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Docket # 04-7984

July 11, 2004

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

Dr. Vogl:

I am the Administrator at Operation PAR Laboratory, we are an independent laboratory which has successfully incorporated Intercept® oral fluid testing into our menu of services. Operation PAR Laboratory is CAP Accredited, with Distinction. The laboratory has been servicing of variety of programs throughout the west coast of Florida since 1986. Since adopting Intercept testing, our company, and those serviced has collected more than ten thousand oral fluid specimens. I have found our Intercept oral fluid testing program to be a cost-effective, convenient, dignified and a reliable way to meet the financial goals of our company and those companies contracted.

I appreciate the opportunity to comment on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and we applaud the efforts by HHS to expand the program. understand that HHS is making these proposed revisions to fulfill a mandate to utilize the "best available technology" for drug-free programs. I need to comment on three recommendations in the proposed regulations addressing oral fluid testing.

Proposal for the collection of oral fluid as a "neat" 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 believe that collection of oral fluid using an FDA-cleared collection device is also an acceptable; if not preferred, collection method. We have experience with this method in the collection of over ten thousand specimens.

The process of requiring the patient to spit into a tube does not necessarily represent the "best available technology," nor do I believe this collection method would be neither practical nor dignified. Our clients appreciate the dignity of an oral fluid collection. The additional cost and time required for collecting "neat" specimens could be significant. The collection environment would require control and possibly sanitizing, and the allowance of 15 minutes to provide a specimen is up to five times longer than the collection process with the FDA-cleared oral specimen collection device. Specimen collection of oral fluid by an absorbent pad is consistent, and the donor is not able to control any variances by attempting to dilute or adulterate the sample.

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."** Simply, two FDA-cleared collection devices would be used. In section 7.1(c), the collection device for oral fluid is specified as a "**single-use plastic specimen container."** I am suggesting that the collection device must be an FDA-cleared absorbent pad, which is then 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 am certain this additional specimen collection is unnecessary. Current scientific data demonstrates that positive oral fluid test results from any realistic exposure situation would be extremely unlikely.

Even though collecting a urine specimen is indicated in some cases, the primary benefit of oral fluid testing is the ability to eliminate costly and inconvenient urine specimen collections. Requiring collection of both specimens not only negates the convenience and timesaving aspect of oral fluid testing; it adds an unreasonable additional cost with no benefit realized for routine analysis.

I must alert HHS that since these proposed guidelines were drafted, authoritative scientific data on the effect of environmental exposure to cannabis smoke on oral fluid tests has been developed and accepted by the Journal of Analytical Toxicology for publication (Dr. Edward Cone et al.). Specifically, this research demonstrates that environmental contamination is limited to only extreme exposure conditions (several marijuana cigarettes smoked in a very small, sealed room), and then for only short periods after exposure (up to 30 minutes).

The likelihood of environmentally caused positive test results is extremely low if not negligible. Additionally, a specimen that might have an elevated cannabinoid level would need to be collected within 30 minutes of this extreme exposure episode. I believe this new data should allow HHS to draw the same conclusion about oral fluid testing as found with urine testing: **"The Department does not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause a urine specimen to be reported positive."** HHS, Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29908, (1994).

3. Applicability of oral fluids testing to return-to-duty, follow-up testing.

In section 2.2, oral fluid is specified for **"pre-employment, random, reasonable suspicion/cause and post-accident testing."** In Draft 4 of the guidelines, oral fluid was recognized as suitable specimen for all authorized testing scenarios. However in the published Proposed Guidelines, the application of oral fluid testing to return-to-duty and follow-up testing was removed. Although the basis for this change was stated as due to the claimed short detection time for drugs in oral fluids, a review of published epidemiological data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use.

Oral fluid testing is appropriate for all testing scenarios. Our statistics; accumulated over the past twelve months, indicate a positive rate of five percent. This is identical to the rate found for urine testing performed over the same time period. My experience reveals that oral fluid testing is clearly suited for all types of drug abuse monitoring including Return-to-Duty and Follow-Up testing. Oral fluid is suited for Return-to-Duty and Follow-Up testing because it detects recent drug use. A worker successfully completing a substance abuse recovery program and staying clean from drugs will appropriately test clean with random oral fluid testing.

Oral fluid testing is also uniquely able to detect; even recent, illicit drug use. A worker trying to cheat on an SAP's program is more likely to attempt to tamper with urine specimens by diluting or adulterating them, or by substituting clean urine. Each oral fluid collection provides a directly observed specimen that virtually eliminates the opportunity to tamper with specimens.

I again thank the Department for this opportunity to provide information to assist it in drafting and finalizing drug-testing guidelines and for their careful consideration of these points. I am eager to offer whatever further information and comments will allow HHS to fulfill its statutory obligations to "establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive order Numbered 12564, ...including standards which require the use of the best available technology for ensuring the full reliability and accuracy of the drug tests ...". Even though these rules do not govern private industry they do influence policies as well as legal challenges.

Sincerely,

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