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QUALITY DETECTION PRODUCTS

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Dr. Vogl,

I am excited about the proposed revisions to the guidelines for federal workplace drug testing programs that might allow the use of point of collection tests for drugs of abuse. I also appreciate the opportunity to voice my recommendations relative to the use of point of collection tests. I have waited until today to submit my comments and suggestion so that I could read the comments and suggestions submitted to date in order to avoid duplicating the suggestions of the other submitters.

As one who has marketed POC DOA tests for over 6 years, I have seen the accuracy of these tests improve to the level where they rival the accuracy of laboratory drug screens. In addition to increased accuracy, these POCT devices have become much easier to use and interpret resulting in accurate interpretation of results by those performing the tests. The most popular format for POC tests steadily migrated to the integrated DOA cup that serves as a collection container, POC test, and confirmation vessel.

The following comments and suggestions are provided in response to the proposed revisions to the guidelines for federal workplace drug testing related urine POCT requirements:

Page 19678 "Advantages of POCTs" – While I agree that the POCTs are well suited for use in emergency/crisis management situations, it can also be argued that POCTs are of tremendous advantage when used for pre-employment and random drug testing. As stated by at least one person who has already submitted their comments, the immediate negative results provided by POCTs eliminates the waiting time required by laboratory screens to produce negative results, and therefore the associated anxiety and stress that can be experienced by employees and potential employees while waiting on the drug screen results to be reported by the laboratory.

2. Page 19580 "the Department believes that the only sensitive and specific manner to perform the initial test for methamphetamine, amphetamine and MDMA is to use two separate initial tests, one for methamphetamine and amphetamine and one for MDMA" – There is currently only one POCT manufacturer that manufactures an immunoassay that detects both methamphetamine and amphetamine. However, it is my understanding from the marketplace that this immunoassay experiences a higher rate of false positives than the immunoassays that individually test for methamphetamine and amphetamine. Therefore, it might be argued that the most sensitive and specific manner to perform the initial test for methamphetamine, amphetamine and MDMA is to use three separate initial tests, one for methamphetamine, one for amphetamine and one for MDMA.

3. Page 19682 " Subpart G – Collection Device – A concern voiced numerous times in the comments already submitted is the ability of the collector to follow proper procedure in collecting and splitting the urine specimen, and in the case of POCTs, administering the POCT and interpreting the POCT results. For laboratory specimen collections and POCT collections, the use of a collection device that automatically splits the specimen into three chambers: "A specimen chamber", "B specimen chamber" and the "POCT specimen chamber". This automatic and simplified process would free the collector from focusing on correctly splitting the specimen and allow them to focus on the chain of custody protocol which is where the vast majority of fatal flaws occur. The desired device to accomplish this separation of the specimen should separate the specimen in such a manner whereby there is no ongoing fluid communication between the three chambers once the urine is split.

4. Page 19719 – Section 12.6 (SAMHSA-Certified POCTs) – The type(format) of POCTs is not addressed in this section. There are two different categories of POCT's that may be submitted for SAMHSA certification:
    1. Non-integrated POCTs – These are the POCTs that do not utilize a collection device that is integrated with the POCT. Examples of these devices are pipette POCT's where the urine is applied to the POCT with a pipette, and dip card POCT's that are dipped into the urine specimen.
    2. Integrated POCTs – These are the most popular type of POCT due to limiting the collector's exposure to the donor's urine specimen and ease of use.

    The integrated POCTs should have the following features in order to get approval for use in federal workplace drug testing:
    1. Integrated POCTs must not be able to be activated by the donor unless they are in the presence of the collector.
    2. Integrated POCTs must provide a tamper-proof POCT with a method to provide evidence to the collector that the POCT has been activated or attempted to be activated by the donor in the event the donor should attempt to activate the POCT.
    3. Integrated POCTs must provide a urine specimen receptacle including at least three separate and selectively connectable chambers. One of the chambers shall serve as a chamber to hold the POCT and the aliquot of urine to run the POCT. One of the chambers shall capture 15 ml of urine to serve as the "B" Specimen. The third chamber shall contain the remainder of the urine specimen (At least 30 ml) to serve as the "A" Specimen.
    4. The "A" and "B" chambers shall not be in continual fluid communication with each other or the POCT chamber.
    5. The "A" and "B" chambers must be able to be sealed separately with the COC donor seals.
    6. The "A" and "B" chambers must be able to be accessed separately by the laboratory so as to preserve the donor COC seal integrity on the chamber that is not being accessed.
    7. The integrated POCT must be made of clear polypropylene to allow the collector to visually inspect the urine specimen and to prevent drug leaching.
    8. The integrated POCT must be able to perform the specimen validity tests dictated by SAMHSA.

9. The integrated POCT results must be able to be scanned or photocopied in order to provide a permanent record of the actual POCT results in the donor's file.

5. Page 19719 – Section 12.8-h (Records of the POCT Results) – As suggested above, the ability to photocopy or scan the actual POCT result in order to file the photocopied or scanned result in the donor's file will be beneficial in several ways:
    1. The photocopy of the POCT result serves as a permanent record of a negative drug screen result for the donor.
    2. Negative and Non-negative POCT result photocopies could be pulled from the donor's file to be compared to laboratory screen results on the 10% of specimens that must be sent to the laboratory and to laboratory confirmation results on non-negative specimens that are forwarded to the laboratory for confirmation.
    3. A photocopy of the POCT result can be checked during government or inner-company audits to insure that the POCTs are be interpreted correctly by the collector/POCT technician.
    4. The photocopied or scanned POCT results could be transmitted to the MRO for review.

6. Page 19720 – Section 12.18 (Requirements for Conducting a POCT) –

    Part (a) – A donor must not have access to the POCT Device – Does this mean access to activate the POCT device? In order to simplify the POCT process, it is important to allow an Integrated POCT device to house the POCT. It is understood that the donor must not be able to activate the POCT (Unless in the presence of the Collector). The Integrated urine Collection/POCT device can and should be allowed to house the POCT, but with the stipulation that the donor cannot access or activate the POCT unless it is designed to be activated in the presence of the collector. The integrated POCT device must and should have safeguards built in to ALERT the collector if the POCT device has been activated by the donor or tampered with by the donor.
    Part (b) – a POCT collector is permitted to break the label/seal on the primary specimen (Specimen "A") and remove an aliquot to conduct the POCT. – This is at least undesirable (Because the tester is breaking the chain of custody) and is not necessary. If a non-integrated POCT device is being used, the collector should split the specimen into three separate containers: Container one for "Specimen A", container two for "Specimen B" and container three for the POCT. If an integrated POCT is being used, then there are two options:
        1. The integrated POCT device should have three separate chambers built into the device. Chamber one for "Specimen A", chamber two for "Specimen B" and chamber three for the POCT. The urine should be either automatically or manually divided in the appropriate volumes into each of the three chambers.
        2. If the integrated POCT device does not have three separate chambers, then the collector must first pour off the appropriate amount of urine specimen into a container for "Specimen A" and "Specimen B" and utilize the remaining urine specimen to run the POCT.

    As the document is currently written, the POCT tester would be allowed to break the

COC donor seal on the "A Specimen" container and reseal the container with a non-donor COC label before sending the specimen to the lab if warranted for confirmation of a non-negative result or for the 10% lab test requirement. The recipient lab would not be able to verify that the COC donor security is in place on "Specimen A" when they receive it. Therefore, there would be only one documented secure specimen "Specimen B". This could effect the defensibility of the lab result on "Specimen A". If the lab was forced to use "Specimen B" due to concerns over the validity of "Specimen A", then there would be no sealed specimen to send to a second lab should the first lab's results be challenged by the donor.

7 Page 19721 – Section12.22 (How is a POCT Negative Result Reported?) – Can the Collector/Tester report a negative POCT result to an employer directly or does the negative POCT result have to be reported to the employer by the MRO? When I originally read this section, I was under the impression that the POCT result could be reported directly to the employer by the tester, and that the POCT result also had to be sent to the MRO within three days. I have read several submitted comments that express concern that if an MRO must report the POCT result to the employer, that the immediate negative result provided by the POCT will be in vain. May I suggest that the tester be allowed to directly report a negative POCT result to the employer, and then send the result to the MRO within three days? In the even that the MRO should somehow discover that the result should not have been negative, the MRO could then notify the employer.

8. Page 19721 – Section 12.24 (What POCT information is Available to the Donor?) – Since it will be required for the Collector/Tester to provide the Donor with specific information on the POCT procedures, it seems that it would make sense to provide the Donor with a photocopy of his/her actual POCT test result. This way the Donor can see the result of the POCT initial screen test for themselves.

Thank you again for the opportunity to provide input from my view-point. If you or anyone in your department should desire to reach me to discuss my comments or suggestions, I can be reached at 1-888-669-4339 (M-F 8:00 am – 5:00 pm CST) or 1-866-683-4660 (evenings and weekends).

Sincerely,

Larry Hartselle
President