FR Doc #04-7985
Public Comment 8500004

June 1, 2004

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

Re: FR Doc 04-7985; SAMHSA Revised 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 revised mandatory guidelines establishing specimen validity testing (SVT) standards (the "Guidelines"), notice of which was published in the *Federal Register* on Tuesday, April 13, 2004 at 69 Fed. Reg. 19644.

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.

The Guidelines are to become effective November 1, 2004, approximately six and a half months after their publication in the *Federal Register*. As a laboratory with multiple locations, we are concerned about this limited period of time to make the SVT changes to the Laboratory Information Management Systems (LIMS) required by the Guidelines. Not only are the changes significant within each laboratory, a multiple laboratory system requires significant resources and time to address the impact of these changes on electronic reporting and interfaces. Our experience indicates that the Medical Review Officers (MROs) receiving results from LabCorp require significant lead time to have their electronic systems rewritten and to have interfaces tested and validated. The timeframe set forth in the Guidelines does not reflect an appreciation of the need for these software and hardware changes to be written, validated and tested between LabCorp and the MROs.

2. The proposal requires new SVT reporting criteria, including modifications to the electronic reports and the Custody and Control Form. It is unclear in the Guidelines how the new Custody and Control Form is to be structured, how long the laboratories have to implement the new Custody and Control Form, and what policy is to be implemented with respect to receipt of old Custody and Control Forms. It is our position that replacement of Custody and Control Forms as they are requested is the best and most economical way to ensure that current Federal Workplace clients are receiving new Custody and Control Forms. Complete, immediate replacement of all Federal Workplace forms is not practical and extremely costly.

3. The proposal suggests applicable confirmation equipment methodologies for SVT; however, it is unclear what are acceptable confirmation procedures. It is imperative to know what confirmation procedures will be allowed under the new Guidelines, due to the significant cost of all equipment options and the limited time laboratories have to begin testing proficiency specimens (July 2004). We urge SAMHSA to provide additional guidance on approved confirmation procedures.

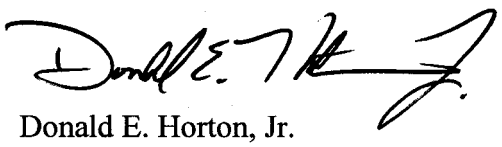
4. Section 2.4(h)(12) of the Guidelines indicates that for a specimen that has an invalid result, the laboratory shall "contact" the MRO to reach a joint decision as to whether testing by another laboratory would be useful in being able to report a positive or adulterated result, and if no further testing is necessary, the lab is then to report the invalid result to the MRO. We urge SAMHSA to clarify that the "contact" referred to in this section may be conducted by various electronic means (for example, teleprinters, facsimile, or computer) or by telephone, and that this "contact" can occur simultaneously with reporting. Many MROs are not readily available by phone, especially for multiple laboratory environments covering all three time zones. Delays in reporting Federal Workplace specimen test results could be significant if direct phone contact is required prior to reporting.

5 Many of the new tests required under the Guidelines, including the pH, creatinine, and oxidant tests, are not currently commercially available. Further, the confirmation procedures for nitrite, chromate and halogens are currently either under patent protection by their original developers or are held by commercial vendors which have been unable to demonstrate an ability to meet the new Federal requirements.

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, please contact me at (336) 436-5040.

Very truly yours,

LABORATORY CORPORATION OF AMERICA HOLDINGS



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