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**Re: COMMENTS ABOUT DOCUMENT # FR Doc 04-7984**

Dear Dr. Vogl,

Below are comments from Immunalysis Corporation about the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

*Section 2.5 (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)*

We concur with the need to be able to collect a known amount of neat Oral Fluid. We believe the regulations should include devices that ensure a known amount of "neat" non-stimulated Oral Fluid is collected i.e. collection should not involve the use of salts, citric acid, gelatin, or other stimulant. The absorbed Oral Fluid may then be diluted in a known volume of dilution/extraction buffer prior to shipment to a laboratory. If "expectoration" is the only approved method to collect a specimen it is very likely that drug users will use the dry mouth defense to ensure that inadequate specimen is collected.

Unlike clinical testing where a patient has a definite interest in providing the requested body fluid sample, drug users have a definite interest in either not providing the sample requested or in adulterating the sample being provided. Thus any drug user who is requested to expectorate will use the dry mouth defense to ensure inadequate sample collection. Separately, collection of neat Oral fluid necessitates expectoration into a wide-mouth container. The bubbles that one always sees in saliva, makes it difficult to determine the actual volume of sample collected.

With current immunoassays and bench top confirmation analytical equipment 1 mL of neat oral fluid is sufficient to conduct an initial screen and confirmation, hence a second collection device collecting 1mL of the specimen almost simultaneously should suffice for the split specimen requirement.

*Section 3.8 Validity tests to be performed on a hair sample.*

All the validity tests recommended for hair would not be able to distinguish natural hair from the scalp from a wig made out of natural hair. Since hair specimen collection is an observed process, the training of the collector to distinguish a wig or other hair piece from scalp hair is far more critical than the validity tests to ensure that the sample provided is human hair.

*Section 3.9 Validity tests to be performed on an oral fluid specimen.*

Oral fluid collection is an observed process. Waiting for a 10 minute period prior to collection and having potential donors answer a few questions and open their mouth prior to collection should ensure that any adulterant liquid kept in the mouth prior to Oral Fluid collection is swallowed before the collection process begins.

IgG concentrations vary greatly with secretions from the various salivary glands. A concentration of 0.1 µg/mL, as required by proposed rules, would not tell whether if a specimen was diluted significantly with an external liquid.

In any observed collection process training of the collector is very critical to ensure a valid specimen is obtained. The defense employed by some proponents of the IgG test is that it will detect if the saliva is non human. However, observed collection easily allows one to determine if the donor is human or not.

*Section 3.12 and Section 3.13 Criteria to report an oral fluid specimen or hair specimen as adulterated.*

There are no adulterants or levels of adulterants for hair and oral fluids. Would adulterant compounds and levels be determined based on feedback and experience of laboratories?

*Section 3.16 Criteria to report an oral fluid specimen as substituted.*

Oral fluid collection is an observed process and having an additional test adds an unnecessary cost burden to the process.

*Section 11.14 Batch Quality control requirements when conducting an initial drug test.*

The criteria of one control at 75% of the cutoff and one at 125% of the cutoff is too stringent for low level screening of alternative matrices especially hair and oral fluids. It would be more appropriate to have the cut-off be half the value of the high positive control and have the low positive control be half the value of the cut-off employed.



*Miscellaneous comments:*

1. We concur with the Department that the only sensitive and specific manner to perform the initial tests for the amphetamines class of compounds is to use two initial tests. However, these should either be one test for Methamphetamine/ amphetamine and a separate test for MDMA/MDA or one test for Methamphetamine/MDMA and a second test for Amphetamine/MDA.
2. There is evidence that as a result of the vastly improved analytical capability for THCA, laboratories have found THCA in oral fluids at pg/mL levels. This means that THCA is transferred from the plasma to Oral Fluids at an extremely low Oral Fluid/Plasma ratio. The presence of this metabolic marker should remove the need to collect urine at the same time an oral fluid collection is done.
3. Clearly, the proposed requirement that a urine sample be collected concurrently with an Oral Fluid sample is to avoid passive inhalation Oral Fluid positives. There have been no studies to date showing that Oral Fluid THC concentrations in real-world passive inhalation situations can reach or exceed the cut-off proposed for Oral Fluid. Rather than require concurrent collection of urine, we believe the Agency should encourage such studies and defer regulations requiring concurrent collection of urine until such studies prove this is necessary.

Please contact me at [jsoares@immunalysis.com](mailto:jsoares@immunalysis.com), if you require any further information.

Sincerely,

A handwritten signature in black ink that reads "James R. Soares". The signature is written in a cursive style and is placed over a light gray rectangular background.

James R. Soares, Ph.D.  
President.