Document Information
Procurement Folder: 311309
Procurement Type: Central Master Agreement
Vendor ID: 000000175568
Legal Name: PHAMATECH INC
Alias/DBA:
Total Bid: $96,930.00
Response Date: 04/10/2017
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SO Dept: 0621
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Status: Closed
Solicitation Description: ADDENDUM 3 DRUG TESTING KITS AND SUPPLIES
Total of Header Attachments: 11
Total of All Attachments: 11

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

# State of West Virginia
# Solicitation Response

**Proc Folder :** 311309

**Solicitation Description :** ADDENDUM 3 DRUG TESTING KITS AND SUPPLIES

**Proc Type :** Central Master Agreement

| Date issued | Solicitation Closes | Solicitation Response | Version |
|---|---|---|---|
| | 2017-04-11 13:30:00 | SR 0621 ESR04101700000004885 | 1 |

**VENDOR**

000000175568

PHAMATECH INC

**Solicitation Number:** CRFQ 0621 DJS1700000009

**Total Bid :** $96,930.00 **Response Date:** 2017-04-10 **Response Time:** 19:23:13

**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 | 13 Panel Urine Test Kit | 8000.00000 | EA | $3.900000 | $31,200.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** 13 Panel Urine Test Kit

**Comments:** ECO II Test Cup or QUICKSCREEN Test Cup

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 2 | 6- Panel Oral Swab Test Kit (Standard) | 500.00000 | EA | $4.050000 | $2,025.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** 6- Panel Oral Swab Test Kit (Standard) WV DJS USE

**Comments:** ORAL CUBE On-Site Saliva Kit

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 3 | 6- Panel Oral Swab Test Kit (Customizable) | 500.00000 | EA | $4.050000 | $2,025.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** 6- Panel Oral Swab Test Kit (Customizable) WV DOC USE

**Comments:** ORAL CUBE On-Site Saliva Kit - may take up to 4 weeks depending on drugs of abuse required and order quantity

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 4 | 8 Panel Urine Test Kit (Standard) | 600.00000 | EA | $2.400000 | $1,440.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 85121805 | | | |

**Extended Description :** 8 Panel Urine Test Kit (Standard) WV DJS USE

**Comments:** ECO II Test Cup or QUICKSCREEN Test Cup

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 5 | 8 Panel Urine Test Kit (Customizable) | 600.00000 | EA | $2.400000 | $1,440.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** 8 Panel Urine Test Kit (Customizable) WV DOC USE

**Comments:** ECO II Test cup or QUICKSCREEN Test Cup - may take up to 4 weeks depending on drugs of abuse required and order quantity

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 6 | Nicotine Test Only | 1200.00000 | EA | $0.450000 | $540.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** Nicotine Test Only

**Comments:** Single Panel Dipcard

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 7 | Buprenorphine Test Only | 800.00000 | EA | $0.450000 | $360.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** Buprenorphine Test Only

**Comments:** Single Panel Dipcard

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 8 | Laboratory Confirmation Services 8 Panel Urine | 2000.00000 | EA | $9.500000 | $19,000.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** Laboratory Confirmation Services 8 Panel Urine (Price Per Drug)

**Comments:** Overnight shipping of specimen samples to the laboratory is included in the cost if there are 4 or more samples in the Lab Pak. A Flat Fee of $10 will be assessed for every Lab Pak containing fewer that 4 samples.

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 9 | Laboratory Confirmation Services 13 Panel Urine | 2000.00000 | EA | $9.500000 | $19,000.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** Laboratory Confirmation Services 13 Panel Urine( Price Per Drug)

**Comments:** Overnight shipping of specimen samples to the laboratory is included in the cost if there are 4 or more samples in the Lab Pak. A Flat Fee of $10 will be assessed for every Lab Pak with fewer than 4 samples.

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 10 | EtG and EtS Testing (All Inclusive) | 2000.00000 | EA | $9.950000 | $19,900.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** EtG and EtS Testing (All Inclusive)

**Comments:** Overnight shipping of specimen samples to the laboratory is included in the cost if there are 4 or more samples in the Lab Pak. A Flat Fee of $10 will be assessed for every Lab Pak with fewer than 4 samples.

| Line | Comm Ln Desc | Qty | Unit Issue | Unit Price | Ln Total Or Contract Amount |
|---|---|---|---|---|---|
| 11 | MRO or Lab Rep As Expert Witness | 5.00000 | HOUR | $0.000000 | $0.00 |

| Comm Code | Manufacturer | Specification | Model # |
|---|---|---|---|
| 46151606 | | | |

**Extended Description :** MRO or Lab Rep As Expert Witness (Price Per Hour)

**Comments:** Phamatech will provide at no cost to the Agency testimony by telephone, web conference and video conferencing, or through sworn affidavit.

## SPECIFICTIONS

**Note: Any reference to The Agency, or Agency, refers to the *WV Division of Juvenile Services, West Virginia Division of Corrections and Parole Services and their respective agents or departments listed in the project.***

1. **PURPOSE AND SCOPE:** The West Virginia Purchasing Division is soliciting bids on behalf of the Division of Juvenile Services, West Virginia Division of Corrections and Parole Services 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.

   Within these Agencies there are multiple sites throughout the State of West Virginia. Locations for both WV Division of Juvenile Services and WV Division of Corrections.

   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.

**Phamatech understands the purpose and scope of CRFQ DJS1700000009 and concurs. Phamatech agrees to provide drug testing kits and associated supplies to the existing AGENCY facilities listed on Attachment A and 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 **"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.

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

Division.

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

**2.6** **"RFQ"** means the official request for quotation published by the Purchasing Division.

**2.7** **"STATEWIDE"** means that the vendor must provide services and commodities to all Division of Juvenile Services facilities and West Virginia Division of Corrections facilities including Parole Services facilities within the state of West Virginia.

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** - synthetic drugs such as ecstasy and bath salts
**MTD** - Methadone
**OPI** Opiates
**OXY** - oxycodone
**PCP** - Phencyclidine
**PPX** - Propoxyphene
**SynCANN** - Synthetic Cannabinoids (K.2/Spice)
**TCA** - Tricyclic antidepressants
**THC** Tetrahydrocannabinol/Marijuana
**NIC**-NICOTINE

**Phamatech understands the definitions and acronyms as noted in items 2.1 through 2.7.**

**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 detention and youth reporting centers, adult correction facilities, probation and parole testing, and employee testing, with a proven ability to process a high quantity of drug screens

**PHAMATECH is a minority owned corporation founded in 1991 by a group of dedicated toxicology experts. By combining, technical expertise, sound business strategies, and forensic and clinical experience PHAMATECH has grown from five employees to over 200 employees. PHAMATECH has become a major national provider of laboratory-based drugs of abuse testing services.**

**Currently, PHAMATECH performs laboratory-based drug testing on more than 100,000 specimens per month, PHAMATECH has the capacity, equipment, and resources to accommodate drug testing laboratory services for more than 300,000 specimens per month. PHAMATECH believes it is more than qualified and prepared to provide the services requested by The Agency.**

**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, (2009 – current)**
- **Maryland, Department of Public Safety and Corrections (2012 – current)**
- **County of Fresno, CA Department of Probation & Parole (2010 – current)**
- **Contra Costa County, California – Children and Family Services (2015-current)**

**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, web-based result reporting and statistical reporting. PHAMATECH specializes in high volume screening and confirmation testing. Phamatech's goal is to provide a customized turn-key drug testing program that follows strict chain of custody regulations and is defensible in court.**

**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.

**See Tab B - References**

**3.3** For laboratory services, Vendor should provide curriculum vitae ofLaboratory Director with bid. Documentation must be received prior to award.

**See Tab C – Key Personnel/Resumes**

**3.4** For laboratory services, Vendor shall be certified by the Substance Abuse & Mental Health Services Administration(SAMSHA), Current Controlled Substance Registration Certificate, and Clinical Laboratory Improvement Amendments (CLIA) for drug testing confirmations. Vendor shall provide proof of such certifications upon request by the Agency.

**PHAMATECH currently holds a Laboratory Permit with the Department of Health in the United States, and has been issued a license to operate a Clinical Laboratory for Toxicology testing of urine screening**

**and urine confirmations. Phamatech is also accredited by CAP-FUDT and certified by SAMHSA. In addition, PHAMATECH is CLIA certified, demonstrating compliance with the federal guidelines for human specimen testing.**

**See Tab D - Certifications**

3.5 Successful vendor must have their own laboratory and cannot contract out to a third party. Vendor must hold a clinical laboratory license to conduct the testing requested in this solicitation.

**Phamatech, Inc. meets this requirement and will not contract laboratory services to a third party; laboratory facility is located at 15175 Innovation Drive, San Diego, CA 92128.**

**See Tab D – Certification for Clinical Laboratory License**

## 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. Customizable All Inclusive On-site Urine Screening Device I Cup Instant Drug Test Kit 13 Panel or Equivalent

**4.1.1.1** The product shall render accurate results based on historical data and
overall averages for the device and drug configuration, within a (5) minute timeframe.

**4.1.,.2** The product shall have built in adulteration detection to aid in the prevention of sample tampering.

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

**4.1.1.4** 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.

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

**4.1.1.6** The product shall not leak during air/ground shipping.

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

**4.1.1.8** 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.

**4.1.1.9** The Product shall have a minimum 12 month shelf life.

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

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

A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimen cup
C. Chain of custody form

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

**Phamatech understands all requirements as listed in Items 4.1 through 4.1.1.12 in reference to the Customizable All Inclusive On-site Urine Screening Device (CUP) Instant Drug Test Kit 13 Panel being requested and proposes the ECO II™ Cup or the QUICKSCREEN CUP® for this purpose. We can guarantee that both products will meet or exceed all requirements as stated and can be easily customized to contain the drugs of abuse combination and cut off levels as desired.**

**Samples of the following will be provided upon request:**

- **Shipping Bag**
- **Shipping Container**
- **Chain of Custody Form**
-

Please see TAB E – Directional Inserts for complete details of both products

### 4.1.2 Panel Saliva Test for oral fluids 6 panel

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

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

**4.1.2.3** The product shall render accurate results based historical data and overall averages for this device and drug configuration within a five (5) minute timeframe

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

**4.1.2.5** 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

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

**4.1.2.7** The Product shall have a minimum 12-month shelf life.

**4.1.2.8** The product shall include Clinical Laboratory Improvement Amendments (CLIA) cutoff levels';"

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

A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimens
C. Chain of custody form

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

**4.1.2.11** The product shall have fast tum-around time from receipt of specimen (48 hours for negative, 72 hours for positive).

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

**4.1.2.13 For West Virginia Division of Corrections only:** 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.

**Phamatech understands all requirements as listed in Items 4.1.2 through 4.1.2.13 in reference to the Panel Saliva Test for oral fluids 6 panel to include AMP BAR COC MAMP OPI and THC being requested and proposes the ONE-STEP DRUG TEST ORAL CUBE Oral Fluid Drug Screen Device for this purpose. We can guarantee that it will meet or exceed all requirements, will be non-invasive and provide gender neutral collections. In addition, this product has a fast laboratory turn-around time and results will be available in the time frame requested.**

**Samples of the following will be provided upon request:**

- **Shipping Bag**
- **Shipping Container**
- **Chain of Custody Form**

**Please see TAB E – Directional Inserts for complete details of product**

**4.1.3 ALL Inclusive On-Site Urine Screening Device- I Cup Instant Drug Test Kit 8 panel or equivalent**

**4.1.3.1** The Product shall be an 8 panel test including COC, AMP, MAMP, THC, OPI, PCP, BAR, and BZO.

**4.1.3.2** The agency will need the ability to test separately for Nicotine (NIC) only and will be listed as separate line item.

**4.1.3.3** The agency will need the ability to test separately for Buprenorphine (BUP) only and will be listed as separate line item.

**4.1.3.4** The product shall render accurate results based

on historical data and overall averages for the device and drug configuration, within a (5) minute timeframe.

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

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

**4.1.3.7** 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

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

**4.1.3.9** The product shall not leak during air/ground shipping.

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

**4.1.3.11** The Product shall have a minimum 12 month shelf life.

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

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

A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimen cups
C. Chain of custody form

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

**4.1.3.15 For West Virginia Division of Corrections only:** 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.

**Phamatech understands all requirements as listed in Items 4.1.3.1 through 4.1.3.15 in reference to the Customizable All Inclusive On-site Urine Screening Device (CUP) Instant Drug Test Kit 8 Panel to include COC, AMP, MAMP, THC, OPI, PCP, BAR, BZD being requested and proposes the ECO II™ cup or the QUICKSCREEN CUP® for this purpose. We can guarantee that both products will meet or exceed all requirements as stated and can be easily customized to contain the drugs of abuse combination and cut off levels as desired.**

**Samples of the following will be provided upon request:**

- **Shipping Bag**
- **Shipping Container**
- **Chain of Custody Form**

**In reference to 4.1.3.2 NICOTINE (NIC) – Phamatech will provide a single panel dip card test for detection of this substance.**

**In reference to 4.1.3.3 BUPRENORPHINE (BUP) – Phamatech will provide a single panel dip card test for detection of this substance.**

**Samples of the following will be provided upon request:**

- **Shipping Bag**
- **Shipping Container**
- **Chain of Custody Form**

**Please see TAB E – Directional Inserts for complete details of products**

**SUPPLIES AND MATERIALS**

**PHAMATECH will provide all supplies; chain of custody forms, test result reporting forms, and testing supplies. Testing supplies will include all items necessary to maintain chain of custody requirements such as: bottles, caps, wands, bags, forms, seals, packing materials, and labels. Shipping will be included in the pricing cost.**

**PHAMATECH will provide each site with pre-printed labels, identifying the program and site, for tracking purposes. However, before pre-printing any labels PHAMATECH will consult with The County authorized contact(s) to get their approval on the information being printed on the labels.**

### 4.1.4 Training

**4.1.4.1** 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 any change 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.

**PHAMATECH will provide in-person training at no additional cost to the Agency. In person training sessions include:**

- **Different types of drug screening available; urine, saliva, hair, etc. with advantages and disadvantages of each**
- **Drug of abuse trends; locally and nationally**
- **How to spot the drug abuser**
- **Drug chart handouts**
- **Drug cross reaction sheet handout**
- **How to perform drug screens with on-site devices consistent with manufacturer recommendations**
- **How to read drug test results with interpretation**
- **Minimum and maximum detection periods for drug of abuse**
- **Adulterants/Substitution in urine and saliva**
- **Explain what a chain of custody form is and how to complete chain of custody form that is defensible in a court of law**
- **Other subject matter at the request of the Agency**
- **Certificate upon completion of training**

### 4.1.5 Additional Testing Kit Requirements

**4.1.5.1** 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.

**The 13panel cups and 8panel cups will have built in validity testing for three or more of the above stated adulterants. This will not be possible for the salvia test or the single panel dipcards.**

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

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

**4.1.5.4** Drug testing kits shall be capable of producing results

within five (5) minutes and results shall be stable for a minimum of one hour.

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

**4.1.5.6** Drug testing kit shall not require refrigeration.

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

**The 13panel test cups and 8panel tests cups will have a built in temperature strip to indicate the validity of the specimen. This will not be possible for the salvia test or the single panel dipcards.**

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

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

**4.1.5.10** 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.

**4.1.5.11** The label shall provide a place to enter collection time, date, and juvenile's initials.

**4.1.5.12 For West Virginia Division of Corrections only:** 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.

**Phamatech understands all requirements as listed in Items 4.1.5.1 through 4.1.5.12 in reference to the Additional Testing Kit Requirements being requested and will provide only product that meets the requirements unless otherwise noted.**

**The single panel NIC and BUP tests and the Oral Cube saliva tests will not include a built-in temperature strip or adulteration strip.**

### 4.1.6 Packaging

**4.1.6.1** The Drug Test Kits shall be provided in a sealed bag with

lot number, expiration date, drugs cut- off levels.

**4.1.6.2** Vendor shall to supply clear sealable shipping bags and sturdy cardboard shipping containers or lab packs for shipping positive results for lab confirmation.

**4.1.6.3** The name and location of each Division of Juvenile Services (DJS) Facility as listed in Attachment A. The Vendor shall provide the contract items) at contract price, to any additional DJS facility(s) that may open, or require equipment and supplies during the course of the contract.

**Phamatech will meet all packaging requirements as listed in items 4.1.6.1 through 4.1.6.3 and also understands that there may be a time when The Agency adds additional facilities. Phamatech is willing to accommodate additional facilities when and if this situation occurs.**

### 4.1.7 Laboratory Confirmation Services

**4.1.7.1** 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

**SUPPLIES AND MATERIALS**

**PHAMATECH will provide all supplies; chain of custody forms, test result reporting forms, and testing supplies. Testing supplies will include all items necessary to maintain chain of custody requirements such as: bottles, caps, wands, bags, forms, seals, packing materials, and labels. Shipping will be included in the pricing cost.**

**PHAMATECH will provide each site with pre-printed labels, identifying the program and site, for tracking purposes. However, before pre-printing any labels PHAMATECH will consult with The County authorized contact(s) to get their approval on the information being printed on the labels.**

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

**Phamatech will confirm necessary tests by GC/MS Gas Chromatography Mass Spectrometry (GC/MS) and/or Liquid Chromatography (LC/MS/MS) as appropriate. Our pricing is all inclusive and will include**

all charges/costs necessary to provide results.

**4.1.7.3** The confirmation laboratory shall be currently certified and maintain certification by the Clinical Laboratory Improvement Amendments (CLIA) for offender confirmations, meet the industry standards for the drug testing programs. A copy of the certification should be provided upon request.

**4.1.7.4** The confirmation laboratory may, for offender testing, be performed by certified Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories and meet industry standards.

**4.1.7.5** If the SAMSHA, and/or CLIA certification of the confirmation laboratory is suspended or revoked, Vendor shall notify Agency within ten (I 0) business days.

**Phamatech is a SAMHSA and CLIA certified laboratory; if at any time a certification is suspended or revoked, the Agency will be notified immediately.**

**Please see TAB D – Laboratory Certifications**

**4.1.7.6** 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) itmust 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).

**Juvenile/Adult Offender and Staff:** The purpose of this testing is for juvenile/adult justice purposes. As such, the Agency requires that the confirmation lab test to limit of detection (LOD), which is 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 facility discipline and juvenile court proceedings.

**Phamatech understands the confirmation requirements and will use GC/MS and/or**

LC/MS/MS as appropriate; both methods meet the criteria as stated in item 4.1.7.6 and will be defensible in court. Phamatech's lab will test to limit of detection (LOD) and will be able to provide testimony for any court proceedings if requested.

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, web conference and video conferencing, or through sworn affidavit. At all times the following expert witnesses will be available: Dr. Thomas Aucoin (VP of laboratory), and/or 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.

Chain of Custody:

Since the Chain of custody protocol is extremely vital with the entire specimen collection process, PHAMATECH will ensure that all involved are aware of the importance of this process. The following represents the entire Chain of Custody protocol (both external as well as internal controls) that must be adhered to in order to maintain the legal defensibility in a court of law.

External Chain of Custody (Control)-ECC - The test request/referral initiates Chain of Custody (CC) form. The external chain of custody documentation process follows proper legally defendable procedures if required in a court of law. The CC process adheres to strict SAMHSA guidelines. The CC form is completed during the specimen collection. For efficiency and standardization the test request and forensic CC form are integrated on the same form. Every CC form has a preprinted number with like numbered temper evident security seals for proper cross-referencing with the specimen sample. The preprinted CC forms will provide a smoother collection process for the specimen collector and mitigates errors.

The required information on the test request and CC form include the following: The collection site name, Donor I.D., the collection site address, Collector (collection site) contact telephone numbers, verification of Donor, specimen temperature, type of specimen collection (single or split), whether the specimen collection was observed, Donor contact telephone numbers, Donor date of birth, type of drug test request panel that is requested by the AGENCY, Donor authorization to perform the specimen collection (printed name and signature) with date of specimen collection, specimen collector certification of donor identification with date and time of specimen collection, specimen collector release of specimen to the specified courier, and finally, certification from PHAMATECH laboratory technician receiving the specimen with notation if specimen was intact or not (specimen container seal, specimen bio-bag sealed, etc.) at the time of receipt, (see External Chain of Custody Control overview below).

After the specimen collection has occurred, the test request and CC form is completed, as stated above. The completed original CC form with the specimen (Donor initialed/dated tempered

evident seal placed over specimen bottle) is placed inside the bio-bag. The bio-bag is sealed with another temper donor initialed temper evident seal (every PHAMATECH CC form has two temper evident seals; A &B). The bio-bag is partitioned. On one side the sealed specimen bottle is placed and in the other partition the completed CC form is inserted. The partition protects the CC form from getting wet, in the event that the specimen leaks in transit. At this point the specimens are ready to be picked up by PHAMATECH's own courier network or overnight delivery service. Since the specimens are sealed with tamper evident material the Federal Register (Section 40.25) does not apply. However, PHAMATECH will maintain daily specimen receipt logbooks. The delivery of the specimens by PHAMATECH's couriers/overnight delivery service to PHAMATECH's laboratory starts the documentation associated with Internal Chain of Custody standards. The entire External Chain of Custody standards cited above assures that the drug test results are correctly processed and that the specimen is not compromised.

ECC overview

The AGENCY (orders the drug test) Chain of Custody Form/Test Request/Referral

A. Specimen Collector Responsibilities

-Agency name/address/telephone numbers ***

-Donor ID verification

-Reason for test

-Collection site address ***

-Collection site contact telephone numbers***

-Specimen temperature recorded (within 4 minutes of collection)

-Single/split specimen collection

-Observed specimen collection

-Test request ***

-Specimen collector certification

-Specimen collector authorize release of specimen to courier – specimens will be sent to PHAMATECH within 24 hours of collection M-F, Saturday & Sunday will be sent to the lab on Monday.

***This information will be preprinted on the CC forms

B. Specimen Donor Responsibilities

-Contact telephone numbers

-Provide date of birth and identification

-Reason for test

-Authorizes specimen collection

-Prints name

-Provides signature

-Dates specimen authorization

-Initials and dates temper evident seals

C. Courier

-Accepts specimen from specimen collector

-Daily specimen receipt log is noted

D. PHAMATECH

-Certifies receipt of specimens

- Initiates Internal Chain of Custody

Internal Chain of Custody (Control)-ICC – this process begins with the acceptance of the specimens from PHAMATECH's courier or overnight delivery service. The courier completes the specimen delivery with shipment logs to PHAMATECH at the end of the day. All specimens are delivered to a secured area of the laboratory following SAMHSA federally regulated protocol. Only authorized PHAMATECH laboratory technicians are granted access into the locked secured area (every door has a keypad lock system with technician log in/out books). Each and every specimen is physically opened and inspected ensuring that the CC form matches the specimen donor, accordingly. To solidify the defendable aspect of the CC protocol, the temper evident seal that appears on every specimen must be intact. Every specimen sent to the laboratory must have a donor temper evident label over the specimen container otherwise the specimen is considered compromised. As additional security the bio-bag containing the specimen container also has a temper evident seal over the bio-bag closure. All findings of the initial specimen observation are documented in the form of deficiencies, problems or fatal flaws. All the specimen observation data is entered into our Laboratory Information Management System (LIMS).

The second step of the ICC process involves a reconciliation of all the information provided on the CC form. The last step of the ICC process consists of a summation of all of the following observations: agreement between specimen identification and unique CC number, agreement between the donor name and any additional identifying information (case ID, social security number, etc.), if specimen volume is sufficient to run the drug test panel, certification of the specimen collector with signature and date of specimen collection, authorization of the donor allowing the specimen collection with date and time of specimen collection, specimen temperature noted within 4 minutes of collection, test requests made and any collector remarks noted during the specimen collection.

The data gathered from the ICC process results in records generated both in LIMS based (electronic) and hardcopy formats. The hardcopy format includes: PHAMATECH's laboratory technicians that received the specimens, opened the specimen containers, generated LIMS barcodes on the specimen containers, and who returned the specimens to the secured sample storage area. The electronic format includes the specific test requests, any ECC process deficiencies, any and all PHAMATECH technicians that handled the specimens with actual date and times, and who ordered the test from the AGENCY.

PHAMATECH will maintain in storage, at no additional cost to the AGENCY, all positive urine specimens for the length of time specified in the RFQ.

**4.1.7.7** 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.

**4.1.7.8** 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.

**Phamatech will test for alcohol (ethanol) as stated in items 4.1.7.7 and 4.1.7.8 and will report EtS in conjuction with EtG using cutoff level of 100ng/ml.**

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

**Phamatech will provide overnight courier service via UPS for all samples and specimens.**

**4.1.7.10** 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.

**Upon receipt of urine specimens and while undergoing initial testing, the specimens are maintained in a secure location within the forensic laboratory. After initial test is performed, specimens that are negative on the initial test are stored for 10 working days pending additional testing or additional test requests. Specimens that are presumptive positives and undergo confirmatory testing are transferred to and stored in a locked walk-in freezer for long term frozen storage for one (1) year.**

**Temporary Storage Space for negative results: 2,000 square feet**

**Long Term Storage Space for confirmed positive results: Freezer 12x53x43 square feet – estimated storage of 1M specimens.**

**All documentation will be kept for a minimum of three (3) years.**

**LAB RESULTS REPORTING:**

**PHAMATECH will provide and maintain a secured web based system for The Agency and other authorized Agency 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 48 to 36 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 The Agency 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.**

**4.1.7.11** 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.

Neil J. Dash MD, P.C.
WEBSITE: drsmro.net

**For over 10 years, Phamatech has used the above stated established MRO Group whose members are physicians and are certified by the American Board of Addiction Medicine as well as the American Association of Medical Review Officers.**

**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, web conference and video**

**conferencing, or through sworn affidavit. At all times the following expert witnesses will be available: Dr. Thomas Aucoin (VP of laboratory), and/or 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.**

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

**Phamatech understands this requirement and concurs.**

## 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.

**Phamatech understands Contract Award and Pricing Pages items 5.1 through 5.2.2 as noted.**

**Please see TAB F – Pricing Page / Exhibit A (Revised)**

**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.

**Phamatech acknowledges and concurs.**

**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.

**Phamatech has the ability to and will accept orders through wvOASIS, regular mail, facsimile, email or any other written form of communication. Phamatech does not currently support a program to accept 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.

**Phamatech acknowledges and concurs.**

**7.3** **Invoicing:** Invoices will be submitted per facility on a monthly basis. Vendor will submit a required backup documentation for every invoice submitted. Vendor will use the chain of custody ID number per test on all backup documentation. No juvenile names are to be used.

**On a monthly basis, Phamatech will submit hard copies of all on-site product ordered and distributed per facility with required backup documentation for every invoice as requested; backup documentation will be dictated by the AGENCY as far as content. For all laboratory tests ordered, the Chain of Custody ID number will be used to identify each test and no juvenile names will be used.**

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: CHAIN OF CUSTODY ID NUMBER, 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:** 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.

**Phamatech acknowledges and concurs.**

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

**9.6** **For West Virginia Division of Corrections:** No keys or passes shall be given to anyone who is not a West Virginia Division of Corrections or Parole Services employee. The agency will allow appropriate and necessary access to what is necessary upon requested approval.

**Phamatech understands and acknowledges items 9.1 through 9.6 in reference to FACILITIES ACCESS however, under the performance requirements of this RFQ, does not anticipate the need to issue access cards and/or keys to any of the Agency's facilities.**

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.0.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.

**Phamatech understands and concurs with Items 10.1 through 10.3 as stated:**

**Phamatech will provide standard five (5) day delivery of on-site product and supply**

orders (F.O.B destination) at no additional charge to the Agency. Emergency orders for on-site product and/or supplies will be delivered within two (2) working days with the Agency being responsible for delivery charges on all emergency

orders; Phamatech will invoice those delivery costs as a separate charge with the original freight bill attached to the invoice.
Phamatech will notify the Agency of any delay in delivery (outside the standard five (5 )days or two (2) day emergency time frames).

In reference to return of on-site devices Items 10-4 and 10-5, Phamatech understands and will honor terms as stated.

## 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.

Phamatech understands and concurs with Items 11.1 through 11.2.3 in reference to Vendor Default.

## 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.

**Phamatech will await prior approval before modification or substitution of any product or service proposed in response to this RFQ. Phamatech will not make any modifications or substitutions prior to receiving approval from The Agency first.**

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.

**Phamatech acknowledges this requirement and concurs.**

12.3 **Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.

**Phamatech agrees to provide quarterly, annual and upon request reports and summaries that include items purchased, quantities and total dollar value as requested.**

**In addition, PHAMATECH has the ability to provide comprehensive laboratory statistical reports that 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 or Quarterly reports of each test performed by site in alphabetical order.**
- **Monthly or Quarterly 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:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

**Contract Manager:** Krystina Blas – Senior Account Manager
**Telephone Number:** 888-635-5840 X 290
**Fax Number:** 858-635-5843
**Email Address:** kblas@phamatech.com

REFERENCES:

1. The Sheriff of Broward County
   Dwight Stephens – Treatment Manager/Drug Court Treatment Division
   Phone: (954) 935-6786
   Email: Dwight_stephens@sheriff.org
   Contract: 01-2009 to present

Phamatech provides and staffs a local specimen collection service center that performs random selection, specimen collection, specimen pickup and transportation to the lab, lab screening and confirmation services, results and statistical reporting – apprx. 60,000 tests per year

2. Maryland Department of Public Safety & Correctional Services
   Victor Caldarola – Contract Compliance Manager
   Phone: (410) 585-3531
   Email: vcaldarola@dpscs.state.md.us
   Contract: 09-2012 to present

Phamatech provides specimen collections, pickup and transportation of specimens, laboratory screen and confirmations, results and statistical reporting – apprx. 135,000 tests per year

3. US Federal Bureau of Prisons
   Donna Grube / Contracting Officer
   Phone: (202) 616-6150
   Email: dgrube@bop.gov
   Contract: 07-2007 to present

Phamatech provides customized on-site drug screening devices (apprx. 260,000 integrated cups per year) to over 180 locations throughout the U.S. Also performs transportation of specimen, screen and confirmation laboratory services, results and statistical reporting – apprx. 12,500 tests per year

4. Commonwealth of Pennsylvania, Department of Corrections
   Russ Ilgenfritz – Purchasing Agent
   Phone: (717) 728-3919
   Email: rilgenfrit@pa.gov
   Contract: 01-2009 to present

Phamatech provides customized on-site drug screening devices (integrated cups and opiate panels) to 70+ locations. Also performs transportation of specimen, screen and confirmation services, results and statistical reporting – apprx. 265,000 tests per year

**KEY PERSONNEL**

Phamatech will utilize an account manager to oversee the account and to act as a liaison between Phamatech and the client. Phamatech will assign a single point of contact and that person will disseminate information to the appropriate department. The account manager will oversee operations and ensure that all the needs and issues are being handled accordingly. The account manager will be involved in account transitions, set-up, training, billing, and all facets of adapting to your program in a timely and efficient manner; fulfilling all of the statement of work. Phamatech will use its knowledge and experience to meet and exceed the current needs and qualifications for this RFQ.

**Krystina Blas – Senior Account Manager X 290**

**Phone: 888 635 5840 Fax: 858 635 5843**

POINTS OF CONTACT

All of PHAMATECH's project team members have between 5-25 years of experiences in providing drug testing services. The following individuals will be responsible for supervision in their respective areas of expertise:

- Dr. Tuan Pham, President and Owner/CEO
- Dr. Tom Aucoin, Vice President of Laboratory
- Justin Pham, Laboratory Manager
- Krystina Blas, Executive Account Manager Supervisor
- John Polanco, Sales Director – Contract Management
- Bonnie Filosa, Customer Service Manager
- Souk Sounakhene – IT Systems Administrator

***President/CEO – Tuan Pham, PhD***

Mr. Tuan Pham founded Phamatech in 1992 and currently is the Company's President and Chief Executive Officer. Prior to founding Phamatech, he held various positions in manufacturing, operation, research, and management with Brunswick Biotechnetics and BD Pharmingen. Mr. Tuan Pham holds a doctorate degree in Biochemistry from the University of California, San Diego and has been awarded numerous US and international patents in biotechnology. He also serves on the board of various local non-profit organizations.

*Laboratory Director*

**Dr. Thomas Aucoin – 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 10 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. *(Complete resume included at end of this section)*

*Certifying Scientist*

**Justin Pham – Director of Lab Operations**

Justin Pham manages all of PHAMATECH laboratory day-to-day functions and holds a B.S. degree from the University of California, San Diego. He has more than 15 years of laboratory experience, the last 9 years with PHAMATECH. He has previously worked in managerial positions in the Toxicology department at LabCorp and Scripps Research. Justin Pham is also qualified as a certifying Scientist. Mr. Pham will be responsible for certifying all laboratory results and answering client's questions regarding interpretation of results. *(Complete resume included at end of this section)*

*Account Manager Supervisor*

**Krystina Blas – Senior Account Manager**

Krystina has been employed at Phamatech for almost three 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 will serve as the Account Manager for this contract and can be reached 24/7 for urgent account situations should any arise.

Prior to Phamatech, Krystina worked with Millennium Laboratories, Home Legal Source and Unitrin Direct Auto Insurance functioning as a supervisor, lead customer service representative and supervisor and sales support specialist for over 11 years. She attended University of Phoenix and Arizona Western College where she majored in business administration and minored in accounting . *(Complete resume included at end of this section)*

*Sales Director*

**John Polanco – Vice President Sales**

John Polanco has been involved in the drug testing industry for more than 19 years and under Phamatech employment for 14 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 had 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 the initial main contact for this contract and is responsible for ongoing consultation to the Department on issues concerning testing, reports, customer services, complaints and any other contractual matters. He will provide account management support to the Senior Account Manager when necessary. *(Complete resume included at end of this section)*

*Customer Service Manager*

**Bonnie Filosa – Customer Service Manager**

Bonnie has been with Phamatech for more than 17 years. She manages a team of customer service representatives that interact with clients daily. Prior to working at Phamatech, Bonnie works in the customer service department at American Airlines. Bonnie holds a B.S. degree. 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. *(Complete resume included at end of this section)*

*IT System Coordinator*

**Souk Sounakhene – Information Systems Administrator /LIMS Specialist**

Souk is a Systems Administrator with more than 10 years of experience in system analysis, laboratory LIMS management and support and has worked in this capacity for Phamatech for over 8 years. 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.

- Knowledge in Microsoft Windows 9x/2000/XP O.S., Microsoft Office Products, Microsoft DOS, Microsoft Group Policies, Novell Client, Local Area Network (LAN), proxy server, system backup, internet, DHCP, TCP/IP, FTP, Anti-Virus software, and software installation and configuration.

- Knowledge in IBM compatible computers, Wi-Fi network, Cisco VPN, routers, switches, VPN, firewalls, network setup, network printer and hard drive sharing, network security, cable routing, VT terminal setup, hardware installation and configuration.

- Troubleshoot PC hardware/software problems and assemble computers. Perform PC repair and upgrades when necessary. PC lockdown and security. Configure and setup new PCs.

EDUCATION: San Diego State University, CA Computer Science Field. *(Complete resume included at end of this section)*

**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

## Professional Experience

***Vice President of Laboratory Operations (2005- present)***
Phamatech, Inc., San Diego, CA
Initiate 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 costs 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, Nashville, TN
Responsible for the establishment of a SAMHSA certified Laboratory. Creation and maintenance of a positive operational income while maintaining the highest quality of 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 of 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 # CA 47671

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

**Publications**

T. AuCoin was a part of (10) ten publications/abstracts.

**Invited Seminars & Presentations**

T. AuCoin has presented information on Forensic Toxicology and other similar areas.

**Memberships**

American Academy of Forensic Scientist- Provisional Member (1988 – present)
Research Associates – Pt. Loma College Past President (1983 – present)
Society of Toxicologists – Student Member (1989)
Society of Toxicology – Student Member (1988)
Society of Toxicology, Northeast Regional Chapter (1985)
Rho Chi, Pharmacy Honor Society, Beta Tau Chapter – (1986)
New England Pharmacologist- (1985)

For court appearances PHAMATECH offers: in person expert witness, teleconferencing, and pretrial litigation packages to defend any legally challenged drug test results, testimony by telephone, video conferencing, or through sworn affidavit. To date PHAMATECH has not lost one case in defending the integrity of any confirmed positive drug test results.

**JUSTIN PHAM**

[redacted]

## CAREER OBJECTIVE:

**To Secure a Technologist Position at Phamatech, Inc.**

## QUALIFICATION PROFILE:

Experienced in forensic drug testing screening using EMIT (Syva) technology.
Enzyme multiplied immunoassay technique (Syva Emit II Plus Reagent).
Using SDS - Page method, Agarose Gel Electrophoresis, skilled in processes of Alkaline Lysis Mini - Preps, Pcr, and Southern Plotting.

## EDUCATION & TRAINING:

**University Of California San Diego** - San Diego, CA
**Bachelor Of Science** - 2000

**Olympus America Inc,** DIAGNOSTIC SYSTEMS GROUP - Dallas, TX
AU5400 Olympus training class - 2005
AU640 Olympus training class – 2006

## EMPLOYMENT EXPERIENCE:

**Phamatech, Inc.** **2006 - Present**
Certifying Scientist

- Producing and analyzing immunoassay (IA) data, certifying negative results, relaying prospective positives for further testing and verifying the completeness and continuity of chain custody documents associated with clients samples.
- Operating, calibrating and maintaining IA instruments (Olympus AU640 and AU400)

**Laboratory Corporation Of America** **2001 - 2006**
Laboratory Technologist

- Producing and analyzing immunoassay (IA) data, certifying negative results, relaying prospective positives for further testing and verifying the completeness and continuity of chain custody documents associated with clients samples.

- Operating, calibrating and maintaining IA instruments (Olympus AU800, AU5200, and AU5400)
- Scrutinizing suspect samples for possible adulteration.

Negative Certifying Scientist

- Evaluate and reviewed IA results from drug screening facility.
- Certifying negative IA results and relaying presumptive positives for verification.
- Evaluating the validity of quality control measures for samples batteries.

Lab Assistant

- Receiving and preparing specimens for analysis.
- Recording and accessioning federal and non - federal specimens.
- Ali quoting samples for IA and GC/MS, data entry,specimen collection, cataloging and storing.

**The Scripps Research institute** **1999 - 2000**
Jr. Research Associate

- Autoclaving, preparing of media, reagent and chemical (I.e.LB agar, Y.E.S, Y.E.P.D 50% Glycerol, TAE/TbA Buffer)

**Biosite Diagnostics, Inc.** **1999**
Lab Assistant

- Assisting lab personnel with antibody production, washing glassware, restocking lab supplies, preparing buffers and autoclaving.

**Herco Technology Corporation** **1999**
Lab Assistant

- Chemical analysis involving titrations, updating pre-control and chemical lab charts.

E-mail kblas@phamatech.com

# Krystina P. Blas

**Summary of qualifications**

Over 13 years of combined experience in sales and customer service. Possess excellent verbal, written and organizational skills. Proficient in Microsoft Outlook, Word, Excel, PowerPoint and Access.

**Professional experience**

09/2015 – Current Phamatech Laboratories San Diego, CA

***Senior Account Manager***

- Manage all Government contracts
- Run monthly reports for clients
- Assist clients with contract/specimen inquiries
- Manage the implementation of new accounts
- Manager to out-of-state collectors
- Provide training for new hires
- Supervise Key Account Representatives
- Assist laboratory with pending samples
- Perform DOT and NON-DOT collections

02/2015 – 09/2015 Phamatech Laboratories San Diego, CA

***Account Manager***

- Manage assigned key accounts
- Run monthly reports for assigned key accounts
- Assist clients with order/specimen inquiries
- Perform DOT and NON-DOT collections

05/2013 – 02/2015 Phamatech Laboratories San Diego, CA

***Customer Service Representative***

- Process lab and product orders
- Assist clients with scheduling UPS pickups and specimen inquiries
- Assist the laboratory with resolving any specimen issues
- Assist training new Customer Service Reps
- Perform DOT and NON-DOT collections

08/2010 – 08/2011 Millennium Laboratories, Inc. San Diego, CA

***Sales Support Specialist***

- Manage key accounts
- Run daily, weekly and monthly reports for key accounts
- Assist AR and Billing with invoicing for key accounts
- Assist Sales Representatives in managing standard accounts
- Set up new accounts
- Assist the Specimen Resolution department by obtaining any missing patient and/or specimen information
- Provide training for new hires (Sales Reps and Sales Support Reps)
- Assist direct Manager with interviewing/screening new candidates

10/2008 – 07/2010 Home Legal Source Carlsbad, CA

***Customer Service Supervisor***

- Supervise 10-15 customer service representatives in the Loss

Mitigation Department

- Pre-qualify clients for loan modifications and deed-in-lieu's by completing a Financial Analysis of their income/expenses
- Communicate the status of each file with the client on a weekly basis
- Process approximately 150 loan modifications and deed-in-lieu files
- Maintain details of each file accurately in Sugar CRM
- Act as liaison between clients and lenders

1/2007 – 08/2008 Artisan Confections Company San Francisco, CA

***Lead Customer Service Representative***

- Assist Wholesale Customers with their accounts, setting up new accounts and answering inquiries regarding our product/orders
- Process Wholesale orders in Syspro
- Responsible for processing all Distributor orders
- Assist our Regional Sales Team with managing Distributor accounts
- Responsible for invoicing and delegating aspects of that task to co-workers
- Responsible for distributing Daily Sales Reports to our Sales Department via MS Access
- Responsible for processing orders, invoicing and exporting catalogs via EDI for Retail Accounts

03/2002 – 12/2006 Unitrin Direct Auto Insurance Vista, CA

***Inside Sales Specialist***

- Obtain information and properly qualify customers per underwriting guidelines to provide insurance quotes
- Provide assistance to Sales Representatives by answering underwriting questions and demonstrating various sales techniques
- Met and exceeded monthly sales goals
- Maintained 90% or better quality

**Education**

2003 - 2005 University of Phoenix San Diego, CA
Major: Business Administration
Minor: Accounting

08/1999 – 02/2001 Arizona Western College Yuma, AZ
Major: Business Administration

# JOHN POLANCO

## NATIONAL SALES DIRECTOR

OCT 2001- PRESENT — PHAMATECH, INC.

Merged my company, Elite Health Services, with Phamatech, Inc. Laboratories & Diagnostics (Phamatech) on October 11, 2001 and accepted full time employment under contract. Primary responsibility was to develop the product business, selling instant drug screening diagnostic devices to the corrections market. Additionally, instituted my government contract knowledge and expanded Phamatech's market presence. Currently, in addition to product expansion, I am also responsible for all laboratory sales and management with National Key Account Management responsibilities for all awarded contracts.

I am responsible for Phamatech being awarded numerous local, state, and national contracts - GSA, MMCAP, TXMAS, CMAS, etc. Was also instrumental in generating millions of dollars in new business to Phamatech; inclusive of the multi-million dollar Federal Bureau of Prisons contract.

Hired, trained and supervised several personnel. Have experience in all levels of drug testing specimen collection: hair, urine, saliva, etc. Also, have trained hundreds of staff from various contract clients nationally in the area of drug testing procedures and proper specimen collection, (DOT, Workplace, probation, corrections, etc.).

## PRESIDENT/CEO

1996-2001 — ELITE HEALTH SERVICS, INC.

Started a drug testing company as a third party administrator generating thousands and thousands of dollars worth of, laboratory and product, drug testing sales. I was awarded numerous contracts, i.e., Harris County ($500,000 dollars per year), Tarrant County ($250,000 per year), American Airlines Arena ($100,000 per year- with demands of over 100 urine specimens daily), and various other smaller contracts. Also, held the Dallas County Child Protective Services Contract. Provided urine, hair and saliva specimen collection and laboratory processing with occasional court testimony.

Additionally, well versed with numerous instant drug screening products. Eventually, becoming one of the top national distributors of instant drug testing devices.

## SALES/MARKETING INDEPENENT CONTRACTOR

1993-1996 — SELF EMPLOYED

Responsible for establishing sales for various companies in the greater West South Central United States Territory, especially in the state of Texas. Researched statistical data and established numerous professional contacts generating thousands of dollars in new sales for various clients where they didn't have business sales before. Success in this field open the doors for start of my company Elite Health Services, Inc.

## EDUCATION

BS/MA – Arizona State University
DATIA CERTIED PROFESSIONAL COLLECTOR
VARIOUS SALES & MARKETING TRAINING SEMINARS

**Bonnie M. Filosa**

[redacted]

## RELEVANT SKILLS

- Advanced computer skills, proficient in Microsoft Word, Excel, Outlook, Great Plains, FileMaker, Horizon, BarTender and GoldMine.
- Exceptional communication skills.
- Management experience.
- Resourceful, motivated, dedicated, team player.

## WORK EXPERIENCE

### Customer Fulfillment Manager

**Phamatech, Inc.**, San Diego, CA — July 1998 – Present

- Responsible for managing a highly professional Customer Service team.
- Interface with diverse range of clientele.
- Responsible for managing a Kit Assembly Department and for scheduling final production of goods in a timely, efficient manner.
- Liaison with retailers such as Walgreen's and Rite-Aid regarding new product development and order status.
- Implementing new products (packaging, design, components, operations).
- Setting and maintaining minimum and maximum inventory levels of both finished goods and raw materials.
- Maintaining strong vendor relations.
- Handling escalated customer service calls and resolving them quickly and courteously.
- Processing Retail, Domestic and International orders while following the strictest standards and procedures.
- Continuously providing training to over twenty full-time employees.
- Implementing cost saving methods whenever possible.

### Customer Service Representative

**US Airways, Inc.**, San Diego, CA — August 1997 – July 1998

- Completed extensive six week training course at corporate headquarters in Pittsburgh, PA.
- Handled hundreds of inbound calls per day courteously and professionally.
- Performance evaluations approached 100%.
- Adhered to strict scheduling guidelines.

### Student Advisor

**Kaplan Educational Center**, San Diego, CA — August 1996 – August 1997

- Interact with up to two hundred customers per day in fast-paced office environment; answer phones; conduct marketing events; sell product over the phone and to walk in customers; perform general office duties. (Awarded merit raise after first six-month review).

### Server

**Filippi's Pizza Grotto**, San Diego, CA — August 1995 – August 1996

### Merchandise Sales

**Disneyland**, Anaheim, CA — March 1993 – September 1993

## EDUCATION:

***Bachelor of Arts***, San Diego State University

SOUK SOUNAKHENE
[redacted]

## PROFESSIONAL EXPERIENCE

### PHAMATECH INC., San Diego, CA

**Information Systems Administrator I** 2007 to Present

Information System Administrator providing hardware and software supports for on-site and remote users. Horizon LIMS support, implementation and project management. Implement and support client interface with Horizon LIMS system.

- System administration for both internal and remote employees.
- Perform scheduled maintenance and backup on servers.
- Program writing and table configuration in Horizon LIMS to accommodate laboratory needs.
- Ensured that all personnel are properly informed and communicated to in a timely efficient manner.
- Ensured that the laboratory information system is properly validated.
- Provide acceptable responses to internal or external corrective actions.
- Project management of new interface projects, Horizon LIMS testing and client side testing.
- Project management of new/modified Horizon LIMS projects. Validate new codes with vendor and implement new features into Horizon LIMS system.

### LABORATORY CORPORATION OF AMERICA, San Diego, CA 2002 to 2007

**Computer Support Administrator**

Information System Support Administrator providing hardware and software support for both on-site and remote lab users. Provide client onsite training and installation of LabCorp's patient management software. Implement and support customer interface with LabCorp's system.

- System administration for both internal and remote employees.
- Support multiple pc configurations (laptops and desktops) physically for on-site support and remote application (realVNC and pcAnywhere) for remote employees.
- Configuration of pc and software installation. Upgrade systems to meet software requirements.
- Network security. PC security and lockdown. Setup and configure Microsoft Group Policies.
- Setup/configure lab VT terminal and hand held scanners.

- LIS (Laboratory Information Systems) setup and support in both pc and VT terminal setup.
- Provide software training to LabCorp employees.
- Open and resolve problem tickets in a timely manner.
- Maintain software licensing records.
- RMA and service calls with vendors to resolve instrument issues.
- Train client to use LabCorp' s patient management software.
- Patient Service Center site DSL/Cisco VPN/Netgate Wireless installation and troubleshooting. Connecting remote LabCorp sites with main lab systems.
- Install bridge software interfacing client's Practice Management software with LabCorp's patient management software.
- Client Product Software installation, training and support.
- Client printer and software support for patient result reporting.

- Client site survey for EDI interface requirement. Test and verify that EDI solution performs as required by client's specifications. EDI validation testing between LabCorp and client's Practice Management system. Verify and validate HL7 files between LabCorp and client duringtesting.
- Project Management: validate, implement, test and train usage of new programs for both internal and external clients.

**QUEST DIAGNOSTICS, San Diego, CA 1992 to 2002**

***Substance Abuse Forensic Laboratory Supervisor***

Manage forensic laboratory of 40 employees in compliance with U.S. Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Transportation (DOT), and Occupational Safety & Health Administration (OSHA) guidelines. Laboratory provides health care substance abuse testing for clients involved in mandatory employee drug testing. Materials handled are forensically secure and confidential in a forensic controlled environment.

- Managed day-to-day activities, production schedule for employees and provided training to employees to meet with regulated state and governing laws.
- Involved in projects such as Implementing Process Improvement to cut down redundant work processing and improve employee productivity.
- Revise and update department Standard Operation Procedure (SOP) manuals.
- Managed Records Department and all forensic Chain of Custodies.
- Implemented employee recognition programs and ensured employee satisfactions within the company.
- Conducted employee yearly evaluations and merit increases.
- Handled and processed specimens for testing, including data entry,

specimen labeling and sample aliquots.

- Counseled employees with personal and professional needs ai ld provide moral support.
- Provided safe and hazard free work environment for employees.
- Provided IT support to technical part of the laboratory (networking, software and hardware support and pc configurations).
- Managed External Quality Control Department for three years; duties included client interaction, external Quality Control support, clinical testing, sample preparation, sample testing and validation and sample stability studies.

## COMPUTER SKILLS

- Knowledge in Microsoft Windows 9x/2000/XP O.S., Microsoft Office Products, Microsoft DOS, Microsoft Group Policies, Novell Client, Local Area Network (LAN), proxy server, system backup, internet, DHCP, TCP/IP, FTP, Anti-Virus software, and software installation and configuration.
- Knowledge in IBM compatible computers, Wi-Fi network, Cisco VPN, routers, switches, VPN, firewalls, network setup, network printer and hard drive sharing, network security, cable routing, VT terminal setup, hardware installation and configuration.
- Troubleshoot PC hardware/software problems and assemble computers. Perform PC repair and upgrades when necessary. PC lockdown and security. Configure and setup new PCs.

## EDUCATION

San Diego State University, CA
Computer Science Field

# 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services
Center for Substance Abuse Prevention
Center for Substance Abuse Treatment
Rockville MD 20857

JUN 0 4 2007

Thomas G. Aucoin, Ph.D.
Mr. Ken Kodama
Phamatech, Inc.
10151 Barnes Canyon Road
San Diego, California 92121

Dear Dr. Aucoin and Mr. Kodama:

I am pleased to inform you that Phamatech, Inc., San Diego, California, has successfully met all of the requirements for laboratory certification as specified in the Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644).

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

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

If you have any questions concerning the HHS National Laboratory Certification Program, please contact the Division of Workplace Programs at (240) 276-2600.

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

Sincerely,

Terry L. Cline

Terry L. Cline, Ph.D.
Administrator

# 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

COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

**Phamatech Labs**
**San Diego, California**
**Thomas Aucoin, PhD**

CAP Number: 7210751
AU-ID: 1512089

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Forensic Drug Testing Accreditation Program. Reinspection should occur prior to January 27, 2018 to maintain accreditation.

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

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RP0347903 | 03-31-2018 | $244.00 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 1,2,2N<br>3,3N,4,5 | ANALYTICAL LAB | 03-22-2017 |

PHAMATECH INC.
THOMAS AUCOIN PH.D.
15175 INNOVATION DRIVE
SAN DIEGO, CA 92128

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

# State of California Department of Public Health

## CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

**PHAMATECH, INC**
**15175 INNOVATION DRIVE**
**SAN DIEGO CA 92128**

**OWNER(S):**
PHAMATECH, INC
TUAN H PHAM

**DIRECTOR(S):**
NOEMI AMITINA MD

**Lab ID Number: CLF 00336862**
**Effective Date: February 01, 2017**
**Valid Until: January 31, 2018**
CLIA Number: 05D1078844

Robert J. Thomas

Robert J. Thomas, Chief
Laboratory Field Services

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www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

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DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Frances M. Harding
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Sincerely,

Terry L. Cline

Terry L. Cline, Ph.D.
Administrator

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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

COLLEGE of AMERICAN PATHOLOGISTS

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CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RP0347903 | 03-31-2018 | $244.00 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 1,2,2N<br>3,3N,4,5 | ANALYTICAL LAB | 03-22-2017 |

PHAMATECH INC.
THOMAS AUCOIN PH.D.
15175 INNOVATION DRIVE
SAN DIEGO, CA 92128

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

# State of California Department of Public Health

## CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

**PHAMATECH, INC**
**15175 INNOVATION DRIVE**
**SAN DIEGO CA 92128**

**OWNER(S):**
PHAMATECH, INC
TUAN H PHAM

**DIRECTOR(S):**
NOEMI AMITINA MD

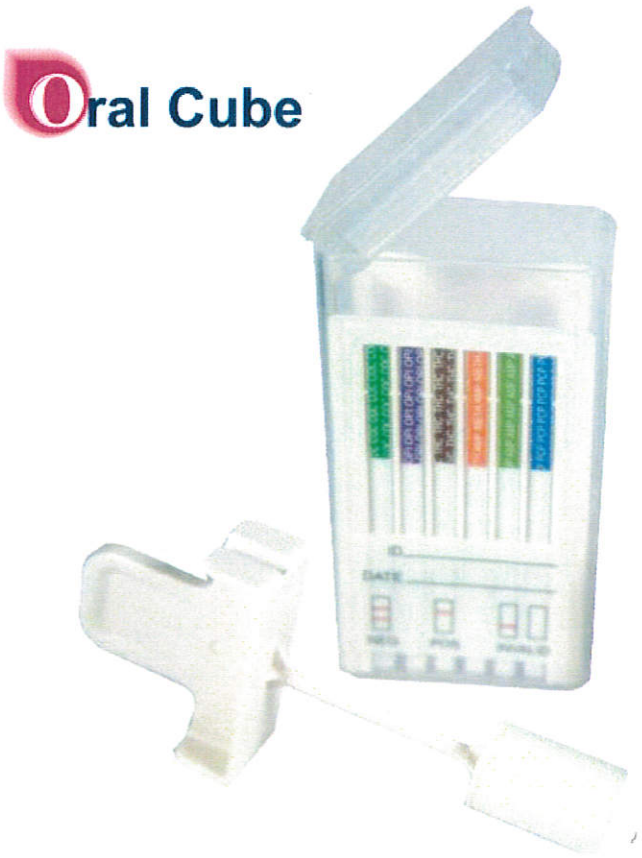
**Lab ID Number: CLF 00336862**
**Effective Date: February 01, 2017**
**Valid Until: January 31, 2018**
CLIA Number: 05D1078844

Robert J. Thomas

Robert J. Thomas, Chief
Laboratory Field Services

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 Oral Cube 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™

## 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-$\Delta^9$-THC-9 COOH | 12 ng/mL |
| | $\Delta^9$-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-$\Delta^9$-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 $\Delta^9$-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[6]

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

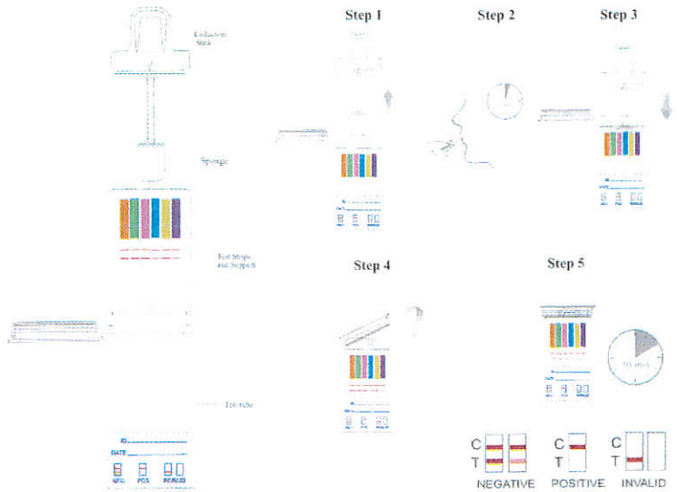
Materials Required But Not Provided

• 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 |

| | |
|---|---|
| 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 |

| | |
|---|---|
| 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.

## BIBLIOGRAPHY


1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox.1984 Sep-Oct.; 8 (5), pp 197-201.
5. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735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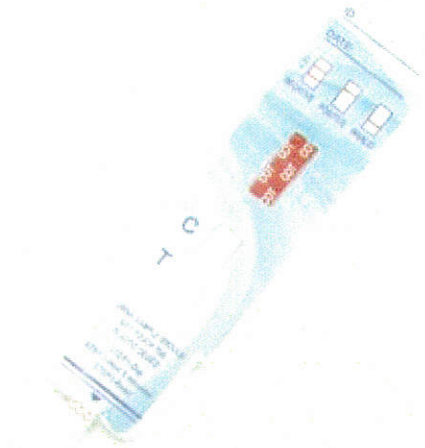


# ONE STEP INSTANT URINE NICOTINE TEST DIP CARD FEATURES

One step instant urine nicotine test dip card is an easy-to-use instant urine test that detects cotinine in human urine. Cotinine is a metabolite left over after the body processes nicotine and is the preferred way to test for nicotine use.

- Detects Tobacco Use For up to 3 Days
- One-Step Cotinine (Nicotine) Urine Dip Card
- 200 ng/ml Cut Off Level
- Read Results Within 5 Minutes
- Easy-To-Use, One Step Instant Drug Testing Process
- Great for Nicotine-Related Studies and Research
- Great For Use in Workplace Testing as Well as Insurance Companies, Medical Practices and Research Programs
- 25 Tests Per Box

# ONE STEP INSTANT BUPRENORPHINE TEST DIP CARD FEATURES

- Detects Buprenorphine Use For up to 4 Days
- 10 ng/ml Cut Off Level
- Read Results in 5 Minutes – Provides an Instant Drug Test Result
- Easy-To-Use, One Step Buprenorphine Drug Test
- Best Alternative to the Traditional Laboratory Urine Drug Test
- 25 Dips Per Box

# COT

## One Step Cotinine Test Dipcard
## Package Insert

*A rapid, one step test for the qualitative detection of Cotinine (nicotine metabolite) in human urine.*
*For Determination of Smoking Status Only.*

### INTENDED USE

The One Step Cotinine Test Dipcard is a lateral flow chromatographic immunoassay for the detection of Cotinine(nicotine metabolite) in human urine.

| Test | Calibrator | Cut-off |
|---|---|---|
| Cotinine (COT) | Cotinine | 200ng/mL |

**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) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

### Summary

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.1 While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.2 Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

### PRINCIPLE

The One Step Cotinine Test Dipcard is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200ng/mL, will not saturate the binding sites of the antibody coated particles in the test Dipcard. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.

### REAGENTS

The test Dipcard contains mouse monoclonal anti-Cotinine antibody-coupled particles and Cotinine-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test Dipcard should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Dipcard should be discarded according to federal, state and local regulations.

### STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Dipcard is stable through the expiration date printed on the sealed pouch. The test Dipcard must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

**Urine Assay**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

**Specimen Storage**

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

**Materials Provided**

- Test Dipcard • Desiccants • Package insert

**Materials Required But Not Provided**

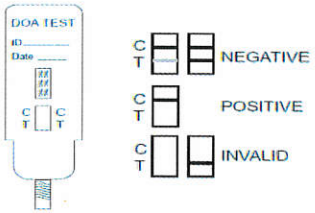
- Specimen collection container
- Timer

### DIRECTIONS FOR USE

**Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.**

1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.




### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:* Two lines appear**. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Cotinine concentration is below the detectable level (300ng/mL).

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

**POSITIVE: One red line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Cotinine concentration exceeds the detectable level (300ng/mL).

**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 Dipcard. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A red 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.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

1. The COT One Step Cotinine Test Device (Urine) 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) is the preferred confirmatory method.1,2
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates only that the presence of Cotinine is above the cut-off concentration. It does not indicate or measure level of consumption.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

**Reproducibility**

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

| Cotinine conc.(ng/mL) | Total number of Determinations | Result | Precision |
|---|---|---|---|
| No drug present | 40 | 40 negative | >99% |
| 100 | 40 | 40 negative | >99% |

| | | | |
|---|---|---|---|
| 300 | 40 | 40 positive | >99% |
| 400 | 40 | 40 positive | >99% |

## Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

| COT Concentration (ng/mL) | Percent of Cut-off | n | Visual Result | |
|---|---|---|---|---|
| | | | Negative | Positive |
| 0 | 0 | 90 | 90 | 0 |
| 100 | -50% | 90 | 90 | 0 |
| 150 | -25% | 90 | 90 | 0 |
| 200 | Cut-off | 90 | 49 | 41 |
| 250 | +25% | 90 | 0 | 90 |
| 300 | +50% | 90 | 0 | 90 |
| 400 | +100% | 90 | 0 | 90 |

## Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step Cotinine Test Dipcard (Urine) at a read time of 5 minutes.

| Drug | Concentration (ng/ml) |
|---|---|
| Cotinine | 200 |
| Nicotine | 6,250 |
| | |

## Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Cotinine Test Dipcard was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

## Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Cotinine Test Dipcard. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

## Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cotinine positive urine. The following compounds show no cross-reactivity when tested with The One Step Cotinine Test Dipcard (Urine) at a concentration of 100 µg/mL.

## Non Cross Reacting Compounds

| | | | |
|---|---|---|---|
| Acetophenetidin | l-Cotinine | Cortisone | d-Pseudoephedrine |
| N-Acetylprocainamid | Creatinine | Ketoprofen | Quinidine |
| Acetylsalicylic acid | Deoxycorticosterone | Labetalol | Quinine |
| Aminopyrine | Dextromethorphan | Loperamide | Salicylic acid |
| Amoxicillin | Diclofenac | Meprobamate | Serotonin |
| Ampicillin | Diflunisal | Methoxyphenamine | Sulfamethazine |
| Ascorbic acid | Digoxin | Methylphenidate | Sulindac |
| Codeine | Diphenhydramine | Nalidixic acid | Tetracycline |
| Aspartame | Ethyl-p-aminobenzoate | Naproxen | Tetrahydrocortisone, 3-Acetate |
| Atropine | β-Estradiol | Niacinamide | |
| Benzilic acid | Estrone-3-sulfate | Nifedipine | Tetrahydrocortisone |
| Benzoic acid | Erythromycin | Norethindrone | Tetrahydrozoline |
| Bilirubin | Fenoprofen | Noscapine | Thiamine |
| d,l-Brompheniramine | Furosemide | d,l-Octopamine | Thioridazine |
| Caffeine | Gentisic acid | Oxalic acid | d,l-Tyrosine |
| Cannabidiol | Hemoglobin | Oxolinic acid | Tolbutamide |
| Chloralhydrate | Hydralazine | Oxymetazoline | Triamterene |
| Chloramphenicol | Hydrochlorothiazide | Papaverine | Trifluoperazine |
| Chlorothiazide | Hydrocortisone | Penicillin-G | Trimethoprim |
| d,l-Chlorpheniramine | o-Hydroxyhippuric acid | Perphenazine | d,l-Tryptophan |
| Chlorpromazine | 3-Hydroxytyramine | Phenelzine | Uric acid |
| Cholesterol | d,l-Isoproterenol | Prednisone | Verapamil |
| Clonidine | Isoxsuprine | d,l-Propanolol | Zomepirac |

## BIBLIOGRAPHY


1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747
2. Hardman JG and Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

# CLIA WAIVED
# One Step Buprenorphine Urine Test
### Catalog No. See Pouch label

One Step Buprenorphine Urine Test is a rapid test for the qualitative detection of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The Buprenorphine assay will yield preliminary positive results when Buprenorphine is ingested at or above therapeutic doses.

*For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.*

## WHAT IS ONE STEP BUPRENORPHINE URINE TEST?

One Step Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine. It is intended for over-the-counter and for prescription use.

The test is intended for over-the-counter (OTC) use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing - the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is not provided.

## WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

| Drug(Identifier) | Cut-off level | Minimum detection time | Maximum detection time |
|---|---|---|---|
| Buprenorphine/BUP | 10 ng/mL | 4 hours | 1-3 days |

## WARNINGS AND PRECAUTIONS

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

## CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is only for storage purposes only, and is not used in the test procedures.
2. Urine cups. (Optional)
3. Leaflet with instructions for use.

## STORAGE AND STABILITY

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

## SPECIMEN COLLECTION AND PREPARATION

### *WHEN TO COLLECT URINE FOR THE TEST?*

The minimum detection time is 4 hours, so you may collect urine samples 4 hours after suspected drug use.

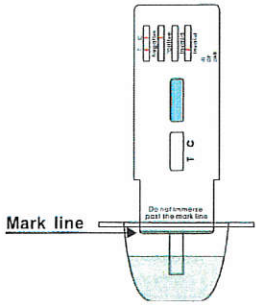
### *HOW TO COLLECT URINE?*

1. Urinate directly into the provided urine cup. Urine samples may be refrigerated (2°C~8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
2. Bring frozen or refrigerated samples to room temperature before testing.

## HOW TO DO THE TEST?

Test must be in room temperature (18°C to 30°C)

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



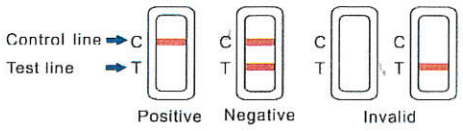

***Note:** Results after more than 5 minutes may be not accurate and should not be read.*

## READING THE RESULTS

**Preliminary positive (+)**
A rose-pink band is visible in the control region. No color band appears in the test region. It indicates a preliminary positive result for the Buprenorphine.

**Negative (-)**
A rose-pink band is visible in the control region and the test region. It indicates that the concentration of Buprenorphine is zero or below the detection limit of the test.

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




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

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

**IMPORTANT:** The result you obtained is ( sample must be tested by laboratory in ord actually present. Send any sample which laboratory for further testing.

**What Is A False Positive Test?**
The definition of a false positive test would is identified incorrectly by One Step Bu common causes of a false positive test are medicines, diet plan drugs and nutritiona positive test result with this product.

**What Is A False Negative Test?**
The definition of a false negative test i present but isn't detected by One Step sample is diluted, or the sample is adulter result.

## TEST LIMITATIONS

1. This test has been developed for te fluids have been evaluated. DO NOT urine.
2. Adulterated urine samples may p oxidizing agents such as bleach (hyp If a sample is suspected of being adı
3. This test is a qualitative screening a the quantitative concentration of drug

**The test is also intended for prescriptio the reference of prescription users. TH AND PRECAUTIONS, CONTENT OF THI HOW TO DO THE TEST, READIN LIMITATIONS also apply to the prescrip**

The test provides only preliminary test r chemical method must be used in order to GC/MS or LC/MS are the preferrec consideration and professional judgment s abuse test result, particularly when the pre

## SUMMARY

Buprenorphine is a potent analgesic ofte addiction. The drug is sold under the tra Temgesic™ and Suboxone™, which cont combination with Naloxone HCl. Therapeu substitution treatment for opioid addicts. medical care offered to opiate addicts (pı similar or identical substance to the drug n Buprenorphine is as effective as Methador physical dependence. The plasma half-li While complete elimination of a single-dos days, the detection window for the pare approximately 3 days. The One Step One S is a rapid urine screening test that can b instrument. The test utilizes a monoclo elevated levels of Buprenorphine in u Buprenorphine Urine Test Strip yield Buprenorphine in urine exceed 10 ng/ml.

## PRINCIPLE

One Step One Step Buprenorphine Urine

% agreement among positives is 100% (95% Confidence Interval 84.5% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 82% - 100%)

Viewer B:

| Result | Drug-free | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|---|---|---|---|---|---|
| Positive | 0 | 0 | 1 | 16 | 24 |
| Negative | 10 | 18 | 11 | 0 | 0 |

% agreement among positives is 100% (95% Confidence Interval 84.5% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 82% - 100%)

Viewer C:

| Result | Drug-free | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) |
|---|---|---|---|---|---|
| Positive | 0 | 0 | 2 | 16 | 24 |
| Negative | 10 | 18 | 10 | 0 | 0 |

% agreement among positives is 100% (95% Confidence Interval 84.5% - 100%)
% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 100%
The average negative agreement is 96.7%

## Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75% and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots. Totally 3 operators participated in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot.

Lot 1

| Approximate concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|---|---|
| 0 | 50 | 50/0 |
| 2.5 | 50 | 50/0 |
| 5.0 | 50 | 50/0 |
| 7.5 | 50 | 50/0 |
| 10.0 | 50 | 5/45 |
| 12.5 | 50 | 0/50 |
| 15.0 | 50 | 0/50 |
| 17.5 | 50 | 0/50 |
| 20.0 | 50 | 0/50 |

Lot 2

| Approximate concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|---|---|
| 0 | 50 | 50/0 |
| 2.5 | 50 | 50/0 |
| 5.0 | 50 | 50/0 |
| 7.5 | 50 | 50/0 |
| 10.0 | 50 | 5/45 |
| 12.5 | 50 | 0/50 |
| 15.0 | 50 | 0/50 |
| 17.5 | 50 | 0/50 |
| 20.0 | 50 | 0/50 |

Lot 3

| Approximate concentration of sample (ng/mL) | Number of determinations | Results Negative/ Positive |
|---|---|---|
| 0 | 50 | 50/0 |
| 2.5 | 50 | 50/0 |
| 5.0 | 50 | 50/0 |
| 7.5 | 50 | 50/0 |
| 10.0 | 50 | 6/44 |
| 12.5 | 50 | 0/50 |
| 15.0 | 50 | 0/50 |
| 17.5 | 50 | 0/50 |
| 20.0 | 50 | 0/50 |

## Specificity and cross reactivity

To test the specificity of the test, the test device was used to test Buprenorphine, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

| Component | Concentration (ng/ml) |
|---|---|
| Buprenorphine | 10 |
| Buprenorphine 3-D-Glucuronide | 15 |
| Norbuprenorphine | 20 |
| Norbuprenorphine 3-D-Glucuronide | 200 |

## Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.0( with Buprenorphine at 25% below and 25% was tested by three batches of One Step E Three laboratory assistants read the result p that varying ranges of urinary specific gravit

## Effect of Urinary pH

The pH of an aliquot negative urine pool is in 1 pH unit increments and spiked with Bu 25% above cutoff levels. Each sample was Step Buprenorphine Urine Test dip card. T the result per batch. The result demonstra not interfere with the performance of the tes

## Interfering substances

Clinical urine samples may contain sub interfere with the test. The following comp urine, urine with a Buprenorphine concentr urine with a Buprenorphine concentratio potential interferents were added at a conc the urine samples showed any deviation fro

| Non Cross-Reacting Co | |
|---|---|
| Acelophenetidin | Mepro |
| Nalidixic acid | Metho |
| Acelylsalicylic acid | Nalidix |
| Aminopyrine | Naloxc |
| Amoxicillin | Naltre |
| Ampicillin | Napro |
| L-Phenylephrine | Niacin |
| Apomorphine | Nifedi |
| Aspartame | Isoxsu |
| Atropine | D,L-Pr |
| Benzilic acid | Ketopr |
| Benzoic acid | Noreth |
| Benzphetamine | D-Nor |
| Bilirubin | Nosca |
| Deoxycorticosterone | D,L-Oc |
| Caffeine | Oxalic |
| Chloralhydrate | Oxolin |
| Chloramphenicol | Oxyme |
| Chlorothiazide | Papav |
| D,L-Chlolrpheniramine | Penicil |
| Chlorpromazine | Perphe |
| Chlorquine | Phene |
| Cholesterol | L-Pher |
| Clonidine | β-Pher |
| L-Cotinine | Pheny |
| Cortisone | Predni |
| Creatinine | Lopera |
| D-Pseudoephedrine | Quinin |
| Dextromethorphan | Quinid |
| β-Dglucuronide | Ranitic |
| Diclofenac | Salicyl |
| Diflunisal | Seroto |
| Digoxin | Sulfam |
| Diphenhydramine | Sulind |
| L-Ephedrine | Tetracy |
| Ecgonine methylester | Tetrah |
| Ethyl-p-aminobenzoate | Morphi |
| β-Estradiol | Tetrah |
| Estrone-3-sulfate | Thiami |
| Erythromycin | Thiorid |

| Pricing Page- Exhibit A (Revised) | | | | |
|---|---|---|---|---|
| CRFQ DJS1700000009 Drug Testing Kits and Supplies | | | | |
| **Item #** | **Description** | **Estimated Annual Qty.** | **Unit Price** | *** Extended Price** |
| **4.1.1** | 13 Panel Urine Test Kit | 8000 | **$3.90** | $31,200.00 |
| **4.1.2** | Oral Swab Test Kit-6 Panel (Standard) WV DJS USE | 500 | **$4.05** | $2,025.00 |
| **4.1.2.13** | Oral Swab Test Kit-6 Panel (Customizable) WV DOC USE | 500 | **$4.05** | $2,025.00 |
| **4.1.3** | 8 Panel Urine Test Kit (Standard) for WV DJS USE | 600 | **$2.40** | $1,440.00 |
| **4.1.3.15** | 8 Panel Urine Test Kit (Customizable) for WV DOC USE | 600 | **$2.40** | $1,440.00 |
| **4.1.3.2** | Nicotine Test Only | 1200 | **$0.45** | $540.00 |
| **4.1.3.3** | Buprenorphine Test Only | 800 | **$0.45** | $360.00 |
| **4.1.7** | Laboratory Confirmation Services 8 Panel Urine (Price Per Drug)** | 2000 | **$9.50** | $19,000.00 |
| **4.1.7** | Laboratory Confirmation Services 13 Panel Urine (Price Per Drug)** | 2000 | **$9.50** | $19,000.00 |
| **4.1.7.7** | EtG and EtS testing (All Inclusive)** | 2000 | **$9.95** | $19,900.00 |
| **4.1.7.11** | MRO or Lab Rep as Expert Witness (Price Per Hour)*** | 5 | **$0.00** | $0.00 |
| | **Failure to use this form may result in disqualification** | | **Total** | $96,930.00 |

*Bidder / Vendor Information:*

Name: Phamatech, Inc.

Address: 15175 Innovation Drive, San Diego, CA 92128

Phone# : 888-635-5840 / FAX: 858-635-5843

Email Address: dconde@phamatech.com

* Multiply bid price by the estimated annual quantity

** **Shipping of specimen sample to laboratory is included in the cost if there are 4 or more samples in the Lab Pak. A Flat Fee of $10 will be assessed for every Lab Pak containing fewer than 4 samples.**

*** **PHAMATECH will provide, at no cost to the Agency, testimony by telephone, web conference and video conferencing, or through sworn affidavit**

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*.**

X 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:** _____

**Date:** March 24, 2017 **Title:** Tuan Pham/President/CEO

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. DJS1700000009

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. Tuan Pham/President/CEO

Authorized Signature: _____ Date: March 27, 2017

State of California

County of San Diego, to-wit:

Taken, subscribed, and sworn to before me this 27 day of March, 2017

My Commission expires Feb. 13, 2019, 20___.

**AFFIX SEAL HERE**

**NOTARY PUBLIC** _____

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

## TABLE OF CONTENTS

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

RE: DRUG TESTING KITS AND SUPPLIES - CRFQ DJS1700000009

Dear Ms. Crystal Rink,

PHAMATECH, Inc. is pleased to have the opportunity to submit the enclosed proposal for DRUG TESTING KITS AND SUPPLIES - CRFQ DJS1700000009 for the State of West Virginia. PHAMATECH will meet and exceed all qualifications and requirements set forth by the State.

PHAMATECH has over 20 years of experience in the field of laboratory and diagnostics. 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. Relying on sophisticated, a state-of-the-art technology, PHAMATECH has successfully developed easy-to-use test devices that provide valuable, reliable, medical information at truly affordable prices.

PHAMATECH has been involved 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 1996. Currently PHAMATECH holds numerous contracts throughout the United States. One of our biggest contracts for almost 10 years has been the United States Federal Bureau of Prisons, where we serve more than 100 locations, with a purchase of over 25,000 drug screening cups per month.

In 1998, PHAMATECH revolutionized drug testing with the announcement that we received the first FDA-clearance in the United States for an over-the-counter drug test. Since then PHAMATECH has become the sales leader in this category, currently selling more than 1.5 million drug test devices to consumers annually. 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.). PHAMATECH is also certified by Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists – Forensic Urine Drug Testing (CAP-FUDT).

PHAMATECH is willing to provide continuing education materials and resources for the successful use of our products on an as-needed basis to the State of West Virginia. Our internet webpage www.phamatech.com is accessible 24/7 for immediate access to training videos, manuals, and step-by-step directions. This information is located under Diagnostics Products–Product Training tool.

Another major advantage of partnering with PHAMATECH is the ease of accessibility of vendor personnel to support and provide for the immediate needs of the State. Whether it be with our expert team of account managers or our dedicated customer service department that is available through our toll free number 24 hours a day/7 days per week. The State of West Virginia can rest assured that PHAMATECH will meet all product requirements and exceed the capabilities of supplying the needs specified in this proposal.

Sincerely,

Dana Conde
Contract Manager
dconde@phamatech.com

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ DJS1700000009

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
- [x] Addendum No. 2
- [x] Addendum No. 3
- [ ] Addendum No. 4
- [ ] Addendum No. 5
- [ ] Addendum No. 6
- [ ] Addendum No. 7
- [ ] Addendum No. 8
- [ ] Addendum No. 9
- [ ] 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 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

March 23, 2017 Dana M Conde / Contract Manager
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*.**
X 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:** _____

**Date:** March 24, 2017 **Title:** Tuan Pham/President/CEO

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. DJS1700000009

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. Tuan Pham/President/CEO

Authorized Signature: _____ Date: March 27, 2017

State of California

County of San Diego, to-wit:

Taken, subscribed, and sworn to before me this 27 day of March, 2017

My Commission expires Feb. 13, 2019, 20___.

**AFFIX SEAL HERE**

**NOTARY PUBLIC** _____

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

POST IN CONSPICUOUS PLACE OR KEEP ON PERSON

# CITY OF SAN DIEGO * CERTIFICATE OF PAYMENT OF BUSINESS TAX

PHAMATECH INC
TUAN PHAM
15175 INNOVATION DR
SAN DIEGO CA 92128-3401

| | |
|---|---|
| Certificate Number: | B1992006128 |
| Business Name: | PHAMATECH INC |
| Business Owner: | PHAMATECH INC |
| Business Address: | 15175 INNOVATION DR<br>SAN DIEGO CA 92128-3401 |
| Primary Business Activity: | WHOLESALE TRADE, NONDURABLE GOODS |
| Secondary Business Activity: | |
| Effective Date: | 07/01/2016 |
| Expiration Date: | 06/30/2017 |

PLEASE NOTIFY THE CITY TREASURER'S OFFICE IN WRITING OF ANY CHANGE IN OWNERSHIP OR ADDRESS – BUSINESS TAX PROGRAM, PO BOX 122289, SAN DIEGO, CA 92112

BUSINESS FILE COPY

**CITY OF SAN DIEGO**
**CERTIFICATE OF PAYMENT OF BUSINESS TAX**
**PO BOX 122289, SAN DIEGO, CA 92112-2289**
**1200 3RD AVENUE, MS 51T, SAN DIEGO, CA 92101**
**(619) 615-1500; FAX (619) 533-3272**
**www.sandiego.gov/treasurer**

PHAMATECH INC
TUAN PHAM
15175 INNOVATION DR
SAN DIEGO, CA 92128-3401

00927
4

| | |
|---|---|
| Certificate Number: | B1992006128 |
| Business Name: | PHAMATECH INC |
| Business Owner: | PHAMATECH INC |
| Business Address: | 15175 INNOVATION DR<br>SAN DIEGO CA 92128-3401 |
| Primary Business Activity: | WHOLESALE TRADE, NONDURABLE GOODS |
| Secondary Business Activity: | |
| Effective Date: | 07/01/2016 |
| Expiration Date: | 06/30/2017 |
| Mailing Address: | PHAMATECH INC<br>TUAN PHAM<br>15175 INNOVATION DR<br>SAN DIEGO CA 92128-3401 |

This certificate acknowledges payment of business taxes pursuant to the San Diego Municipal Code. This **is not** a License to do business within the City of San Diego in violation of any section of the Municipal Code or regulation adopted by the City Council including, but not limited to: Zoning restrictions; Land Use specifications as defined in Planned Districts, Redevelopment areas, Historical Districts, or Revitalization areas; Business Tax Regulations; Police Department Regulations; and Fire, Health or Sanitation Permits and Regulations.

This document is issued without verification that the payer is subject to or exempt from licensing by the State of California.

Payment of the required tax at the time or times due is for the term and purpose stated and is pursuant to City Ordinance. Please refer to delinquency information under "Notice".

**NOTICE:** It is the responsibility of the certificate holder to renew this certificate of payment of business tax within the proper time limits. Failure to do so, even if you have not received a renewal notice, will result in the assessment of a penalty. Please note your expiration date on this certificate above. The certificate holder is requested to notify the City Treasurer's Office upon sale or closure of the business, change of location, or change of business activity.

The tax or fees collected are **Not Refundable** unless collected as a direct result of an error by the City of San Diego.

**This certificate is NOT transferable for a change in business ownership.**

This information is available in alternative formats upon request.

# West Virginia Secretary of State — Online Data Services

## Business and Licensing

Online Data Services Help

## Business Organization Detail

*NOTICE: The West Virginia Secretary of State's Office makes every reasonable effort to ensure the accuracy of information. However, we make no representation or warranty as to the correctness or completeness of the information. If information is missing from this page, it is not in the The West Virginia Secretary of State's database.*

### PHAMATECH, INC.

| Organization Information | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Org Type** | **Effective Date** | **Established Date** | **Filing Date** | **Charter** | **Class** | **Sec Type** | **Termination Date** | **Termination Reason** |
| **C \| Corporation** | 4/15/2016 | | 4/15/2016 | Foreign | Profit | | | |

| Organization Information | | | |
|---|---|---|---|
| **Business Purpose** | 6215 - Health Care and Social Assistance - Ambulatory Health Care Services - Medical and Diagnostic Laboratories | **Capital Stock** | |
| **Charter County** | | **Control Number** | |
| **Charter State** | CA | **Excess Acres** | |
| **At Will Term** | | **Member Managed** | |
| **At Will Term Years** | | **Par Value** | |
| **Authorized Shares** | | | |

| Addresses |
|---|

| Type | Address |
|---|---|
| **Local Office Address** | 15175 INNOVATION DRIVE<br>SAN DIEGO, CA, 92128 |
| **Mailing Address** | 15175 INNOVATION DRIVE<br>SAN DIEGO, CA, 92128<br>USA |
| **Notice of Process Address** | PHAMATECH, INC<br>15175 INNOVATION DRIVE<br>SAN DIEGO, CA, 92128 |
| **Principal Office Address** | 15175 INNOVATION DRIVE<br>SAN DIEGO, CA, 92128<br>USA |
| **Type** | **Address** |

| **Officers** | |
|---|---|
| **Type** | **Name/Address** |
| **President** | TUAN PHAM<br>15175 INNOVATION DRIVE<br>SAN DIEGO, CA, 92128 |
| **Type** | **Name/Address** |

For more information, please contact the Secretary of State's Office at 304-558-8000.

Wednesday, April 5, 2017 — 7:20 PM

PHAMAT1 OP ID: AL

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/23/2017

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<br>Wateridge Insurance Services<br>10717 Sorrento Valley Rd.<br>San Diego, CA 92121<br>George J. Sports | CONTACT NAME: George J. Sports<br>PHONE (A/C, No, Ext): 858-452-2200 FAX (A/C, No): 858-452-6004<br>E-MAIL ADDRESS: |
| INSURED Phamatech, Inc.<br>15175 Innovation Drive<br>San Diego, CA 92128 | INSURER(S) AFFORDING COVERAGE — NAIC #<br>INSURER A : Hartford Casualty Insurance Co — 29424<br>INSURER B : Twin City Fire Insurance Co. — 29459<br>INSURER C : Medmarc Casualty Ins. Company<br>INSURER D : Evanston Insurance Company — 35378<br>INSURER E : Axis Insurance Company — 37273<br>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 | | | | | | EACH OCCURRENCE | $ | 10,000,000 |
| | EXCESS LIAB CLAIMS-MADE | | | 72RHUTR9385 | 06/01/2016 | 06/01/2017 | AGGREGATE | $ | 10,000,000 |
| | DED X RETENTION $ 10,000 | | | | | | | $ | |
| B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N | | | | | | X PER STATUTE OTH-ER | | |
| | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A (Mandatory in NH) | | | 72WEFO4109 | 03/15/2017 | 03/15/2018 | 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 | 03/17/2017 | 03/17/2018 | Claim/Agg | | $2M/$4M |
| E | Cyber Liability | | | ESF00244680 | 03/28/2017 | 03/28/2018 | 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

PROOF10

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