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Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Dr. Vogl,

I would like to submit the following comments regarding the proposed Mandatory Guideline for Federal Drug testing Programs.

Before articulating my comments, I'd like to thank HHS for it's efforts to modernize to the new technologies that have been developed for drug of abuse detection. For many years these new technologies, especially oral fluid testing, have received attention from researchers and clinicians to build a body of evidence to support their routine use.

Given the programs ultimate aim of deterrence, providing various means of testing gives those performing drug of abuse testing the greatest tools to maximize and achieve the goal.

In regards to specific issues cited in the draft guidelines of April 13, 2004 I would like to submit the following comments for each section listed below;

Section 1.5 What do the terms used in these Guidelines mean?

Split Specimen. For oral fluid, one specimen collected that is subdivided or two specimens collected almost simultaneously.

COMMENT: Regarding oral fluids split specimens, it is entirely possible to collect a split specimens using two devices. The guidelines should not limit the ability to use existing technologies by requiring the collection of expectorated saliva.

Section 2.2 Under what circumstances can the different types of specimens be collected?

Oral Fluid… Pre-employment, random, reasonable suspicion/cause, post-accident

Comment: Existing literature based on valid scientific studies have demonstrated that the use of oral fluid for pre-employment testing is comparable to existing urine testing in prevalence rates (*JAT.* 26: 541-46 (2002). Additionally, the proliferation of urine adulterants which are effective have compromised the utility of urine alone for pre-employment testing. Based on the scientific evidence available, oral fluid should be used in all testing situations.

Section 2.3 - Can more than one type of specimen be collected at the same time from the same donor?

(a) When an oral fluid specimen is collected, a urine specimen must also be collected;

Comment: It is illogical to collect a urine specimen in parallel to an oral fluid specimen for the purpose of THC analysis. Sufficient studies have shown that the prevalence rates with oral fluid are comparable to urine for all drugs typically detected (*JAT* 26: 541-546 (2002). Additionally, recent studies have shown passively exposed subjects to THC side-smoke may be detected in oral fluid for less than 1 hour (in press JAT). This situation is similar to urine testing which demonstrates comparable results in extreme circumstances. Therefore, proposing simultaneous collection of urine and oral fluids defeats the purpose of adding new matrices to the regulations and further enhances the effectiveness of adulterants to hide urine THC positives. By allowing both fluids to be used in all situations individuals are most deterred from taking drugs.

Section 2.5 What is the minimum quantity of specimen to be collected for each type of specimen?

(b) Oral Fluid: 2 mL collected as a "neat specimen" (divided as follows: at least 1.5 mL for the primary specimen and at least 0.5 mL for the split specimen)

Comment: The collection of an expectorated oral fluid specimen is not compatible with routine testing or human physiology.

Humans salivate approximately 0.4mL/min thus the collection of 2mL can take a minimum of 5 minutes. Additionally, oral fluid will contain a mixture of glandular secretions that will vary in consistency and viscosity. Therefore, pouring 0.5mL is not feasible for oral fluid specimens.

More practical, is the utility of existing collectors that gather a smaller amount of fluid which can be used for both screening and confirmation. The Intercept Device, Orasure Technologies, Inc, utilizes on average 0.4mL of specimen which is diluted into 0.8mL of a transport buffer. The total 1.2mL of specimen is more than sufficient for all testing requirements.

Finally, the proposed requirement of 2.0mL prevents the development of more advanced technologies in the future that can utilize extremely small amounts of fluid. Nano-techniques are becoming widely available to quickly screen for multiple compounds simultaneously. It is vary possible that the current list of target drugs of abuse will expand as new designer drugs become available. HHS should anticipate this and allow innovation by simply stating that new technologies must collect a sufficient amount of sample for both screening and confirmation. Validation that the amount collected is sufficient will be demonstrated through FDA clearance and commercial laboratory validation.

Section 7.1 What is a collection device?

(c) For oral fluid, it is the single-use plastic specimen container.

Comment: An oral fluid collection device should be any device that has been cleared by the FDA. To state that it must be a single-use plastic container is inconsistent with other sections of the proposed guideline that suggest products must be FDA cleared.

Section 7.2 Which collection devices may be used?

(b) These Guidelines do not determine if a collection device must be cleared by the FDA.

Comment: Not specifying that devices for collection of oral fluids allows the proliferation of substandard products that have no external verification of performance. The purpose of the FDA is not only to determine safety and efficacy of marketed products prior to introduction, but also to inspect manufacturers on an on-going basis. Therefore I believe that HHS should require all products used to have an FDA clearance and therefore be registered medical device manufacturers.

Section 8.3 What procedure is used to collect an oral fluid specimen?

(a) The collector must use the following procedure to collect an oral fluid specimen:
(5) The collector will give the donor a clean specimen tube.
(6) Under direct observation, the collector will instruct the donor to expectorate (to spit) 2 mL of oral fluid into the specimen tube. This can be accomplished over a 15 minute time period or until the appropriate volume of specimen is collected. (7) Both the donor and the collector must keep the specimen tube in view at all times prior to its being sealed and labeled.

Comment: This section should be written more generically to mimic the procedures used by existing FDA approved collection devices. As previously stated, the collection of 2mL of expectorated oral fluids is not practical.

Thank you for the opportunity to comment on some of the issues in the proposed guidelines.

Sincerely,

Sam Niedbala. Ph.D.