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#### ADDENDUM 4

**To:** All Interested Proposers

**From:** Lucy Balderama, Inventory Bid Technician

**Date:** January 07, 2008

**Subject:** Bid # 07-166, Drug Testing and Laboratory Services for Juvenile Probation Department

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The Purchasing Department received questions relating to the above referenced proposal; the response to the following questions:

1. What is the projected number of tests that will be done on an annual basis?

As reflected on the bid (pg. 4) JPD estimates 8,000 urine specimens are collected on-site and 100 are sent to the laboratory for confirmation on an annual basis.

2. Under #1 Scope of Work, Cup Design Requirements, it is asking for a 5 panel drug screen cup, but a few pages into the bid it is listing 7 different drugs along with Ethanol. Can you please clarify this for us?

We are seeking a 5 panel cup at a minimum. The department may request specific drugs to be tested at the laboratory if there is suspicion of illegal/legal substance abuse that the cups do not detect (ie. dextromethorphan).

3. You have listed Ethanol as a drug. Will this be expected to be a part of the drug-testing cup or will it be part of the laboratory testing?

Part of the laboratory confirmation if requested by the department.

4. You indicate 100 laboratory tests. Is this actual lab test or confirmatory tests on the presumptive drug screen cups?

This would be the number of specimens sent to the lab for confirmation on the presumptive drug screen cups.

5. What do you consider your percent of positive rate to be on the 8,000 drug screens?

We are averaging between 8-10% of positive drug screens per year.

6. (Pg 5) g. Label must have line to enter collection time, date, and client's initials, and two additional smaller self adhesive peel off labels with matching specimen ID---If this is not a split specimen, the chain of custody form will usually only have one(1) smaller self adhesive peel of label to put on the cup, not two(2).

Two seals are necessary to protect the integrity of the sample. One for the sample and one for the specimen / evidence bag.

7. (Pg 6) i. The client's identity must be blocked out on the copy (Client's name, identification number, and certification/signature)  
The Chain of custody is usually a 3-part form. There is the original, which is sent to the lab, a middle copy for the JPD and a final copy for the client/donor. What is the purpose of having the clients name blocked out?

We do not use the client's name. We only use their personal identification number which is only identifiable by JPD personnel as a means of protecting confidential information.

8. (Pg 7) All confirmed positive samples must be maintained for a minimum of twelve (12) months. Is this in reference to the paperwork (Chain of Custody) or the actual donor specimen (urine)?

Both would need to be kept for the required time period.

9. Though this information presented for the council is not the actual RFP there are some contradictory statements. Is El Paso requesting onsite screening devices and laboratory confirmation or all lab based testing?

We are seeking onsite screening devices that will allow JPD personnel to collect the specimens. Additionally, we are seeking laboratory confirmation that will be utilized at the discretion of the department.

10. The information also is contradictory regarding cut-off levels. The drug concentrations levels listed are NOT SAMHSA cut-off levels. Does El Paso want SAMHSA cut-off levels for screening devices and confirmations or LOD/LOQ levels for screening devices and confirmation?

We are requesting LOD/LOQ on all specimens sent to the lab for confirmation.

11. Is there cause for concern of contamination of the specimen by the testing assays if a participating agency were to send the specimen collected in the test cup specified as "Fully integrated, without a separate testing device" into a SAMHSA certified confirmation laboratory?

This is issue or concern has never been brought to our attention by the laboratory.

12. Most SAMHSA-certified labs will not accept collection cups with integrated testing reagents due to possible contaminations, is considering using laboratories with less stringent guidelines to accommodate the test cups described or will the participating agency require the collector/tester to pour of urine specimen into the laboratory's approved collection container; resulting in more urine specimen handling and breach of specimen integrity?

We have never had such an issue with providers utilized historically. This department has been utilizing integrated testing cups for several years and this has never been a concern brought forth by a laboratory.

13. Vicodin (hydrocodone) is one of the most widely abused drugs in the country. Do you want the product you buy to detect Vicodin at:
- a. 50,000 ng/ml
  - b. 20,000 ng/ml
  - c. 5,000 ng/ml

d. 400 ng/ml

Hydrocodone would show up under the opiates panel of any POCT device that tests for it.

14. Cocaine is an illegal drug Texas participating agencies' policies state "NO" drug use is allowed. When someone taking Cocaine has a level detectable in their system of 100 ng/ml, do you want this test to report as a positive or a negative test?

Positive - any amount regardless of the level if detected shall be reported as a positive.

15. Opiates are an illegal drug class and Texas participating agencies' policies state "NO" drug use is allowed. When someone is taking an Opiate and has a level detectable in their system of 100 ng/lm, and is admissible in court, do you want this test to report out as positive or negative?

Positive - any amount regardless of the level if detected shall be reported as a positive.

16. Consider Amphetamines as an example. If the cut-off level used by the product is 1000 ng/lm, do you want the accuracy of the product to be a least 97% at 1000 ng/lm or 97% at a level much higher than the proposed cut-off level? Does your answer apply to other drug classes?

97 % at 1000 ng/lm at least would be acceptable

17. What is the highest error rate you would accept for any drug at the cut-off level when compared to GCMS.

3 %, 5 %, 10 %, 20 %, or 40 %

The highest acceptable would 5 %.

18. Can test strips be shipped from China on boats in non-temperature controlled chambers be considered as usable here if they have temperature storage requirements after being inserted in a test?

If the requirements are after being used , yes. If the test requires temperature control for storage then this would render these tests invalid.

19. Since ALL criminal justice agencies state that no drugs are to be used, why would you use a test that the FDA product insert states that it allows drug use? Doesn't it make more sense to use an FDA approved product that shows positive if virtually any drug is in the urine?

JPD is using the drug tests currently on the market and affordable.

20. Bid states lab must be certified by SAMHSA. As much of this testing is outside the regulatory scope of SAMHSA (i.e. LOD detection limits, opiate 300 cut-off, etc,) will a CAP-FUDT certified laboratory be considered?

Certification only needs to be considered for court testimony and verifiable In court. If the lab is capable and does the tests on a normal basis of operation and can testify and verify procedures and training.

21. Must vendor provide COC forms for specimens that are NOT sent to lab for testing?

No.

22. What method of shipping is currently utilized for shipping specimens to the laboratory?

DHL

23. Pricing asks for confirmation charges per specimen and drug class. However, bid states the Department will not consider pricing based on "per analyte" basis. Is the County currently paying for confirmations per drug class (analyte), or per specimen?

Currently paying per drug class.

24. On Average, how many specimens are shipped together (in the same shipping container) to the laboratory?

1 to 2 per container.

25. Does pricing "per analyte" mean that if a specimen requires confirmation for amphetamines that a charge is passed on for both amphetamine and methamphetamines? (2 confirmation charges)

Yes that would be correct, as to how different tests are being conducted. Such as an initial fee then a lesser secondary fee for the second test.

26. Does pricing per analyte mean that if a specimen requires confirmation for amphetamines, and cocaine, that a charge is passed on for both amphetamine/methamphetamines confirmation and a second charge for cocaine metabolite confirmation? ( 2 confirmation charges)

See the answer for question # 25.

27. Can the County provide the approximate % of specimens that require confirmations for multiple drugs?

At this time that information is not readily available. Most frequently the two drugs that are most commonly used which provide positive on-sites is marijuana and cocaine.

28. Approximately how many times per year does the County request on-site training with regards to this BID?

Approximately once or twice per year.

29. Did past/current vendor accomplish electronic data transfer of results?

Yes

30. Did the County request that past/current vendor to accomplish electronic data transfer of results?

No. However the vendor did provide this service.

31. Is the cost of the development of electronic data transfer to be included in the bid?

Yes

32. Please clarify that statement under Laboratory Services: The laboratory shall perform an initial test on all specimens that includes the validity testing and immunoassay. How can the laboratory perform this test if JPD is using POCT devices?

The lab conducts these tests upon receiving the specimen. Some of the POCT Devices have built in validity and contamination tests, which are being used by JPD.

33. Under the pricing, you have listed: Screen-Laboratory Service per specimen and Screen and GC/MS Confirmation per specimen. How many specimens will be sent to the lab for Screening and Confirmation?

Approximately 100 in a one year period.

34. What does Screen-Laboratory Services mean? Is it POCT or lab based testing?

Some labs conduct and emit test and will provide GCMS if requested by the department thus reducing cost for the department. Being that the vast majority of positive drug use goes uncontested and the results are utilized more for treatment purposes and sanctioning the lab confirmations provide a

reassurance that the reading on the cups was accurate and also provides a concentration level that cannot be obtained on the on-site cups. GCMS testing becomes important when a positive drug screen is going to be contested in court and a higher standard of laboratory confirmation is necessary.

35. Are you accepting overseas product, namely China?

If approved by the FDA

36. Do you care about accuracy levels?

Yes, we are seeking that the on-site cups render at a minimum a 97% accuracy level.

37. Will you be requiring levels greater than 96% per drug screen?

Need further clarification on this question.

38. Will all lab supplies be shipped to one location?

That is for the bidder to let us know. Bidder shall provide us the lab address and we will ship according to the contractor's instructions.

39. Will there be only one location that ships the specimens overnight to the lab?

All shipments will be sent from the Juvenile Probation Department only..

40. Substance Abuse and Mental Health Services Administrations (SAMHSA) Certification is the highest level of certification a Laboratory can receive. Why would the department also consider College of American Pathologist (CAP) accreditation?



We are seeking bids and the department will take the labs certification levels along with cost into consideration when awarding the contract(s).

41. Would it not be in the best interests of the department to only allow SAMHSA Certifies Laboratories to submit a proposal if they wish to receive the highest level of laboratory services?

Please refer to the answer on question 41.