pennsylvania
DEPARTMENT OF GENERAL SERVICES
BUREAU OF PROCUREMENT

SOLICITATION ADDENDUM

Date:	**December 7, 2017**
Subject:	**Drug and Alcohol Testing**
Solicitation Number:	**6100042295**
Due Date/Time:	**12/15/2017 @ 1:30 PM**
Addendum Number:	**2**

To All Suppliers:

The Commonwealth of Pennsylvania defines a solicitation "Addendum" as an addition to or amendment of the original terms, conditions, specifications, or instructions of a procurement solicitation (e.g., Invitation for Bids or Request for Proposals).

Below is a list of the Questions and Answers for this solicitation:

1. On eMarketplace it shows 1:00pm on Dec 5 as the bid submission deadline; however, on the PA Supplier Portal it indicates 10:30 (a.m.?) as the deadline. Please advise as to the correct deadline.
   The bid has been extended until 12/15 at 1:30 PM EST.

2. Regarding Appendix C, we cannot find any cells highlighted in yellow on the Cost Submittal Worksheet. Please verify that vendors simply need to complete the second tab of the worksheet and then submit their own pricelists in their own preferred format.
   This is an oversite on our part. You only need to complete the second tab of the worksheet and submit your pricelist.

3. Regarding the Pricing List to be provided by Suppliers: This contract is potentially for 5 years. Will Suppliers be able to add or remove products from this pricing schedule following contract award if necessary (e.g. discontinued product, new products, demand for related products by state or COSTARS members) by formal amendment at any time, or will changes only be allowed at certain times/under certain circumstances?
   All products will have to be reviewed and agreed upon by the Commonwealth before adding to the contract.

4. In section C.3 on page 4 of the Statement of Work, the Commonwealth identifies SAMHSA/HHS and PA DOH and/or NCLP as required lab certifications. However, SAMHSA certification is specifically meant to regulate **federal workplace** drug testing. As such, SAMHSA licensure and practices may not be quite as appropriate or necessary for agencies needing non-employee testing, such as the criminal justice (CJ) sector (e.g. DOC inmates, PBPP probationers). In contrast, CLIA is also a federal certification by the DHHS; it may be used for forensic or clinical testing purposes, and is often much more cost effective. ***Would the Commonwealth consider requiring SAMHSA for employee and DOT testing, but allowing CLIA as an alternate option for non-DOT/non-employee testing?*** Agencies could still specify on their individual RFQs if they require SAMHSA processing of specimens and will not allow CLIA. Here are the compelling reasons to open up the bid to include CLIA or other laboratory certifications as options:
   Language can be changed to SAMHSA or CLIA certification. However, Department of Corrections requires that suppliers have CLIA certification.

a. SAMHSA certification only outlines regulations for 5 drugs--Amphetamines/Methamphetamines, Cocaine, Opiates, PCP and Marijuana (THC)—and now Ecstasy (MDMA) (a sub-group under amphetamines) and Heroin (6-MAM) (under the opiates class). In the ITB, the Commonwealth clearly includes other standard drugs (e.g. Barbiturates, Benzodiazepines) and synthetic substances as desired tests. PA DOC currently uses our CLIA laboratory to perform their synthetic substances testing.
b. SAMHSA licensure requires split specimen collection, which means that two separate samples have to be collected, labeled, etc. This becomes especially burdensome if the original specimen is collected using a rapid test device. In particular, agencies performing their own collections may not want or need this extra step. Non-SAMHSA laboratories can aliquot (pour off from) single samples and save the rest of the original sample for future retesting instead of requiring double specimens. The single specimen process still maintains chain of custody and is forensically defensible in a court of law.
c. SAMHSA licensure requires that an MRO reviews positive results before they are sent to the agency requesting the test. This practice of MRO review is to protect HIPAA rights of employees being drug tested. However, criminal justice agencies do not need the buffer of an MRO review--they have full access to inmate/probationers' prescriptions and histories as part of their incarceration/probation terms. Instead, the MRO review adds time and expense to their testing.
The MRO description in our current IFB certifies all results for controlled substances and to testify in cases when needed, the current language states: Awarded Supplier(s) must provide the following, as applicable and in accordance with the individual agency RFQ requirements.
d. SAMHSA licensure requires automatic confirmation of tests that screen positive. From experience, we know that many COSTARS agencies (especially CJ agencies, like County Probation) like having the option of separate screens with confirmation available upon request (such as when a donor denies use). The screen-only option allows for faster results and cost effectiveness. In particular, CJ agencies can confront their donors more quickly and get admission of guilt, which may be used to take action without the extra time and expense of waiting for confirmation testing.
We are using the cups for screening and to send to the lab for confirmation when wanting to detain parolee. We also use the lab for screening and confirmation of substances the cup won't detect such as synthetic drugs-we do want reflexive confirmation. Our lab currently is CLIA certified as well as SAMHSA. DOC requires CLIA certification

5. Similarly, on page 12 of the SOW, section I, Laboratory, the Commonwealth indicates that "The Awarded Supplier(s) shall provide an HHS certified laboratory, to perform specimen analyses. ... 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." Could an agency RFQ (or COSTARS member) set forth a requirement for CLIA guidelines, practices, etc. instead, if they do not require DOT or employee testing? Testing in accordance with SAMHSA/DOT may provide a cost impact due to added steps or restrictions.
It also states, "Or in accordance with standards set forth in the agency RFQ." Again, Department of Corrections requires CLIA certification.

6. Regarding section H, Collection Sites, on page 12 of the Statement of Work document, please confirm that this should only apply to Lot 3, and not Lot 1, as suppliers are not required to provide collection sites as part of Lot 1.
This only applies to Lot 3. DOC has to have collection sites where they have facilities and contracted facilities.

7. Regarding Section J.2 on page 13 of the Statement of Work:

a. Are suppliers required to submit a list of synthetic substances they test with their response for this ITB, or only when they respond to individual agency RFQs requesting synthetic substances testing?
Suppliers should submit a list of synthetic substances they have the ability to test for with their response to this IFB. When the agency does their RFQ they will then know what services are provided by specific suppliers.

b. If a list is required as part of this ITB, please identify how this list will be used by the Commonwealth. Please note that suppliers' lists will likely change over the course of this contract as new substances emerge or tests are developed.
The list would be used for reference to the popular, common drugs being used by our offenders.

c. How does Appendix F relate to this list? Must vendors provide tests for all substances on Appendix F, or is this merely informational regarding PA banned substances?
Appendix F was provided for information purposes only.

8. On page 8 of the Statement of Work, the Commonwealth indicates that, for Lot 1, the supplier needs to "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." Please confirm that the items to be provided at no cost would be standard laboratory collection supplies (i.e. not a rapid/on-site device, not a specialty collection supply such as a commode hat or infrared thermometer).
This would include their standard collection supplies such as mailing vial, mailing pouch, chain of custody form, mailing box and security seal strip.

9. On page 8 of the Statement of Work, the Commonwealth indicates that the specimen will be "collected in an approved Federal Drug Administration (FDA) cup or device pre-purchased by the Agency." Later, on page 20, the Commonwealth states that "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."
   a. Would the Commonwealth allow agencies to use non-FDA-cleared devices for non-DOT/non-employee (forensic use only) testing? Many newly-developed drug tests (e.g. test strips for synthetic cannabinoids, fentanyl, etc.) are not FDA-cleared, meaning industry-wide there will be no FDA-cleared devices for those drug tests. Agencies like the DOC or PBPP require may desire or require testing for some of these drugs in their devices. Similarly, any agencies wanting to use oral fluid rapid test devices would have to use Forensic Use Only (FUO) product, as there is only a single oral fluid device currently FDA-cleared.
   Title 61-6137.e states screening test approved by the Department of Health
   b. The link provided by the Commonwealth on page 20 is for the FDA's guidance, compliance, and regulation of *pharmaceutical drugs*, not drug test devices. Did the Commonwealth instead mean to imply that suppliers' devices need to be FDA 510k cleared? Can the link be stricken as a reference and either a substitute link or description be provided instead?
   Screening devices shall conform to U.S. Food and Drug Administration (US FDA) regulations, as applicable. Please disregard the link provided in the original statement of work.

10. On page 14 of the Statement of Work, section J.4, the Commonwealth states the following: "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)." This specification is specific to a single agency (the PADOC), and therefore it seems like this information would be part of an RFQ, not of an overall contract requirement for the Commonwealth. Other agencies may not require a single "combo" panel, or be specific about which methodology is used for confirmation. Would it be possible to strike this requirement and

leave this to the RFQ phase? If not, would the Commonwealth please indicate why a combination panel is required (this could easily be performed by selecting two tests instead of one combination panel) and why LC-MS/MS methodology is required for the confirmation (as opposed to leaving it open for GC-MS to be utilized instead)?

RFQ is fine as long as it's included.

11. On page 14 of the Statement of Work, section J.5, the Commonwealth states the following: "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)."
    a. Again, this is an agency-specific requirement; could this be stricken and left to the RFQ phase?
    New drugs may be added at the mutual agreement of supplier and Commonwealth.
    b. If this will not be stricken, we respectfully request that the "at no additional cost" be stricken, modified, or clarified. While some emerging compounds, like additional synthetic cannabinoids, may be able to be added to an existing panel at no additional cost, other emerging drugs may be considered a new class of drugs, and may need to be kept as a separate test and/or priced differently. This type of distinction needs to be evaluated against the current industry standard and/or discussed by the agencies and the suppliers during each annual RFQ process instead of included under this broad type of statement.

12. On page 15, section K, Designer Drugs, the Commonwealth indicates that "bidders must be able to detect and quantify the following substances, and their metabolites, intended to treat erectile dysfunction (ED) in men." We have not found that ED drugs are highly desired or required by many agencies; in fact, this might be considered a sort of specialty testing. Would the Commonwealth consider modifying the "must" to "may" so that this specialized testing does not eliminate otherwise-qualified bidders from participating in the contract?
    Language can be changed to say may.

13. Regarding page 14, section J.6, Specimen Screening, and Confirmation Timeframes, would the Commonwealth consider extending the possible turn-around times from 24 to 48 hours for screening and 48 to 72 hours for confirmation? The narrow turn-around window provided in the ITB is not standard in the industry; it may eliminate qualified bidders from participating in the contract and/or result in inflated prices in order for vendors to handle these as "priority" specimens. Instead, faster turn-around time requirements could be left to individual RFQ terms and negotiated as necessary for those agencies who absolutely will not accept industry standard turn-around times. We have found that, especially for COSTARS members, the industry standard turn-arounds are acceptable.
    The timeframes listed in the IFB are reasonable. This is a vital part of the drug testing program and timeliness is important for decision making. The DOC standards require 24-48 hours as test are time sensitive.

14. Regarding page 14, section J.6, Specimen Screening and Confirmation Timeframes, the specification only identifies GC-MS as a confirmation method. However, LC-MS/MS is increasingly common in the industry as a confirmation method. LC-MS/MS is more sensitive and specific than GC-MS, and increases compound identification specificity through the use of two mass spectrometers, versus a single one for GC-MS methods. In Volume 73, No. 228, page 71868 of the Federal Register, the Department of Health & Human Services, Substance Abuse & Mental Health Services Administration (SAMHSA) indicates that LC-MS/MS methodologies have proven to be reliable to test specimens, and produce forensically and scientifically supportable results. Moreover, LC-MS/MS results have proven to be defensible in courts of law across the country. Will the Commonwealth change this to "GC-MS or LC-MS/MS?"

We can change the wording to GC-MS or LC-MS/MS as long as the confirmation is accurate. LC-MS/MS test are more accurate for the confirmation of Cannabinoids Cathinones.

15. Regarding page 15, section L, Reflexive Confirmation Testing, would the Commonwealth consider striking "without cost to the Commonwealth?" Again, some agencies (especially COSTARS members) prefer screen-only tests as a more cost effective option, and would then be able to order confirmation testing separately, at cost. Agencies could always indicate that they require no cost for confirmations as part of their individual RFQ.
No we require reflexive confirmation. The language in the IFB is correct.

16. Regarding page 15, section M, Specimen Validity Factors, the Commonwealth says this must be done "in accordance with HHS regulations." SAMHSA/HHS regulations has very specific protocols as to how they identify a specimen as "substituted" or "adulterated" or "diluted" that is not necessarily practiced in non-SAMHSA labs. Would the Commonwealth allow for laboratories that identify specimens with abnormal/low creatinine levels ("diluted") and identifies unusual results for specific gravity and pH (shows quantitative values found as well as the normal ranges for these factors) without identifying them specifically as substituted or adulterated?
We prefer this stays as is.

17. Regarding page 11 of the SOW, section E.3 MRO, will the Commonwealth allow non-DOT/non-employee testing to be performed without mandating that an MRO be utilized (i.e. could the MRO requirement be left to agency-specific RFQs)? Again, forensic testing such as that utilized for the DOC, PBPP, or other criminal justice COSTARS members does not require MRO review--in fact, MRO review could delay results and add unnecessary expense. Forensic labs have toxicologists on staff who are able to provide similar analysis (e.g. whether a prescription drug could have caused a positive result) and legal/administrative assistance as needed and at no charge.
The language indicates as applicable and in accordance with the individual agency RFQ.

18. Regarding page 16, section O, Logistics - Storage, will the Commonwealth allow for a shorter storage of negative specimens, such as 2 business days instead of 30 days? We have found that most negative specimens are requested to be retested within 2 business days; longer storage times of negative specimens could create impacted retrieval and higher cost to accommodate the extra storage space necessary. Instead, longer storage times could be specified on individual agency RFQs, if necessary.
This can be put in the RFQ. But note that DOC requires a minimum of 30 days.

19. Regarding page 16, section P, Expert Testimony, will the Commonwealth allow for a cap on the number of instances of expert testimony at no cost--such as 5 free cases of in-court expert testimony per agency? As suppliers have no reference for how many cases they will need to provide, this will limit excessive use.
We have no way of knowing how many cases we will have in a year's time. We will not issue a cap on this service.

20. Regarding page 10 of the SOW, section E.1, Account Manager, will the Commonwealth allow for suppliers to have Account Managers available at 9:30 instead of 7:30am, to accommodate laboratories in different time zones?
The IFB requires a cell number and alternate contact. As long as we always have someone available to contact during our business hours.

21. Regarding page 11 of the SOW, section E.2, Customer Service, will the Commonwealth consider a modified window, such as 9am to 8pm instead of 24-7-365 customer service? **We need someone available 24/7/365 as we are a 24/7/365 operation.**

22. Regarding pages 13-14, section J.1 Testing and the cutoff charts, the Commonwealth states in J.1 that "the Awarded Supplier(s) must be capable of detecting and confirming the following substances at the minimum cutoff levels listed;" however, the ITB then states that "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." If this list could change at any time, we would request that the Commonwealth indicate that these charts are representative of current needs and are informational (as opposed to required), and that actual required cutoff levels are to be determined by each Agency (or COSTARS Member). At the very least, we respectfully request that the **PADOC cutoffs chart** be treated as informational (as opposed to required), as their specific chart utilizes non-industry standard, non-SAMHSA "zero tolerance" cutoffs that are not utilized by most certified laboratories. The requirement for laboratories to meet the PADOC's special cutoffs may prevent otherwise-qualified laboratories—for instance, those who only perform SAMHSA/DOT employee drug testing at SAMHSA-required cutoff levels—from participating in this contract. Instead, these cutoffs could be required as part of the PADOC's individual RFQ.
The levels need to stay as they are currently listed in the IFB.

23. Regarding page 17, section S. Information Technology Bulletin (ITB) Compliance Requirement, the 194 policy documents listed at http://www/oa.pa.gov/Policies/Pages/itp.aspx are internal IT policies and do not pertain to suppliers. It is unreasonable and impractical to comply with the entire set of IT policies. If the Commonwealth has supplier-specific requirements, could these be identified either in this bid or on the agency RFQ?
The IT policies can be found at http://www/oa.pa.gov/Policies/Pages/itp.aspx under the section for Policies, section T. WWW.OIT.State.PA.US is the site in Section S.

24. Regarding page 17, section T. Information Technology Polices: The OA/OIT's Accessibility (ITP-ACC001) policy does not specify the required accessibility guidelines. It contains a reference to specific product standards in policy STD-ACC001B, but this policy is not listed and the link in the Accessibility document to this policy is broken. The links to the agency's IT Accessibility Website and Manual Testing Strategies and Techniques for Web Site Accessibility Validation are also broken. The agency's website itself does not comply with standard accessibility guidelines. Would the Commonwealth please identify supplier-specific requirements for this bid, or leave this to the agency RFQ?
The link for the IT Policy is http://www.oa.pa.gov/Policies/Documents/itp_acc001.pdf. The supporting links are: http://www.oa.pa.gov/Policies/Documents/opd_acc001a.pdf, http://www.oa.pa.gov/Policies/Documents/opd_acc001c.pdf and http://www.oa.pa.gov/Policies/Documents/std_acc001b.pdf.

25. Regarding page 18, section W.1.a Reporting Method, the implementation timeline for customizations will depend on the scope of the customizations. Will the Commonwealth allow for longer than 30 days if deemed necessary after deliberation by the supplier and the Agency?
The Commonwealth will agree to a maximum of 45 days.

26. Regarding page 19,section W.1.b: for criminal justice agencies, individuals being tested (donors) are typically not notified of their results by the laboratory. Please specify that this will be only upon request by the Agency.
The lab is not to notify reentrants/inmates of the results. This can be specified in the RFQ.

27. Regarding page 19, section W.1.e, for suppliers who do not yet have invoicing on their web-based reporting system, would the Commonwealth allow for an interim period where computerized invoices may be sent electronically (such as via email, fax, or FTP site) and identify a start-up window for adding computerized invoicing to the web-based tool?
An interim period will be granted.

28. Regarding the following from page 28 of the Terms & Conditions: "The terms and conditions of this Contract shall be the exclusive terms of agreement between the Contractor and the Commonwealth. ... Other terms and conditions or additional terms and conditions included or referenced in the Contractor's quotations, invoices, business forms, or other documentation shall not become part of the parties' agreement and shall be disregarded by the parties, unenforceable by the Contractor and not binding on the Commonwealth." If the Contractor and a COSTARS member agree to a modified term or condition--such as a Net 45--would this be acceptable to the Commonwealth, as long as it is documented and/or included as an Amendment for that COSTARS member, according to their own agency's policies?
If a supplier wants to participate in the COSTARS program, it must complete and return the COSTARS Program Election to Participate form. The Terms and Conditions and Form states that by participating in the Program, the bidder is willing to sell the awarded items/services at the same prices and/or discounts, and in accordance with the contractual terms and conditions.

29. Would the Commonwealth consider the following changes requested by our legal counsel?

    a. Regarding T&C page 19, section V.28.a Default: Would the Commonwealth consider adding “and an opportunity for Contractor to cure the default within 30 days” after “default by written notice?” **The Commonwealth will not consider changes to the Terms and Conditions.**
    b. Regarding T&C page 21, section V.28.f Default: Would the Commonwealth consider replacing “Board of Claims” with “a court of competent jurisdiction?” **The Commonwealth will not consider changes to the Terms and Conditions.**
    c. Regarding T&C page 21, section V.30.a Termination for Convenience: Would the Commonwealth consider replacing “The Commonwealth” with “Either party,” so both parties have the right to terminate for convenience? **The Commonwealth will not consider changes to the Terms and Conditions.**
    d. Regarding T&C page 21, section V.30.c Termination for Cause: Would the Commonwealth consider adding “and an opportunity for Contractor to cure the default within 30 days” after “upon written notice?” **The Commonwealth will not consider changes to the Terms and Conditions.**
    e. Also regarding section V.30.c Termination for Cause, would the Commonwealth consider adding the following to the end of the section: “In addition, Contractor shall not be liable for any damages as identified in Paragraph V.28 Default.” **The Commonwealth will not consider changes to the Terms and Conditions.**
    f. Regarding T&C page 22, section V.31.a Contract Controversies: Would the Commonwealth consider replacing “accrues” with “is discovered?” **The Commonwealth will not consider changes to the Terms and Conditions.**
    g. Regarding T&C page 22, sections V.32.b and V.23.c Assignability and Subcontracting: Would the Commonwealth consider striking “may be withheld at the sole and absolute discretion of the Contracting Officer” and replacing with “shall not be unreasonably withheld?” **The Commonwealth will not consider changes to the Terms and Conditions**.
    h. Regarding T&C page 25, section V.35.2.d, Contractor Integrity Provisions: Would the Commonwealth provide the names of all contractors working under this contract to ensure that Contractor can comply with this provision? **The Commonwealth will publicly post all contracts that are entered into as a result of this IFB once they are fully executed**.
    i. Regarding T&C page 26, section V.35.2.j, Contractor Integrity Provisions: Would the Commonwealth consider striking this whole section? **The Commonwealth will not consider changes to the Terms and Conditions.**
    j. Regarding T&C page 28, section V.43, Changes: Would the Commonwealth consider adding “subject to the availability of testing provided by Contractor” after “changes to the services within the scope of the Contract?” The issue here is that if a new drug and/or

validity testing measure is requested/demanded by the Commonwealth it may not be available at the time of the request/demand. As this is scientific testing, the validation of said testing may require additional time. **The Commonwealth will not consider changes to the Terms and Conditions.**

k. Regarding the Appendix E, Business Associate Agreement, labs such as ours are covered entities as that term is defined by federal law and therefore this BAA is an unnecessary document. Would the Commonwealth consider removing this document, or indicating that it is only applicable to suppliers who are not considered covered entities? **The Business Associate Agreement is only applicable to suppliers who are not considered covered entities.**

30. On the Domestic Workforce Utilization Certification (Appendix B), are both spots at the bottom for officers of our company to sign? Do we need to have two signatures, or will one suffice? **Yes, both spots are for the company to sign. The form must be signed by someone at the company (such as the President, CEO, etc.) and then witnessed by a separate person.**

31. Do you require all customer service and all personnel with access to your company's information and/or applicant's information to be US based? **We do not require US based.**

Type of Solicitation: Electronic Bid (SRM) - Review the Questions section of your solicitation response to ensure you have responded, as required, to any questions relevant to solicitation addenda issued subsequent to the initial advertisement of the solicitation opportunity.

Except as clarified and amended by this Addendum, the terms, conditions, specifications, and instructions of the solicitation and any previous solicitation addenda, remain as originally written.

Respectfully,

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