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Walter F. Vogl, Drug Testing Section, Division of Workplace Programs, CSAP

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

Dr. Vogl and or whom it May Concern:

We represent a small area in Mashpee, Massachusetts, successfully using Intercept Oral Fluid Testing for our company's workplace to stay drug free. Our company works with Quest Diagnostics to process our Intercept fluid samples. Since coming out with Intercept testing our company has been able to test far more employees, with it being cost effective, convenient and a reliable way to keep our workplace drug free.

We appreciate the opportunity to make comments on the proposed revisions to the mandatory Guidelines for Federal Workplace Drug Testing Programs. We also commend the efforts by the HHS to expand the program. We understand that HHS is trying to utilize the best available technology for drug free programs. I would like to comment on a few of the proposed regulations for oral fluid testing.

1. Proposal for the collection of oral fluid as a "neat" sample (specimen)

In section 2.5(b) the collection of oral fluid is specified as **"2ml collected as a 'neat specimen' (divided as follows: at least 1.5mL for the primary specimen and at least 0.5mL for the split specimen)."** I feel that the collection of oral fluid using an FDA-cleared collection device is an acceptable, and more convenient method of collection. I have used this method with many specimens.

Spitting into a tube does not represent a clean comfortable way to take a drug test. It is also just as embarrassing and almost as invasive as a urine sample. The additional cost and time of collecting "neat" samples would be highly ineffective and not as convenient. The donor of an oral specimen through the use of the absorbent pad does not have the ability to alter any part of the test. We have had problems in the past with urine samples where on the way there or when they get there; attempts were made to alter the sample. However there is not even an option to do this with the absorbent pad.

In addition, section 1.5 defines a split specimen for oral fluid as **"one specimen collected that is subdivided or two specimens collected almost simultaneously."** Two FDA-cleared collection devices could be used. In section 7.1(c), the collection device for oral fluid id specified as a **"single-use plastic specimen container."** I propose that the collection device must be and FDA-cleared absorbent pad, which then is placed into a fixed amount of transfer buffer. The issue

of an FDA-cleared collection device is also addressed in section 7.2(b). Finally the collection device is also addressed in the specific collection procedures in section 8.3(a)(5) through 8.3(a)(10).

2. Proposal for collecting a urine specimen with each oral fluid specimen.

In section 2.3(a) and section 8.3(a)(16) addressing the specific collection procedures for an oral fluid specimen, it is specified to also collect a urine specimen, for the purpose of addressing the possibility of a positive oral fluid test result from passive exposure to cannabis smoke. I feel that this extra collection is unnecessary. The data demonstrates that positive oral fluid test results from any realistic exposure would be extremely unlikely.

The primary benefit of oral fluid testing is the ability to eliminate costly and inconvenient urine specimen collections. Requiring collections of both specimens not only negates the convenience and time saving features of oral fluid testing, but it adds an additional and unreasonable cost.

I would like to note that since these proposed guidelines there has been extensive research done on the environmental exposure to cannabis smoke on oral fluid tests. It was accepted by the journal of Analytical Toxicology that environmental contamination is limited to only extreme exposure conditions, such as several joints in a small sealed room, and then for only short periods after exposure, such as 30 minutes.

The likelihood of environmentally caused positive test results is extremely low if no negligible. I believe this new data should allow HHS to draw the same conclusion about oral fluid testing as it did with urine testing: **"The Department does not believe that passive inhalation is a reasonable defense are that significant exposure can occur through passive inhalation to cause a urine sample to be reported positive."** HSS, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29908, (1994).

I again thank the department for this opportunity to provide information to assist in drafting and finalizing drug-testing guidelines and for their careful consideration of these points. I would be eager to offer further comments if needed.

Sincerely,

Sarah L. Reghitto