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Bamburgh Marrsh

Bamburgh Marrsh LLC ***Pioneering Oral Fluid Diagnostic Solutions***

July 6th 2004

Walter F. Vogl PhD
Drug Testing Section, Division of Workplace Programs
CSAP,
5600 Fishers Lane,
Rockwall II, Suite 815,
Rockville, MD 20857

Re: Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug testing Programs

Fed Register April 13, 2004 (Volume 69, Number 71)

Docket Number: fr13ap04-143

Dear Dr. Vogl,

On behalf of Bamburgh Marrsh LLC ("BAMA"), a Company involved in marketing and developing Products for abused drug testing, let me firstly say that we welcome SAMHSA's stance to expand the Federal Drug Test Program to include alternate specimens. We believe that alternate specimen types can provide additional valuable information, as well as options for providing significant economic benefit to testing centers in the future if adopted appropriately. In this correspondence, in response to the opportunity to comment in a public forum, we would like to address specific issues in the current Draft Guidelines, particularly as they pertain to oral fluid ("OF") or saliva testing, as this is where our core expertise lies.

1. Federal Register Page 19676 (Preamble)

(a) In the Preamble it is stated: "further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination". From our experience we would expect that the concentration of THC in the oral cavity from direct drug use would be significantly higher than from environmental contamination but we agree that a study should be done to confirm this hypothesis. At some point in the future, BAMA would be interested in participating in such a study.

(b) The proposal to take an alternate (urine) specimen at the same time an oral fluid ("OF") specimen is taken, in the event of a possible marijuana positive specimen, eliminates many of the positive benefits (particularly the non-invasive specimen collection, less potential for adulteration, etc.) of having a donor provide an OF versus urine specimen, so it is important to have this study performed at the earliest time. Is SAMHSA aware of any ongoing studies in this

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area by current manufacturers, for instance, OraSure, Immunalysis or others?

What might be proposed as an interim and more cost-effective alternative is to perform urine testing on only those specimens indicated to be positive in the primary screen. While there will be a delay in the receipt of the results of laboratory testing, presumably, the longer window of opportunity for testing with urine will allow these tests shown to be initially positive to be confirmed as such (or otherwise) at a later date. If not, then alternative testing methods (hair, sweat) could be employed to confirm positivity in those small numbers of cases testing initially positive. In this way, instead of testing each and every specimen essentially in duplicate, only those initially positive for marijuana would need to be tested a second time. A measure such as this would ultimately saving a considerable amount of money for the Federal Dry Testing Program.

2. We welcome SAMHSA's opinion to allow OF collection and testing methodologies to be an integral part of the Federal Drug Testing Program despite perceived issues related to oral fluid collection. New devices are coming to market, which will help alleviate some of the difficulties currently encountered by standardizing the sample and the integrity of the sample collected. I think it is key to ensure that all such devices are subjected to validation and clearance though the FDA 510 (k) process, especially as the integrity of the Federal employee and future employment with the Federal Government will be dictated by the test results.

3. We also applaud the initiative to monitor ongoing quality assurance of future POC devices for OF, which will eventually meet SAMHSA's proposed cut offs and other guidelines for performance. This will ensure a high standard of quality for all manufacturers. It is important that similar programs are applied to other POC drug test technologies in development at this time.

4. SAMHSA has obviously spent a great deal of time debating the issue of sampling for alternative specimens and it is encouraging to see that its conclusions confirm that split specimens should be taken for all specimen types. Increasingly, drug-testing personnel are faced with questions regarding sample integrity, chain of custody and adherence to good laboratory practices. The establishment of a clear mandate to collect split specimens during the initial screening process will go a long way to alleviating a lot of the issues mentioned above. Results of the subsequent testing process, if followed according to SAMHSA testing protocols would also be more legally defensible.

5. One area for concern in the current SAMHSA proposal is the suggestion that 2mL of OF or saliva be collected into a collection tube, rather than via a collection device, which does not incorporate a sample volume adequacy indicator. This may be reasonable for collecting "raw" whole saliva, however, in instances where a suitable collection device is used, incorporating an accurate means for determining sample adequacy, 2mL of fluid may not be possible, nor required. If we take the example of the SDS Inc. device Saliva•Sampler™, sold in the US by

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Immunalysis Corporation under the trade brand Quanti-SAL™, this device is limited by the absorption characteristics of the "filter paper" used as the absorbent material in the device. The device is reported to collect 1 mL of raw saliva sublingually then the sample is diluted in buffer 1:1. The individual assay requirement is only 10 microliters of diluted specimen for each drug being assayed, so in order to test for up to 10 drugs, the sample requirement is only 100 microliters. Other test kits may be run with OF or saliva collected using the SDS device and these kits could have a greater sample requirement of perhaps 25 microliters per test. Even allowing for this increase in sample volume requirement, the maximum volume required for up to 10 drugs is 250 microliters. With this in mind, and the fact that SAMHSA will only mandate testing for a maximum of 5, the NIDA – 5 drugs at this time, I believe SAMHSA should rethink its proposal to require such high volume requirements for saliva / OF, or perhaps, should restrict this requirement to saliva collection devices, where no means of sample volume adequacy is possible. For devices incorporating sample adequacy, no such requirement should be imposed, providing sufficient oral fluids are collected for subsequent analysis.
In the case of confirmation, the requirement for 0.5 mL seems acceptable.

6 Additional Drugs

Section 3.2a, Page 19697 specifically solicits comments on assays for additional drugs of abuse, particularly MDMA. There are a number of suppliers providing assays for Methamphetamine, which cross-react with MDMA. Two such suppliers are International Diagnostic Systems (IDS, St Joseph MI) and Neogen Corporation ((Lansing MI). These manufacturers have carried out preliminary studies on the performance of their respective Methamphetamine / MDMA assays and subsequently reported cross reactivity data with MDMA from OF specimens. These reported data are described below in response to SAMHSA's interest in learning of reported MDMA data:

Manufacturer	Concentration (ng/mL)	% Cross Reactivity (MDMA)
Neogen	1.5	733%
IDS	1.0	171%

Additional information including data on existing Ampthetamine assays cross reacting with MDA can be obtained by contacting the companies above directly.
The above may not be an exhaustive list but is provided by way of reference.

7. Cut offs

Section 3.5 Page 19697 addresses the initial and confirmatory cut-offs for OF fluid specimens. We feel that these cut offs are appropriate for laboratory based (ELISA microplate) technologies and GC-MS, LC-MS, etc. Current point-of-care testing devices (POCT) at this time are unable to meet the low cut-off for marijuana, mainly due to technical issues and the lack of a good antibody for parent THC. SAMHSA may wish to consider a specific (higher) cut off for OF POCTs.

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8 Section 3.8 Page 19698 defines the validity tests that must be performed on an OF specimen. The current proposal calls for determination of IgG concentration on every specimen, however, if current testing protocols for OF collection are adhered to and chain of custody rules are enforced, an observed collection by drug testing personnel should be sufficient to confirm that the sample was collected from the subject in question and that the sample is of human origin It would seem that if strict observed collection rules are enforced, the need to run an IgG test would be redundant and would only add unnecessary cost to the process. Enforced observed collection with additional safeguards will also eliminate opportunities for OF substitution as described in Section 3.16.

9 In Section 7.2 Page 19700, the use of alternate specimen collection devices and technologies is discussed. We agree 100% that any devices used should be confirmed not to affect the specimen collected, for each drug under evaluation. This should apply to ALL sample matrices (saliva, urine, hair or sweat). Ultimately, manufacturers should be urged to seek regulatory clearance through the FDA 510(k) processes for new devices and technologies.

10 Section 12.2 Page 19718 establishes criteria for the certification by the Secretary of POCT devices for use in Federal Drug Testing Programs. We support SAMHSA's requirement for FDA clearance for such devices and a determination that such devices effectively test for the presence or absence of established drugs.

11 Section 12.4 Page 19718 identifies two types of POCT available. We would like to suggest a third option to be added as a separate category. This designation would combine a non-instrumented (manual) device with an instrumented means of visually reading and providing a permanent record of the results. Technology such as this is in development by more than one company at this time.

12 Section 12.18 Page 19720 describes the steps for conducting a POCT. These guidelines appear to refer to tests that initially require sample collection prior to use in the POCT. In certain devices for instance, the Branan Corporation (Oratect™) device and several others on the market, OF is immediately delivered to the test strip providing results for 6 drugs of abuse in about 10 minutes. At the same time the device can be processed immediately to afford a confirmation sample, without the need for collection of a secondary specimen. This specimen may be separated into two aliquots for subsequent use as second and confirmation specimens, respectively.

13 As mentioned earlier Section 15.7 Page 19726 may be eliminated if observed collection is carried out along with adequate precautions to prevent adulteration and /or substitution.

Conclusions

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Dr Vogl, these comments are addressed to you in the spirit of wishing to provide constructive dialogue. If you have any questions at all, please do not hesitate to contact me
Thank you for the opportunity to provide our feedback.

Sincerely

Paul D. Slowey PhD
Managing Member
Bamburgh Marrsh LLC

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