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July 12, 2004

Walter F. Vogl, Ph.D.
Division of Workplace Programs
CSAP
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, Maryland 20857

Re: FR Doc 04-7984; SAMHSA Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs

Dear Dr. Vogl,

The following comments are being offered by Laboratory Corporation of America Holdings ("LabCorp") in response to the above-captioned proposals to revise the mandatory guidelines for Federal workplace drug testing programs ("Guidelines"), notice of which was published in the *Federal Register* on Tuesday, April 13, 2004 at 69 Fed. Reg. 19673.

With six SAMHSA-certified laboratories throughout the United States, LabCorp is one of the largest occupational substance abuse testing providers in the world. As a provider of Federal workplace drug testing services, LabCorp is directly affected by these Guidelines.

LabCorp appreciates the opportunity to comment on these Guidelines and respectfully requests SAMHSA to reconsider its position on these issues. If you have any questions concerning these comments, you may contact me by phone at (336) 436-5040 or by e-mail at hortond2@labcorp.com.

Very truly yours,

LABORATORY CORPORATION OF AMERICA HOLDINGS

Donald E. Horton, Jr.
Director, Public Policy & Advocacy

cc:

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LabCorp
Laboratory Corporation of America

Comments on Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs

Agency Name: Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA)

Docket Number: FR DOC 04-7984

The Added Specimens: We agree with the Department's assessment of concerns regarding:

- the Pilot PT program that would provide results from testing laboratories that are consistent with the current program;
- the sensitivity, accuracy and precision of hair, saliva, sweat, and POCT tests as compared to urine;
- inconsistent results in the literature relating to hair, saliva, sweat and POCT as compared to urine; and
- the variability of compounds and metabolites detectable in the various types of specimens.

Alternative Specimens

Hair: As a result of unresolved questions concerning the effect of hair color on drug test results, we are concerned that ethnic and racial variations could affect hair testing results.

Oral Fluid: We question the adoption of oral fluid as an alternative specimen for drug testing at this time since not all appropriate drug metabolites can be detected using this specimen type. The acknowledged limitations for THC analysis, including the inability to distinguish between drug use and environmental contamination (passive inhalation), and the proposal that a urine specimen must also be collected when oral fluids are to be tested, suggests that oral fluids testing should not be adopted until such time as all appropriate drug metabolites can be detected through oral fluid testing. It is not practical to collect and test two alternative matrix specimens and perform partial testing on one and partial testing on the other, using two different standards of quality control. Further, linking individual results for separate oral fluid and urine testing is both analytically and administratively difficult.

We disagree with the Department's position that oral fluid testing is appropriate for pre-employment testing.

We also wish to bring to the Department's attention our concern regarding the commercial availability of FDA approved reagents for oral fluid testing.

Sweat: We question the adoption of sweat as an alternative specimen for drug testing because of the limited availability and relative unreliability of the primary collection device. First, as the Department admits, there is currently only one FDA-cleared sweat patch device. Second, by its very nature the sweat patch may be affected by the temperature of the individual or the environment, resulting in variations independent of drug administration. References cited by the Department which attempt to minimize concerns regarding external contamination and external absorption appear to have been funded, at least in part, by manufacturers of the product; the objectivity of these studies are therefore questionable, and the significant possibility of adulteration of this product is not adequately addressed.

The Added Types of Testing Options and Locations – Major Change

POCT for Drugs: No supporting data indicates that current POCT devices even begin to approach the accuracy and precision of current urine analysis. As a result, we are concerned that the approval of POCT may lead to a significantly higher false positive screen rate and a significantly higher false negative screen rate for the Federal workplace drug testing program. However, we support POCT for mandated testing if the procedure is forensically defensible and meets the same rigorous standards as the current program.

POCT Specimen Validity Testing: POCT should be subject to specimen validity tests comparable to those performed in the laboratory, but we are concerned about the commercial availability of such products. We question the accuracy and precision of existing POCT specimen validity testing.

Subpart B – Specimens

Section 2.2: The Department does not present any documentation to support the position that hair is a viable specimen for return to duty; the period following the last specimen may be less than 90 days. Further, due to its short detection times, we disagree with the Department's position that oral fluid is an appropriate specimen for pre-employment testing.

Section 2.5: The Department provides no evidence of the benefits of collecting a 2ml specimen instead of a 1ml specimen, when the oral fluid is placed in an appropriate buffered solution providing for screening and confirmation testing and the collection device is capable of measuring 1ml of oral fluid. In addition, the minimum quantity requirement for sweat specimens, 2 FDA-cleared patches worn up to 7 days, does not adequately define the amount of sweat to be collected. As discussed elsewhere in these comments, we question the adoption of sweat as an alternative specimen, and the sweat patch collection technique, due to the many unanswered questions surrounding them and their potential for adulteration. The hair collection requirement of 100 mg, split into two equal portions, does not recognize the "A" lab's need for more of the specimen. Two-thirds of the specimen for lab "A", and one-third of the specimen for lab "B", is more consistent with the technical requirements, and more similar to the urine program.

Subpart C – Drug and Validity Tests

General Comments:

Hair: The specimen validity guidelines as stated do not specify how the testing is to be conducted, what parameters are acceptable, or who is qualified or authorized to perform the testing. No guidelines for specimen validity testing controls comparable to those for urine are provided. Further, such testing will consume an already limited specimen. Up front validity testing on hair samples is not necessary since it requires an observed collection. Validity testing could always be conducted if there is a problem with analysis, or specimens could yield an "invalid" result in a manner similar to current urine testing rules. An invalid result could then require a second specimen to be collected under more stringent conditions, such as the addition of a witness. The emphasis must be placed on collector accountability, not on validity testing.

The digestion, dye, and solubility tests are not sufficiently specific to identify hair as being of human origin, or as being the donor's hair. Interference from "weaves" is a training concern for the collector and the laboratory. There should be no requirement for the lab to make any other special accommodation for dyed or bleached hair; scientific evidence is equivocal on the effect of such treatments, so the laboratory's role should be a strictly analytical determination of the presence or absence of the drug.

It is not currently possible within the limits of current screening technology and the extremely low levels of drugs in hair to require the open QC criteria to be +/- 25% of the cutoff. It is recommended that an initial requirement of +/- 50% of the cutoff be adopted.

The confirmation cutoff for THCA should be 0.1 pg/mg. The rationale for this cutoff is that a 40% control is not analytically feasible for routine analysis using current technology if based on a 0.05 pg/mg cutoff.

Collection containers consist of opaque foil or cardboard sleeves; if the primary and split samples must be compared, the chain of custody or specimen integrity could be compromised.

Oral Fluid: IgG does not prove the validity of a specimen, but only that the specimen contains protein. Levels of IgG necessary to indicate an "undiluted" saliva sample are not proven. Since the collection is observed, substitution, dilution or adulteration is averted if reasonable precautions are observed in the collection process. We recommend that the donor should be required to wait in the presence of the collector for 5-10 minutes and demonstrate that his or her mouth is empty prior to commencement of the collection.

It is not currently possible within the limits of current screening technology and the extremely low levels of drugs in oral fluid to require the open QC criteria to be +/- 25% of the cutoff. It is recommended that an initial requirement of +/- 50% of the cutoff be adopted.

Sections 3.4, 3.5, and 3.6: The cutoffs established for the alternative specimens are inconsistent with what is available in the marketplace. The cutoffs should be established by FDA approved procedures, which may vary from manufacturer to manufacturer. In addition, if the

Department lowers the cutoffs for amphetamines and cocaine for these alternative specimens as compared to the cutoffs for amphetamines and cocaine for urine specimens, even greater discrepancies between the various specimens will be created. We do not believe the Department would want to establish significant differences in positive detection rates among Federal programs, but the differences in cutoffs could result in Federal agencies selecting methods of testing based on detection rates to select a more or less sensitive employee pool. Further, lowering cutoffs will result in increased positive detection rates, resulting in increased testing being sent to laboratories and therefore increased costs being passed on to clients.

Section 3.11(a)(5): It is not clear what is meant by "additional validity tests" in this paragraph. Laboratories are required to test each sample routinely for oxidants, pH, creatinine and specific gravity in the case of low creatinine. Does this paragraph require testing in addition to these routinely required tests (i.e., different types of tests)? If so, what other types of validity tests are required?

Subpart D – Collectors: Ensuring that a collector has been properly trained, and maintaining documentation of the collector's training records, should be the sole responsibility of the collector or the entity that employs the collector. We urge SAMHSA to clarify that with respect to a collector who is an independent contractor of a laboratory rather than its employee, the laboratory is not required to ensure the collector's proper training or to maintain documentation of the collector's training. Laboratories often contractually allocate these responsibilities to the collector, because it would be infeasible for the laboratories to perform such tasks themselves.

Subpart E – Collection Sites, Section 5.4(6): While we agree that specimens should be transported in containers that will minimize the possibility of damage during shipment, we do not believe the cited examples, specimen boxes or padded mailers, are necessary to meet that standard.

Subpart F – Federal Drug Testing Custody and Control Forms: The current custody and control form (CCF) can be modified to incorporate a space or checkbox to identify the specimen type (saliva, hair, urine, sweat patch) for laboratory testing; separate forms for each specimen type is neither practical nor cost effective. Separate certification statements for the initial test and confirmatory test results (if needed) may be required.

Subpart H – Specimen Collection Procedures:

Section 8.2: Body hair should be a permitted specimen source when bald or shaved individuals show up for specimen collection. The collection requirement of 100 mg, split into two equal portions, does not recognize the "A" lab's need for more of the specimen. Two-thirds of the specimen for lab "A", and one-third of the specimen for lab "B", is more consistent with the technical requirements, and more similar to the urine program. Meeting the proposed requirement would also depend on the collector's ability to estimate the amount collected and the amounts as split; therefore, picture examples of numerous types of hair (100 mg samplings of numerous hair types) needs to be part of collector training materials. The collection procedure for hair specimens must require the collection agent to wear gloves to prevent possible transfer of

drug residue or other contaminants present on the hands of the collection agent to the donor's hair during the collection process.

Section 8.3: The Department should adopt FDA approved collection devices to be used for collection of oral fluid specimens. Quantitative collection devices that employ an untreated sorbent pad are recommended. Such procedures would allow a specimen to be split while providing a medium in which the integrity of the oral fluid specimen would be preserved, avoiding the necessity of transferring a viscous sample between two collection vials. We agree that stimulation devices are inappropriate due to possible dilution effects.

Section 8.4: If sweat patch testing is to be permitted, at a minimum Section 8.4(13) should be revised to read as follows (additional language is in bold type): "The donor must be asked to read and sign a statement on the Federal CCF certifying that the sweat patch identified as having been collected from him or her **was in fact worn continuously by him or her from the time of placement by the collector until its removal by the collector, a period of no less than three and no more than seven days.**"

Subpart I – HHS Certification of Laboratories and IITFs: Separate certifications, inspections and PT sets have been proposed for each type of specimen tested. Laboratories which perform multiple specimen tests should not be subject to multiple inspections, since the inspection questions would be similar for each specimen type. For example, the data review portion of the current inspection process accounts for the majority of the Department's resources during a multi-day inspection. The data review would not be significantly different from specimen type to specimen type to justify an additional data review inspection and a subsequent inspection fee. We urge the Department to be sensitive to the cost of current inspections for large laboratories ($49,000 per inspection, per laboratory). We understand that technical aspects of the inspection may be different based on specimen type, but the technical ability of the inspection team will allow them to cover all aspects of each specimen type.

The Department is recommending that IITFs undergo inspections and PTs similar to those of a full HHS certified laboratory, but is also proposing that POCT testing, providing the same screening to Federal employees, not be subject to the same inspection criteria. We find this to be a major discrepancy in the Department's proposals.

We also question the availability of consistently accurate hair, oral fluid, and sweat PT specimens that reflect true donor specimens.

Subpart K – Laboratory, Section 11.35: We submit that requiring an HHS-certified laboratory to notify a private sector client when it uses procedures to test private sector client specimens that are different from those for which it is certified is beyond the appropriate scope of the Guidelines and imposes an unnecessary administrative burden on such laboratories. The Guidelines are intended to establish the scientific and technical guidelines for Federal workplace drug testing programs, not the testing of private sector client specimens, and are meant to establish standards for certification of laboratories engaged in urine drug testing for Federal agencies, not to regulate the private sector activities of laboratories that have met the certification standards. Statistical

summaries do not specify positives coming to the laboratory from POCTs or IITFs.

Subpart M – Instrumented Initial Test Facility (IITF):

Quality Assurance: Immunoassays are validated by the analysis of immunoassay positive and negative samples by GC/MS. GC/MS departments within full service laboratories provide important information about the quality of the immunoassay analysis by the continuous confirmation of initial test positives. Low GC/MS confirmation rates, for example, may indicate a problem with the cross reactivity of the immunoassay. IITFs lack this direct feedback and are not likely to function with the same level of quality assurance as immunoassay departments within full service laboratories.

Certification: The National Laboratory Certification Program and HHS have consistently required the review of all data and chain of custody documentation for a non-negative sample by a single certifying scientist. This comprehensive review includes a comparison of the initial test and confirmatory test data to ensure the accurate certification of test results. Should IITFs be approved, it will no longer be feasible for a single individual to evaluate all the data since the screening data and associated documentation will be generated at one laboratory, and confirmation data will be generated at the full service laboratory. The Guidelines need to detail how this major change will affect the accuracy of the certification process.

The revised Guidelines need to describe the role of each of the certifying officials (for the initial test and the confirmatory test) in the final certification of results, including answering the following questions:

1) How and where will the certification of the initial test be documented?
2) How and where will the certification of the confirmatory test results be documented?
3) Will a single certifying scientist be responsible for the final non-negative result? If so, how can this be accomplished without access to all the data?

Electronic Technology Applications: While electronic technology applications should not yet be required for the Federal drug testing program, the Guidelines should address standards for electronic signatures, electronic storage and transmission of records, and appropriate security precautions for confidential information, for those entities which choose to employ electronic technology applications. The Guidelines should specifically address the protection of the integrity of the chain of custody in electronic technology applications. Electronic information must accompany the specimen to the laboratory.

Executive Order 12866: Economic Impact: We question the Department's assessment that the Mandatory Guidelines will have an annual impact of less than $100 million and will not have a material adverse impact on productivity, competition and jobs. Based on the nature and extent of our comments, we estimate that the national impact of these Guidelines would be significant enough to trigger the detailed analysis requirements of Section 6(a)(3)(C) of Executive Order 12866.