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From: "Dr. Leo Kadehjian" <drleo@worldnet.att.net>
To: <wvogl@samhsa.gov>
Date: 7/12/04 10:13PM
Subject: Comments on the Proposed Revisions to Mandatory Guidelines forFederal Workplace Drug Testing

Dr. Vogl,
Attached please find my comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing, specifically addressing POCT.

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Docket # 04-7984

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,

First, I wish to take this opportunity to commend HHS and its staff for their exemplary efforts in drafting Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, availing itself of advances in drug testing technologies to allow more effective drug testing programs.

I am also thankful to have this opportunity to provide my comments to HHS to assist the Department in fulfilling its statutory responsibility 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 ..." Pub. L. 100–71, Title V, § 503 (a)(1)(A)(ii)(I).

My comments herein specifically apply to POCT testing. Below I address those sections of the Proposed Rules addressing POCT testing on which I wish to comment.

First, I again commend HHS and its staff for their recognition of the accuracy and reliability of non-instrumented drug test devices. I have had extensive experience in studying a large number of these devices with challenging specimen sets as well as using both scientist and non-scientist operators and have found an impressive level of performance. I agree that these devices are wholly suitable in federal workplace testing programs.

However I wish to comment on one part of the Proposed Guidelines addressing quality control testing.

Section 12.19 What are the quality control requirements when conducting POCTs?
(a) For drug POCTs:
(1) Each day testing is performed using devices with visually read endpoints (i.e., a color appearing or disappearing that indicates a positive result using that device), each individual performing drug tests using these devices must test at least one negative control (i.e., a sample certified to contain no drug or drug metabolite) and one positive control (i.e., a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) before donor specimens are tested. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.
(2) Each day testing is performed using devices with semi-automated or automated testing devices

with machine read endpoints (i.e., spectrophotometer), at least one negative control (i.e., a sample certified to contain no drug or drug metabolite) and one positive control (i.e., a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) must be tested on each device used. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.
(b) For validity POCTs, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested.
(c) At least one specimen out of every 10 specimens that test negative must be submitted to an HHS-certified laboratory as part of a quality assurance program.

Comments:
Although running a positive and negative control each day of testing provides the greatest assurance of accuracy and reliability, such a requirement for daily positive and negative controls may be unnecessary given the demonstrated level of performance of many of these devices. Furthermore, such a level of quality control may prove overly burdensome for those situations where only a few specimens may be likely to be performed. Rather, I would allow agencies to follow any FDA-cleared manufacturer recommended quality control practice.

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 to the Department that will allow it 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 ..."

Sincerely,

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