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<<69FR19673AltMatrices.doc>> Comments and questions on the April 13, 2004 notice of proposed revisions to mandatory guidelines.

July 12, 2004

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RE: Comments on 69FR19673, April 13, 2004

The following are comments and questions we have regarding the proposed new mandatory drug testing guidelines for alternative matrices.

Oral Fluid.

Requirement to collect urine along with oral fluid.

It does not seem necessary to require an agency to collect a urine specimen when they collect an oral fluid specimen because of concern about passive THC contamination. When a donor has actually smoked marijuana, it is difficult to detect THC in oral fluid. The published Lab One study demonstrates that oral fluid drug testing yields results that are comparable with urine drug testing as long as the cutoffs are set appropriately. I have not read any studies that support the potential for an oral fluid THC positive from passive inhalation. This requirement will essentially eliminate oral fluid as a testing matrix. It is hard to imagine anyone collecting an oral fluid specimen if you also have to collect a urine specimen. In addition, with this stipulation in place, the only time you might want to collect an oral fluid specimen is in a case of very recent usage. In such a case, the THCA probably won't even have shown up in the urine yet, which is why you wanted oral fluid in the first place. So the proposed remedy doesn't fully address the alleged problem. Before this rule is finalized, more published work is necessary.

Oral Fluid collection and validity.

Section 8.3 paragraph 8. How should the oral fluid be mixed and then transferred? If collection devices were allowed, the handling of oral fluid specimens would be simplified. Collection devices should measure the amount of oral fluid collected. If recovery issues are viewed as "affecting" the collected specimen, some collection devices may violate section 7.2. Perhaps 7.2 could be clarified. If collection devices are allowed, the substituted specimen criteria for oral fluids may need revision, since you would have to know how much oral fluid you obtained in order for the IgG concentration to have meaning.

Hair testing.

Should hair testing be allowed for follow-up or return to duty. Since you can detect drugs in hair for a long time, how can you distinguish drugs detected in the hair from last week's drug use from drugs detected in the hair from last month's drug use? I didn't see any guidance in the proposed rule on collection or testing to address this concern.

Should baldness be treated like dry mouth or shy bladder? Guidelines on how to handle such situations would be helpful. Is head hair defined? Does head hair include eyebrows, moustache and beard hair?

How is the collector to know when the hair specimen is 100 mg? Is the collector supposed to weigh it? Are there guidelines for rejecting a hair specimen at the laboratory for insufficient specimen as there are for urine?

CCF.
On page 19682, it is suggested that one CCF be used for all types of specimens. This would simplify the whole process. There should be some extra room on the CCF for specimen choice boxes especially since the "split" specimen box can be removed since all specimens will be split. Collectors should be able to write comments on CCF. Allowing the writing of comments on the CCF was questioned in the guidelines.

Quantitative Reporting.
Drug concentrations should be printed on the report without special MRO request. This is already done for all of our non-regulated clients. The MRO would be responsible for maintaining objectivity.

Electronic Technology.
On page 19687, the question is asked if the new regulations should give guidance on electronic technology applications. Yes, I think this would eliminate a lot of the guesswork for laboratories that want to modernize their operations.

Definitions.
1) Should the definition of "Laboratory" be revised to include the "CT" as a releaser of results?

2) Should the definition of a "negative result" be modified to state "....MRO when a '**valid**' specimen contains no drug....."

6AM Initial Test.
Section 3.7 allows for screening all specimens for 6AM. It makes more sense to only test specimens for a 6AM test that are positive for opiates (same aliquot). If it is negative, there is no need to run a 6AM GC/MS test even if the specimen is positive for morphine by GC/MS. If the specimen is positive for 6AM by immunoassay, you have additional supporting data for the 6AM GC/MS result. This would result in faster turnaround times and less cost for the laboratories.

Specimen Collection.
Procedures for collections do not seem to fully take into account the nature of the different matrices. Having a donor empty his pockets for a urine collection is pertinent because he is given privacy and an opportunity to adulterate his specimen. Those precautions don't seem pertinent to hair, oral fluid and sweat patch collections.

The certification statement for the donor in alternative matrices collections should be more pertinent to the specific matrix. For example, should the certification statement for a hair collection include language about the collected specimen being their natural hair and that they do (or do not) dye their hair, etc. (It is suggested in the guidelines that hair be digested and tested for dye.) Will digestion detect the use of a human hair wig. Is dying your hair an attempt to adulterate a hair test?

For oral fluids instead of just asking the donor if they had anything in their mouth in the last 10 minutes, have the collector take a look in their mouth or have the donor rinse their mouth with water 2 minutes before collection. Some of the validity test requirements for oral fluids could be eliminated if precautionary procedures were followed.

Second Specimen.
On page 19686, the question is asked whether the second specimen collected in an invalid situation be of a different matrix. I believe that many of the invalid situations would go away if the donor knew they would be required to submit to a hair test for the second test. We can expect a lot more invalid specimens in the future due to the new validity test regulations so a better way to address the issue seems warranted.

The guidelines ask the question about collecting a second type of specimen should a shy bladder situation occur. As the current guidelines stand, oral fluid would be eliminated as a second specimen since you by definition you are unable to obtain a urine specimen. If the rule of oral fluid specimens were relaxed, I think agencies should be allowed to advocate a second type of specimen in such situations. Section 2.3.

POCT testing.
To ensure that all non-negative specimens are detected, the cutoffs for onsite testing could be lower than the initial test cutoffs. A similar practice is utilized on colorimetric pH testing to send any potential non-negative to the pH meter for testing.

Typographical error.
On page 19697, under oral fluid and urine confirmation cutoffs, phencyclidine appears to be listed as an opiate.

Sincerely,

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