

STATEMENT OF WORK

INVITATION FOR BID

FOR

Department of General Services

Drug and Alcohol Testing

ISSUING OFFICE



COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF GENERAL SERVICES

BUREAU OF PROCUREMENT

555 Walnut Street

Forum Place, 6th Floor

Harrisburg, PA 17101

IFB NUMBER

6100042295

DATE OF ISSUANCE

November 9, 2017

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STATEMENT OF WORK
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**PART IV
STATEMENT OF WORK**

IV-1. GENERAL INFORMATION

- A. PURPOSE:** The Department of General Services (DGS) is issuing this Invitation to Bid (IFB) to establish a multiple award Contract for Commonwealth agencies to procure Drug and/or Alcohol Laboratory Testing Services and/or On-Site Screening Devices.
- B. METHOD OF AWARD (MULTIPLE AWARD):** Award will be made on a multiple award basis to all responsible and responsive bidders who comply with the "Eligibility Requirements" set forth in this IFB. When services are needed, using agencies will issue Request for Quotes (RFQ) to suppliers on the List of Awarded Suppliers and will issue a Purchase Order (PO) to the Selected Supplier(s) based on best value determination. Specific agency requirements will be provided on each individual agency's RFQ. There is no guarantee that the award of a Contract will result in the award of a Purchase Order.
- C. CONTRACT TERM:** The contracts shall commence on the Effective Date listed on the contracts and expire on December 31, 2020.

Contracts may be renewed two (2) additional one (1) year term by mutual agreement between the Commonwealth and the supplier(s) per Section V.3. CONTRACT-002.2b of **Appendix A – Standard Contract Terms and Conditions.**

- D. ISSUING OFFICE:** DGS has issued this IFB on behalf of the Commonwealth. The sole point of contact in the Commonwealth for this IFB shall be Cheryl Barth-Taylor, Issuing Officer. Please refer all inquiries to the Issuing Officer via e-mail at cbarthtayl@pa.gov.
- E. QUESTIONS AND ANSWERS:** If a bidder has any questions regarding this IFB, the bidder must submit the questions(s) via e-mail (*with the subject line "IFB 6100042295 Question"*) to the Issuing Officer named above. Question(s) must be submitted via e-mail no later than November 30, 2017. The Issuing Officer shall post as an addendum to this IFB the answers to the questions on the DGS website. Each bidder shall be responsible to monitor the DGS website www.emarketplace.state.pa.us for new or revised IFB information.
- F. BEST VALUE DETERMINATION (BVD):**

- 1. Definition:** Best Value Determination refers to the process of selecting the quote (or quotes) which provides the greatest value to the using agency based on the evaluation and comparison of all pertinent criteria, including cost, so that the supplier(s) whose overall quote best suit(s) the using agency's needs is selected.
- 2. Best Value Criteria. Best Value criteria, can include but not limited to:**
 - a) Supplier's past performance;
 - b) Reliability in Responding to Service Requests;
 - c) Timely response to service requests;

- d) Ability to provide sufficient staff;
 - e) Availability; and
 - f) Price
3. **Best Value Determination Process:** Through a Request for Quote (RFQ), the agency will select the supplier(s) whose quote is determined to provide the best value based on the best value criteria set forth on each individual agency's RFQ issued to the Awarded Supplier(s). The best value process must be documented in writing and be retained in the agency file for the particular request.

IV-2. CRITERIA FOR QUALIFICATION

- A. **SUPPLIER REGISTRATION:** Interested bidders must register as a supplier on the PA Supplier Portal at www.pasupplierportal.state.pa.us. If your company is already registered in the PA Supplier Portal, registration is not necessary. Prior to registration, bidders are strongly encouraged to review the Supplier Registration and Bidding guides available at the Supplier Service Center at: <http://www.dgs.pa.gov/Businesses/Materials%20and%20Services%20Procurement/Supplier%20Service%20Center/Pages/default.aspx#.WJSPQuIo6Uk>

For any questions or issues related to the registration process, contact the Supplier Service Center (CSC) at 877-435-7363 Option 1. For any questions or issues related to the online bidding process, contact the Supplier Service Center (CSC) at 877-435-7363 Option 2.

- B. **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) REGULATIONS:**

The selected Supplier will comply with all federal or state laws related to the use and disclosure of information, including information that constitutes Protected Health Information (PHI) as defined by the Health Insurance Portability and Accountability Act (HIPAA). By submitting a response, the Supplier agrees to the Business Associates Addendum contained in **Appendix E** of the IFB.

- C. **ELIGIBILITY REQUIREMENTS:** Suppliers interested in submitting a bid to become an Awarded Supplier must meet all the eligibility requirements. Bidders who fail to meet all the following eligibility requirements may result in bid rejection:
1. **SRM Registration.** Bidders must be a registered supplier within the PA Supplier Portal, www.pasupplierportal.state.pa.us.
 2. **Experience.** Provide documentation on company letterhead of a minimum of three (3) years' experience in providing or administering drug and/or alcohol testing services.

3. **Licensing/Credentials.** Bidders must provide as an attachment to their bid response valid and current copies of the following licenses, regulations, and/or certificates for all applicable laboratory(ies) and personnel (i.e. Medical Review Officer (MRO) and Third Party Administrator (TPA)), as applicable. Individual RFQ's will identify agency specific requirements.
 - a) Federal Department of Health and Human Services (HHS)/Substance Abuse and Mental Health Services Administration (SAMHSA); and
 - b) PA Department of Health (DOH) Certification; and/or
 - c) National Laboratory Certification Program (NLCP).

4. **Insurance.** Provide a copy of the Bidder's current insurance certificate which, at a minimum, should include the following:
 - a) Carrier (name and address);
 - b) Type of Insurance;
 - c) Amount of coverage;
 - d) Period covered by insurance

5. **Collection Site Network.** Bidder(s) must provide a Collection Site List with its bid response indicating at least one (1) collection site per county (fixed and/or mobile), as well as if the site is a primary or secondary site, for the collection services for both drugs and alcohol. Bidder(s) must indicate if a site is fixed or mobile. The Collection Site List must consist of a minimum of site name, indicating fixed or mobile, site address, phone number, county, site operation hours, and specify drugs and/or alcohol collection. The bidder must also provide a list (or indicator on the collection site list) for collection sites to be used for 24/7 time sensitive/emergency collections. Refer to Part IV-4, Section 1 of the IFB for further details. *This requirement is for Lot 3 services only.*

D. BID SUBMISSION: Bids must be electronically received through the PA Supplier Portal, www.pasupplierportal.state.pa.us . To be considered for Contract award, bidder must complete and return the following documents in response to this IFB.

1. **Appendix B** –Domestic Workforce Utilization Form
2. **Appendix C** – Cost Submittal Form

The Cost submittal worksheet contained in Appendix C of this IFB shall constitute the Cost Submittal. Bidders will not provide individual agency pricing with its bid response. Bidders will submit a percentage discount off their published or customized price list and include a copy of the most recent price list with its bid response, either published or customized. Percentage discount may not decrease throughout the term of the contract.

3. **Appendix E** - Health Insurance Portability and Accountability Act (HIPPA) Regulations
4. **Appendix H** – Iran Free Procurement Form
5. Documentation that the bidder has at least three (3) years' experience in providing drug and alcohol testing services for public or private organizations.

Acceptable documentation would be, but is not limited to, references, invoices, tax returns, articles of incorporation, etc.

6. Proof of Licenses/Credentials for lab and personnel
7. Proof of Insurance
8. Collection Site List (Lot 3 Only)

IV-3. RFQ PROCESS (AGENCY ORDERING PROCEDURE)

A. SUPPLIER SELECTION FOR RFQ: All bidders awarded under this Contract, who meet the eligibility requirements as set forth in Part IV-2, will be placed on the *List of Awarded Suppliers*. When an agency requires services covered under this Contract, all Awarded Suppliers who have indicated an interest in providing service under the Lot of need, shall be issued a Request for Quote (RFQ) by the using agency. A sample RFQ Template is attached to this IFB as **Appendix D**.

B. REQUEST FOR QUOTE (RFQ):

1. RFQ Format. The respective state agency will solicit quotes through the RFQ process via E-mail. The Selected Supplier(s) must provide Drug and/or Alcohol Testing Services and/or On-Site Screening Devices for each using agency as set forth in the Invitation for Bid (IFB), and the respective agency RFQ. The scope of service and specification should clearly define (but not be limited to) the following information:

- a) The required service Lot(s);
- b) Specific agency requirements;
- c) Term of Purchase Order;
- d) Best Value Determination Criteria;
- e) How award will be made (i.e. – multiple award, by location, etc.)
- f) Specific training needed by the requesting agency; and
- g) Pricing Format.

2. RFQ Pricing Format. The respective state agency will outline the specific pricing structure within their RFQ, to include but not limited to, single-substance screening, single-substance confirmation and multiple-substance screening, panel, and/or bundle analyses, as well as test type, test description, estimated volume, CPT code, unit price, and total cost. Awarded Supplier(s) may offer an explanation of method(s) and positive reading(s) must automatically be quantitatively confirmed for same substance(s) at no additional cost to the Commonwealth. Awarded Suppliers must submit their quote, at an equal to or greater percent discount off their original published or customized prices list submitted in **Appendix C – Cost Submittal** of the IFB.

C. QUOTE: Interested Suppliers receiving an RFQ from a using agency under this t Contract must adhere to the following:

1. Awarded Suppliers receiving a RFQ from a using agency under this Contract are not obligated to respond to the RFQ but are encouraged to return a “No Quote”

submission, providing information why the Supplier is not interested in providing a quote for the respective agency.

2. Completed quote must be returned by the method specified on the RFQ. It is the responsibility of each supplier to ensure that its quote is submitted to the location specified on the RFQ prior to the date and time set for the opening of quotes, regardless of medium used. If a supplier is permitted to and decides to mail in its quote, it is advised to allow adequate time for delivery. No quote shall be considered if it arrives at the location specified on the RFQ after the date and time set for the quote opening. Agencies are not required under law to conduct a public "bid opening" of quotes but should provide quote results if requested.
3. Quotes submitted in response to the RFQ submitted via email. Quotes submitted electronically must be submitted by an authorized signatory of the company or the quote will be rejected.
4. Quotes must be firm. If a quote is submitted with conditions or exceptions or not in conformance with the terms and conditions referenced in the Contract and the RFQ, it shall be rejected. The quote shall also be rejected if the services offered by the supplier are not in conformance with the scope of service and specifications contained in the RFQ.

D. PURCHASE ORDER: After a RFQ is solicited, and quotes are received and evaluated, the issuing agency shall execute and issue a Purchase Order(s) to the supplier(s) offering the best value in response to the RFQ. If only one response is received to an RFQ, the using agency is under no obligation to re-issue an RFQ and may proceed to issue a Purchase Order to the single respondent to the RFQ.

Suppliers may not proceed to provide services under this Contract until receipt of the Fully Executed Purchase Order from the issuing agency. The Purchase Order will constitute authority to furnish the specified services and/or on-site screening devices and must be referenced when invoicing. Each RFQ and Purchase Order will be deemed to incorporate the terms and conditions set forth in this Contract. If any conflicts or discrepancies should arise in the interpretation of a PO, the order of precedence shall be: The Contract; The PO and any attachments thereto, including: (1) the Supplier's quote, as accepted by the Commonwealth; and (2) the RFQ.

E. TERM OF PURCHASE ORDER: Agencies may issue purchase orders for the initial term of the contract.

F. START-UP/IMPLEMENTATION: The Selected Supplier(s) must ensure a smooth transition of service from the current contractor(s).

1. The Selected Supplier(s) shall be afforded up to a sixty (60) day period to develop and ramp-up services.
2. The Selected Supplier(s) must coordinate and work with the using agencies and current contractor(s) to ensure that transfer of records occurs in such a manner to successfully carry out the requirements of this IFB in an effective and timely manner.
3. All records (including testing records from previous contractors) must be maintained and retained in accordance with individual agency RFQ requirements.

4. Full implementation is required sixty (60) days from award of purchase order. No payments will be rendered until services are provided.

G. **RECORD TURNOVER:** The Selected Supplier(s) must transfer all records in a format outlined by the using agency, at the end of the contract to transition contract service delivery to a successor contractor or to the Commonwealth resources.

IV-4. SCOPE OF SERVICES

A. **OVERVIEW:** This Contract will provide statewide Drug and Alcohol Testing services and/or On-Site Screening Devices for using agencies drug and alcohol testing needs. The Department is seeking qualified suppliers with the experience, background, certifications, and services at competitive prices while ensuring that agency requirements are met in compliance with all local, state and federal regulations. The Awarded Suppliers shall provide all facilities, labor, materials, services, skills, supervision, and necessary equipment to manage and conduct provision of services and/or supplies under this Contract.

B. **SERVICE LOTS:** This IFB is divided into a series of service Lots for the various types of services, supplies, and/or on-site screening devices that may be provided under this Contract. Bidders may bid on an individual Lot or any combination of Lots as described below:

1. **Lot 1 – Laboratory Testing Services, Specimen Collected by Agency, cup or specimen collection device provided by Awarded Supplier(s).** Provide all items necessary, at no additional charge, for the Agency to collect, identify, and ship specimens to the Awarded Supplier(s) for laboratory testing.

2. **Lot 2 – Laboratory Testing Services, Specimen Collected by Agency, cup or specimen collection device provided by the Commonwealth.** Provide all items necessary, at no additional charge, for the Agency to identify, and ship specimens collected in an approved Federal Drug Administration (FDA) cup or device pre-purchased by the Agency.

3. **Lot 3 – Laboratory Testing Services, Specimen collected by Awarded Supplier(s) either at collection site or Agency designated site.** Provide all items necessary, at no additional charge, to collect, identify and ship specimens.

4. **Lot 4 – On-Site Screening Devices.** Provide a variety of on-site screening devices, which can render a qualitative result(s) as outlined in Part IV-5.

C. **SERVICES:** The Awarded Supplier(s) shall provide Drug and/or Alcohol Testing Services and/or On-site Screening Devices as defined in IV-4 of the IFB. These services will be provided as an independent contractor, not as an employee(s) of the Commonwealth. The Awarded Supplier(s) shall render services in accordance with the policies, procedures, and standards of each Commonwealth agency. The Awarded Supplier(s) and any sub-contracted entities must have working knowledge and be in compliance with federal, state, and local regulations (HHS, FDA, PA DOH). In any event

where the Awarded Supplier(s) creates a scenario where an Agency is found to be out of compliance with federal, state, and local standards, laws, and regulations (HHS, DOT, PA DOH), the Awarded Supplier(s) will be liable and responsible for any damages (administrative, operational, monetary) suffered by any using agency. All non-compliance issues and service deficiencies must be addressed, in writing, to each affected using Agency, to include a proposed solution, within forty-eight (48) hours of supplier's receipt of notification with the approved resolution in place within five (5) business days thereafter.

Links to associated regulations are as follows:

1. Department of Health and Human Services (HHS) – Substance Abuse and Mental Health Services Administration (SAMHSA) <https://www.samhsa.gov/workplace/drug-testing>
2. US DOT - <https://www.transportation.gov/odapc>

D. AGENCIES & LOCATIONS: For the purpose of this IFB, the following are the known major agencies and sites. The Commonwealth reserves the right to add or delete additional agencies and/or agency sites with drug and/or alcohol testing service and/or on-site screening device needs that are within the scope of the contract throughout the term of this contract and/or as required by the individual agency RFQ.

1. Department of Corrections (DOC)

- a) Inmate testing shall be rendered for twenty-two (22) male institutions, two (2) female institutions, and one (1) co-ed boot camp.
- b) Offender testing shall be rendered for sixty-seven (67) Bureau of Community Corrections facilities.
- c) Employee reasonable suspicion testing shall be rendered for forty-three (43) facilities.

2. Pennsylvania Board of Probation and Parole (PBPP). Offenders throughout the Commonwealth are tested by agency staff from twenty-six (26) office sites.

3. Office of Administration (OA). Applicant and employee testing for commercial driver's license positions (CDL) across the Commonwealth, in accordance with Federal Department of Transportation (DOT) regulations.

4. Pennsylvania State Police (PSP).

- a) **PSP – Bureau of Human Resources.** Applicant testing, including Cadet and Liquor Enforcement Officer (LEO) testing, shall be conducted (currently in Greensburg and Hershey, PA) continually throughout the year, as well as testing for reasonable suspicion.
- b) **PSP-Recruitment & Special Services Section.** Random drug testing of enlisted members. Testing shall be rendered for sixteen (16) troops and various stations throughout the Commonwealth.
- c) **PSP-Internal Affairs Division.** Reasonable grounds testing of PSP enlisted and civilian members for Internal Investigations.

5. **Pennsylvania Turnpike Commission (PTC).** Applicant and employee testing for CDL positions across the Commonwealth, in accordance with Federal DOT regulations, and employee reasonable suspicion testing.
6. **Department of Human Services (DHS)**
 - a) **Office of Mental Health and Substance Abuse Services (OMHSAS)** – Employee reasonable suspicion testing shall be rendered for approximately two (2) facilities. Pre-employment testing for approximately seven (7) facilities.
 - b) **Office of Income Maintenance (OIM)** testing of applicants for and recipients of public assistance currently in three (3) counties.
 - c) **Office of Children, Youth, and Families** pre-employment testing for approximately five (5) facilities.
 - d) **Office of Developmental Programs (ODP)** – Pre-employment testing at approximately five (5) facilities.
7. **Pennsylvania Gaming Control Board (PGCB).** Applicant pre-employment and employee reasonable suspicion testing for approximately fifteen (15) facilities.
8. **Pennsylvania Racing Commission.** Licensees are randomly tested continually throughout the year at six (6) racetracks located across the Commonwealth, in compliance with the following:
 - a) [Race Horse Industry Reform Act:](http://www.legis.state.pa.us/WU01/LI/LI/US/PDF/1993/0/0018..PDF)
 - b) Horse Racing Commission and [PA Code Title 58:](https://www.pacode.com/secure/data/058/058toc.html)
9. **Department of State – Professional Health Monitoring Program (PHMP)**

This drug testing program currently serves 1,105 PHMP Participants.

- E. PERSONNEL:** The Awarded Supplier(s) are expected to utilize standards of professionalism in all aspects of the performance of the contract. All personnel must be fully qualified for the performance of the task to which assigned. In the event of recurring and/or un-resolved personnel performance issue(s), the Commonwealth has the right to request that such personnel be replaced.

Awarded Supplier(s) must provide the following, as applicable and in accordance with the individual agency RFQ requirements:

1. **Account Manager.** Program management and problem resolution. The account manager that will serve as the key point of contact for Commonwealth agencies and will ensure that the managed service provider network meets all Commonwealth requirements. Account managers must be available between the hours of 7:30 am to 5:00 pm. Any changes in the account manager shall be kept to a minimum, and agency Designated Employee Representative (DER) shall be notified immediately. A phone number, cell phone number, fax number, email address, and alternate contact shall be provided for the account manager.

2. **Customer Service.** 24/7/365 – telephone number – live personnel. Customer Service is of the utmost importance. It is expected the Awarded Supplier(s) provide competent professionals qualified to answer questions regarding the status or respond to issues that agencies may have. Problem resolution may include technical support outside normal working hours.
3. **Medical Review Officer (MRO).** The supplier must provide MRO services to certify all results for controlled substances. The MRO must meet all HHS guidelines, requirements, and regulations. The MRO must provide witness statement(s), and/or live testimony in cases of grievances, appeals, or other legal or administrative actions. The supplier must develop and maintain a quality assurance process for MRO services, investigate and resolve deficiencies, and develop corrective action plans acceptable to the Commonwealth.
4. **Certifying Scientist.** The Awarded Supplier(s) shall provide access to a certifying scientist(s) to answer questions regarding the testing procedures or results. The certifying scientist(s) shall be knowledgeable in the areas of cross-reactivity, prescription medication effects, immuno-assay and confirmation procedures, chain of custody, interpretation of drug analyses, and interpretation of adulteration tests. The certifying scientist(s) must be available during normal working hours of operation.
5. **Third Party Administrator (TPA).** The supplier must provide Third Party Administrator services as required by the individual agency RFQ, including provision of chain and custody forms, selection of employee names for random testing, transmission of drug and alcohol test results to the Designated Employer Representative (DER), and creation of reports required under DOT guidelines.

F. LABORATORY SUPPLIES: Supplies necessary to collect, identify, ship, and test specimens – to include, but not limited to:

1. **Chain of Custody Forms.** The Commonwealth requires that all specimens be handled with a thorough Chain of Custody (COC) process. The awarded supplier(s) shall provide pre-printed Chain of Custody Forms (CCF) in accordance with the individual agency's RFQ requirements. At a minimum, the CCF must include a security seal that covers the specimen lid, adhering to both the lid and cup to prevent tampering. The security seal must identify the source of the specimen submitted.

The awarded supplier(s) shall provide the following pre-printed CCFs as required by the individual agency RFQ:

- a) Federal DOT CCF
- b) Non-Federal CCF
- c) Alcohol
 - i) DOT
 - ii) Non-DOT
- d) Criminal Justice
 - i) PA Dept. of Corrections (PADOC)
 - ii) PA Board of Probation and Parole (PBPP)
 - iii) PA State Police (PSP)

2. Shipping Supplies.

- a) Pre-Paid, pre-addressed shipping labels for overnight/same-day service;
- b) Leak resistant shipping containers;
- c) Plastic, double-pouch, sealable bags, and absorbent material;
- d) Shipping containers must comply with all pertinent U.S. Postal, DOT, and International Air Transportation Association (IATA) regulations.

- G. PICK-UP AND TRANSPORTATION:** The Commonwealth's requirements for specimen pick-up and transportation may vary by agency and may include pick-up at fixed collection sites in each county of the Commonwealth, and/or Commonwealth facilities, and/or shipped via U.S. mail or private package delivery service (including overnight delivery). Appropriate procedure manuals, instructions, shipping materials, specimen collection kits, and any other necessary materials shall be provided as identified in the individual agency's RFQ.

The Awarded Supplier(s) must accept and perform tests on specimens submitted by using agency in cup/screening device produced by any manufacturer.

- H. COLLECTION SITES (LOTS 1 and 3 ONLY):** Bidder(s) must designate at least one (1) collection site per county (fixed and/or mobile), within each of the sixty-seven (67) counties in Pennsylvania. One (1) site per county is the minimum requirement; however, multiple sites per county are preferred. Collection sites must collect specimens and perform split specimen collections, if applicable, in accordance with DOT and HHS guidelines/requirements/regulations. Services must be available in all sixty-seven (67) counties 24/7/365. Agencies will outline specific collection site requirements regarding fixed/mobile sites on the individual agency RFQ.

Mobile collection services may require pre-scheduled appointments for less time-sensitive (non-emergent) collections (including pre-employment, random testing, return-to-duty, and/or follow-up). For time-sensitive (emergent) collections (i.e. reasonable suspicion and post-accident tests), mobile collectors shall arrive at the worksite within two (2) hours of receiving notification of the need for a time-sensitive collection. Use of hospital emergency rooms or other specific collections sites may be used in lieu of mobile collectors to meet the two (2) hour response requirement.

Agency collection site needs are subject to change. Collection site changes will be made no more than quarterly and must be pre-approved by the using Agency.

- I. LABORATORY:** The Awarded Supplier(s) shall provide an HHS certified laboratory, to perform specimen analyses. The laboratory must also be certified by HHS to participate in DOT testing. A secondary HHS certified lab must be available for all split-specimen requests, as required by individual agency RFQ requirements, for testing of Vial B of a split urine specimen. All lab services must operate in accordance with DOT and HHS guidelines, requirements, and regulations or in accordance with standards set forth in the agency RFQ.

The Awarded Supplier(s) shall maintain a physical facility that meets all applicable federal, state, and local regulations (e.g. building codes) and shall not endanger the health and safety of employees and the community. The Awarded Supplier(s) shall not have received a citation for violation of fire, safety, health, environment, or building codes for the twelve (12) month period preceding this solicitation.

J. TESTING:

1. When testing for alcohol and/or controlled substances, the Awarded Supplier(s) must be capable of detecting and confirming the following substances at the minimum cutoff levels listed. This list and the cutoff levels are subject to change at any time depending on regulatory or Agency policy changes, usage of drugs of abuse and the introduction of new designer drugs to the public.
2. Vendor must submit all synthetic drug types and chemical makeup that they currently test for, including but not limited to cannabimimetic and cathinones.
3. Vendor must provide any additions or deletions to the type or number of chemical compounds of drug tested for, prior to implementation.

**Testing of Limit of Quantitation
For Lots 1 and 2**

Drug	Initial Screen	Confirmation
**Alcohol	400,000 ng/ml (.4 mg/ml)	100,000 ng/ml (.1 mg/ml)
Amphetamines	500ng/ml	250ng/ml
Barbiturates	200 ng/ml	200 ng/ml
Benzodiazepines	200 ng/ml	200 ng/ml
Cocaine	150 ng/ml	100 ng/ml
Cannabinoid (THC)	50 ng/ml	15 ng/ml
Fentanyl	.5 ng/ml	.5 ng/ml
LSD	.5 ng/ml	.5 ng/ml
Methadone	200 ng/ml	200 ng/ml
Opiates	2000 ng/ml	100 ng/ml
Oxycodone	100 ng/ml	100 ng/ml
Phencyclidine (PCP)	25 ng/ml	25 ng/ml
Buprenorphine	10 ng/ml	10 ng/ml
Methamphetamine	500 ng/ml	250 ng/ml

LOT 1 ONLY (Department of Corrections)

Table A	PADOC	
Drug	Initial Screen	Confirmation
**Alcohol	40 ng/ml	40 ng/ml
Amphetamines	300 ng/ml	300 ng/ml
Barbiturates	200 ng/ml	200 ng/ml
Benzodiazepines	200 ng/ml	200 ng/ml
Cocaine	150 ng/ml	100 ng/ml
Cannabinoid (THC)	40 ng/ml	15 ng/ml
Fentanyl	.5 ng/ml	.5 ng/ml
LSD	.5 ng/ml	.5 ng/ml
Methadone	200 ng/ml	200 ng/ml
Opiates	150 ng/ml	100 ng/ml
Oxycodone	100 ng/ml	100 ng/ml
Phencyclidine (PCP)	25 ng/ml	25 ng/ml
Buprenorphine (Suboxone)	10 ng/ml	10 ng/ml
Opana	300 ng/ml	300 ng/ml
MDMA	300 ng/ml	300 ng/ml
Methamphetamine	1,000 ng/ml	500 ng/ml

LOT 2 ONLY (Department of Corrections)

Table B	PADOC	
Drug	Initial Screen	Confirmation
Cannabimimetics	Any detectable amount	Any detectable amount
Cathinones	Any detectable amount	Any detectable amount

4. Cost shall be provided for single panel screen for Cannabimimetics and Cathinones. An immediate LC/MS/MS confirmation shall be conducted upon receiving a positive for all test results based upon the chain of custody test designation (for inmates under the direct control of the PADOC). **(Lot 2 only)**
5. New or emerging drugs may be added to testing at the direction of the PADOC and drug panel screens may be changed at any time at the direction of the PADOC with no additional cost. **(Lots 1 and 2)**

For Lot 3 only, substances tested for, and screening and confirmation levels will be done in accordance with DOT and HHS guidance/regulations/requirements. The list of drugs and the screening and confirmation levels are found at <https://www.transportation.gov/odapc/part40/40-87>.

6. **Specimen Screening and Confirmation Timeframes.** The Awarded Supplier(s) laboratory will properly store and process the specimen within the following timeframes and in accordance with individual agency RFQ requirements:
 - a) **Immunoassay screening.** Specimen(s) processed within twenty-four (24) hours of receipt.

b) Confirmation by GC/MS. Specimen(s) processed within forty-eight (48) hours of receipt; or

Confirmation by LC/MS/MS.

- i) Common substances, specimen(s) processed within two (2) days of receipt.
- ii) Designer substances, specimen(s) processed within five (5) days of receipt.

K. DESIGNER DRUGS: With the enactment of Act 7 of 2011, the Commonwealth of Pennsylvania's Department of Health added numerous "designer drug" substances to its Schedule I, thus making them illegal to possess or sell under the Controlled Substance, Drug, Device, and Cosmetic Act (35.P.S. 780-101 et. seq.) "*Designer drug*" means a substance other than a controlled substance that is intended for human consumption and that either has a chemical structure substantially similar to that of a controlled substance in Schedules I, II or III of this act or that produces an effect substantially similar to that of a controlled substance in Schedules I, II or III. Examples of chemical classes in which designer drugs are found include but are not limited to, the following: Phenethylamines, N-substituted piperidines, morphinans, ecgonines, quinazolinones, substituted indoles and arylcyloalkylamines. Bidders may be required in accordance with agency requirements to have comprehensive capabilities in the area of detection, quantification, and reporting of a wide array of designer drug substances and compounds, and their metabolites, which is subject to change during the contract term.

Additionally, and in accordance with agency requirements, bidders must be able to detect and quantify the following substances, and their metabolites, intended to treat erectile dysfunction (ED) in men:

- 1. Tadalafil (Cialis)
- 2. Vardenafil (Levitra; Staxyn)
- 3. Sildenafil (Viagra)

L. REFLEXIVE CONFIRMATION TESTING: In the event of an immuno-assay screen yields a positive result(s), an automatic confirmatory test by GC/MS or LC/MS will be performed to confirm the previous result(s). The Awarded Supplier(s) shall perform additional GC/MS or LC/MS confirmation procedures upon request from the using agency and without cost to the Commonwealth for any positive immuno-assay not automatically confirmed. Quantitative levels must be reported for all GC/MS or LC/MS confirmations performed.

M. SPECIMEN VALIDITY FACTORS (ADULTERATION): The Awarded Supplier(s) may be requested to perform analysis on each specimen submitted to detect abnormal deviations for, at minimum, the following factors: creatinine, specific gravity, and pH. A quantitative display and interpretation statement must be printed on all specimen reports indicating diluted, substituted or adulterated specimens based on the results of the adulteration tests, in accordance with HHS regulations.

N. CONFIDENTIALITY: The Award Supplier(s) shall not disclose test results to any unauthorized individual and/or Agency. The Awarded Supplier(s) shall be expected to treat all proprietary information as confidential and to acknowledge that it is only authorized to disclose or otherwise divulge proprietary information to authorized

employees of the Commonwealth or the Awarded Supplier(s) that require access to perform services within the scope of the contract.

- O. LOGISTICS – STORAGE:** For the purpose of drug and alcohol testing specimens shall be stored for a minimum of thirty (30) days. All positive specimens (including adulterated, substituted and invalid specimens) must be held in frozen storage for a minimum of one (1) year or longer, if requested by individual agency.
- P. EXPERT TESTIMONY:** The Awarded Supplier(s) must be able to provide the necessary staff or expert testimony in the event of any administrative or legal action by a donor regarding testing processes.
1. The Awarded Supplier(s) shall provide such expert witness testimony at administrative proceedings, or as needed for court proceedings. Awarded Supplier(s) will provide written and/or telephone consultation to agency and/or attorney representing agency, upon request. The expert witness shall be knowledgeable in all collection, laboratory, and MRO standard operating procedures. Expert witnesses may be required to assist in pre-trial preparation, cross-examination of defense experts. Expert witness services must be provided from the supplier, collection site, laboratory, and MRO, as needed, and will be provided at no additional charge.
 2. The Awarded Supplier(s) shall be responsible for arranging transportation to and ensuring availability for court proceedings.
- Q. TRAINING:** The Awarded Supplier(s) may provide, upon award of purchase order and at no cost to the Commonwealth, a comprehensive, in-person user training module, to be conducted by supplier's staff at the agency's location(s) within the first ninety (90) days and/or upon agency request. Training module content shall be made available to all agency personnel. Subject matter must include, at minimum, chain of custody, forms, overview of laboratory methodology, reporting methods, reporting access and interpretation of results, and any other applicable matter, materials, or knowledge which would aid service users. The Awarded Supplier(s) shall further allow for cross-training of agency staff, to be announced, and at no cost to the Commonwealth, in order for staff to administer the training module. The Awarded Supplier(s) shall provide periodic updates to the training module and related materials as relevant changes occur. Training requirements may vary depending on the using agency's requirements.
- R. MANUALS:** The Awarded Supplier(s) shall provide a manual for each location at no cost to the Commonwealth, to be used as a reference guide. The manual shall include but is not limited to: specimen collection procedure(s); a chain of custody; information outlining shipping methods utilized by the laboratory (i.e. U.S. Postal Service and/or private courier); reporting of test results; laboratory screening procedures; laboratory confirmation procedures; drug detection periods; explanation of specimen validity (adulteration) test; and cross reactivity guide. The manual shall contain examples of all documentation forms and methods used by the collector and the laboratory. The manual shall be updated as needed due to changes in supplier procedure.

S. INFORMATION TECHNOLOGY BULLETIN (ITB) COMPLIANCE REQUIREMENT:

The Awarded Supplier(s) delivering services to agencies under the Governor's jurisdiction are required to comply with the IT standards and policies issued by the Governor's Office of Administration, Office of Information Technology (OA/OIT), for the Commonwealth enterprise (See. www.oit.state.pa.us). When an agency or service provider believes there is a need to deviate from these standards/policies, they must first receive approval from OA/OIT's Deputy Secretary.

T. INFORMATION TECHNOLOGY POLICIES: The Contractor shall comply with the IT standards and policies issued by the Governor's Office of Administration, Office for Information Technology (OA/OIT) (located at: <http://www.oa.pa.gov/Policies/Pages/itp.aspx>), including the accessibility standards set out in IT Policy ACC001, *Accessibility Policy*. The Contractor shall ensure that Services and Supplies procured under this Contract comply with the applicable standards. In the event such standards change during the Contractor's performance, and the Commonwealth requests that the Contractor comply with the changed standard, then any incremental costs incurred by the Contractor to comply with such changes shall be paid for pursuant to a change order to the Contract.

U. INDIVIDUAL SPECIMEN RESULT REPORTING: Individual specimen results report must be transmitted by method specified in the individual agency RFQ within 24 hours of result finding. Laboratory and/or MRO Result Report may include, but is not limited to:

1. Laboratory and/or MRO letterhead with name, address, phone and fax #;
2. Collection location title;
3. Ordering agency/facility;
4. Agency account number;
5. Agency Contact person
6. Employee or individual donor name;
7. Donor Identification number;
8. Reason for test;
9. Authority under which test conducted (CDL only);
10. Name of individual that collected the specimen;
11. Date and time of specimen collection
12. Date and time received by laboratory and/or MRO;
13. Date and time reported by laboratory and/or MRO;
14. Substance or metabolite name(s);
15. Reference ranges/cut-off levels;
16. Qualitative and Quantitative Test results;
17. Adulteration Tests, cut-offs, and results;
18. Rejected specimen and reason(s);
19. MRO original signature (as required by the using agency).
 - a) MRO will certify the lab results within the following timeframes:
 - i) For negative lab results within twenty-four (24) hours of receipt of results and COC.
 - ii) For positive lab results within five (5) days using U.S. HHS and DOT guidelines.

b) Transmission of Results

- i) The Awarded Supplier(s) will report individual laboratory results via web reporting and/or automated upload, in accordance with individual agency RFQ requirements, directly to the appropriate requestor within twenty-four (24) hours of result findings.
- ii) MRO will provide certified result reports in accordance with individual agency requirements.
 - Positive results, Adulterated or Substituted, Results requiring an immediate recollection, and refusals to test – results to Designated Employee Representative (DER) no later than ten (10) minutes after confirmation.
 - Results of split sample (Vial B) – results to DER within twenty-four (24) hours of confirmation
 - Negative results – results to DER within twenty-four (24) hours of confirmation.

20. Certifying Scientist original signature for positive confirmation reports (as required by the using agency)

V. STATISTICAL REPORTING: Reporting may be required for the following reports, including but not limited to:

1. **Quarterly Reports.** Awarded Supplier(s) may need to provide reports pertaining to CDL testing, as required by the Omnibus Transportation Employee Testing Act of 1991 (Act), and any regulations that have been, or will be, implemented because of the Act, as required by using Agency.
2. **Ad-hoc and Special Reports.** Awarded Supplier(s) may need to provide ad-hoc and special reports for individuals with diluted specimens, test history of recipients, monthly summaries of test results, etc., as required by using Agency.
3. **Semi-Annual/Annual Reports.** Awarded Supplier(s) may need to provide semi-annual/annual aggregate reports of drug and/or alcohol tests, as required by using Agency.

W. REPORTING METHOD:

1. **Web-based Reporting.** In accordance with individual agency RFQ requirements, the Awarded Supplier(s) may be required to provide and maintain a secure, web-based management tool that allows access to all drug and alcohol test results for data reporting within thirty (30) days of purchase order award. Adequate security shall include user logon by password, which allows user to access only those records specific to user's agency and program area/facility. Timeframe(s) for delivery of test results to the web-based tool shall be based on the individual agency RFQ requirements.

- a) Upon award of the purchase order, agencies will work with the Awarded Supplier(s) to customize the web-based reporting tool. Per agency request, the Awarded Supplier(s) shall provide an initial orientation at each agency site, to include training on the web-based reporting tool, describe overview of services, and to answer agency questions. During the thirty (30) day implementation

period, the Awarded Supplier(s) must provide reporting by alternate method in accordance with individual agency requirements.

- b) For all verified results and all positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test, the Awarded Supplier(s) shall notify the agency DER and the individual being tested immediately as directed by the agency. Each agency/program will identify the DER on their individual RFQ. Agencies with reasonable suspicion testing may have a DER at each field site.
 - c) In addition to the web-based reporting tool, the Awarded Supplier(s) may also be required by the individual agency RFQ to have the capability to provide duplicate hard copy or electronic reports (i.e. E-mail).
 - d) Awarded Supplier(s) must be able to provide automated upload of test results to automated drug test systems designated by agencies meeting OA and agency IT requirements.
 - e) The web-based tool must have the capability to provide a consolidated computerized invoice that lists each test performed in the previous month for each agency. For auditing purposes, one account number should be established for each agency, and each location should have separate sub-account numbers.
 - f) The MRO must have web-based tool reporting capabilities.
 - g) The web-based tool should also allow agencies to access an online manual.
 - h) The Awarded Supplier(s) must have the capability to provide emergency procedures and backup to its web-based reporting tool in the event that the web-based tool is not in service, including the thirty (30) day implementation period.
2. **PA DOC Random Inmate Selection Process (RISP) database.** For PA DOC only, the Awarded Supplier(s) will report, on a daily basis, individual laboratory results via web reporting and automatically upload to the RISP database within twenty-four (24) hours of result findings. The development of this automated upload transfer will be the responsibility of the Awarded Supplier(s) to coordinate with the PA DOC's Bureau of Information Technology (BIT) and must be designed to PA DOC's specifications and the Commonwealth's security requirements. Further details will be provided within the individual agency RFQ.
3. Additional reporting via secure email, fax, hard copy dependent may be required as per individual agency RFQ requirements.
- X. **NETWORK OF SUBCONTRACTORS:** Awarded Supplier(s) may use a network of subcontractors to perform a significant amount of services. The Awarded Supplier(s) will assume responsibility for managing the subcontractor relationships including payments to subcontractors. The Commonwealth requires that the Awarded Supplier(s) include terms and conditions in their subcontract agreement with each subcontractor that binds the contract that will result from this IFB. Using agencies have final approval of sub-contracted entities.

IV-5. ON SITE SCREENING DEVICES

- A. For Lot 4 only, the Awarded Supplier(s) must have the capability to provide on-site screening devices for the following test types, including but not limited to:

1. Oral Fluid Screening; and/or
2. Urine Screening; and/or
3. Breathalyzer; and/or
4. Retinal Scan.

B. Screening devices shall conform to the following U. S. Food and Drug Administration (US FDA) regulations, as applicable.

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm>

IV-6. SERVICE LEVEL AGREEMENTS. The Commonwealth has developed a set of minimum Service Level Agreements (SLA), defined in **Appendix I**, which the Awarded Supplier(s) are expected to meet, or exceed, in order to be in good standing on the Contract. The SLA's may be reviewed by the Agency DER or designee to identify any issues requiring immediate attention, and will be reviewed between Agency and the Awarded Supplier(s), as requested by the Agency.

The Awarded Supplier(s) will be allowed a thirty (30) day grace period during the implementation phase of the contract to "ramp up" services, without scoring on the performance metrics contained in the **Appendix I**. After the thirty (30) day grace period, tracing of each of the performance metrics shall begin, and the first report shall be due to the Agency designee one (1) month after the grace period ends. The Awarded Supplier(s) should develop a scorecard, which includes the performance metrics and can be reviewed, per agency request. If the Awarded Supplier(s) do not meet the agreed upon Performance Targets, the following actions will be taken. A discussion will take place between the Awarded Suppliers' representative(s) and the agency. The Awarded Supplier(s) will be required to develop a corrective action plan to improve on the problem area(s), submit the corrective action plan to the using agency within five (5) business days of the infraction and correct the issues within thirty (30) days of the date of the corrective action plan is approved.

IV-7. PAYMENT PROVISIONS. The Awarded Supplier(s) will be reimbursed monthly for testing services provided to each using Agency.

Invoices can be emailed to 69180@pa.gov.

If not familiar with the commonwealth's E-Invoicing Program, please visit our [E-Invoicing Program](#) page for details and requirements.

If you are unable to participate in the E-Invoicing Program, you can mail a paper invoice to:

Commonwealth of Pennsylvania – PO Invoice

PO Box 69180

Harrisburg, PA 17106