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July 12, 2004

Walter F. Vogl, PhD
Drug Testing Section, Division of Workplace Programs, CSAP
5600 Fishers Lane
Rockwell II Suite 815
Rockville, Maryland

Dear Sir:

Re: Docket Number 04-7984
Proposed Revisions to Mandatory Guidelines
for Federal Workplace Drug Testing Programs

These comments are of a general nature regarding the proposed guidelines.

1) Personal experience with Point of Collection Testing (POCT) devices has demonstrated that they do not perform similar to that of the instrumented immunoassay tests in certified laboratories as the commentary in the proposed guidelines would lead us to believe.

   a) POCT devices are prone to what has been referred to as a "hook effect". This means that very high concentrations of drug may cause a false negative result. The POCT device manufacturers are amazingly silent on this important limitation with their devices. Although the manufacturer would suggest that these cases are rare, the reporting of these cases will be under-estimated. The fact remains that in the majority of cases a negative POCT sample will never be further investigated. It is only in a rare circumstance that a negative POCT sample will be subjected to laboratory testing. Although the Workplace Drug Testing Program is designed to ensure that false positives do not occur, it does seem that introducing technology in which a highly positive sample is reported as a false negative is incongruous with the mandate of the Workplace Drug Testing Program - trying to identify workers who use drugs.

   b) The devices are not accurate at ± 25% of the cut-off as laboratory immunoasssays are required to be [personal experience; Taylor et. al. *J Anal Toxicol* **23**: 119-124 (1999)]. If POCT devices are indeed as accurate around the cut-off as laboratory based testing then why are ± 25% controls not required to be assayed by testing personnel in the POCT scenario? Why is there a double standard in the accuracy requirement needed by laboratories and POCT facilities?

2) In the proposed guidelines the double standard extends beyond the controls that need to be assayed. In certified laboratories the inspection process incorporates personnel interviews to ensure adequate training, knowledge and practical abilities. How can an

inspection process that is removed from the actual person doing the point of collection test be effective? In addition, in certified laboratories proficiency tests are supposed to be handled in the same manner as donor samples as a test of the laboratory's processes. How can having the device manufacturer perform proficiency tests possibly test the real life process in which POCT is conducted?

Drug testing in the employment related setting is as much about the process as the test result itself. With respect to POCT, I believe that the proposed guidelines will ensure neither the integrity of the result nor the integrity of the process.

Sincerely,

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Penny Colbourne, PhD
Director, Substance Abuse Testing Laboratory