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POCT For Drugs

Given that the devices being considered show an 80% ratio of accuracy as per your documentation, this would leave a 20% margin of error, which could result in both false negatives and false positives.

Maintaining the integrity of the collection site with the use of POCT drug testing devices could become very burdensome and expensive.

Given that POCT testing is most suited for Post-Accident and Random purposes, those facilities that choose to use POCT will be forced to choose additional forms of testing to maintain a complete testing program.

With regard to Section 2.3: Where the department proposes to prohibit routine collections of more than one type of specimen per donor, we believe that if there is an immediate cause to collect an additional or alternative specimen i.e. shy bladder, that such collection should be able to be collected using one of the approved alternative methods, as long as the collector is trained in the additional device without having to seek prior approval for such action.

With respect to requiring oral fluid testing to include the testing of a urine specimen simultaneously, this provision would increase the cost of the collection substantially enough for the end user to be prohibited from using the new technology. Oral fluid testing affords the end user the ability to have observed collections that can eliminate issues involving adulteration and privacy. We believe that the technology supports the use of oral fluid testing as an independent methodology.

Section 3.1 required test for marijuana and cocaine only: The Federal Department of Transportation has been testing for five drugs since it's program inception in 1989. We are in favor of including the same five panel testing for all federal workplaces.

With respect to 3.2a, MDMA testing: Given the prevalence of MDMA we believe that testing for this should be included in all federally mandated testing programs.

Regarding cutoff levels for cocaine and amphetamine, we agree with your decision to reduce these levels, identifying 10% to 20% more specimens containing cocaine metabolites and 5% to 24% containing amphetamine will increase the effectiveness of the drug testing programs and increase the safety benefit created by these programs.

Subpart E Sections 5.5, 5.6, 5.7 and 5.8: We agree that head hair should be the only type collected for a hair sample. We additionally agree with the Departments belief that it would be more appropriate to conduct a drug test using a different specimen rather than attempting to collect hair from another body site.

Subpart F, Federal Custody and Control Forms: This is a difficult comment, although we believe that a single federal CCF should be used for all of the various specimens, it would be imperative that the CCF be created in a manner that would not add confusion to the testing process. We agree that multiplicity of forms to identify each specific testing product could be problematic and difficult to maintain for organizations that chose to incorporate multiple testing products. A single CCF for each individual product would simplify the testing for companies who would chose to select only one product and would have a specific form to use for that product.

With respect to it being useful to add a requirement employees and others could not alter the Federal CCF in any way e.g. comments. Certain comments are essential for communication between the MRO and the collection facility. We do agree however, that changes that effect account numbers, client names, test panels and other various changes should not be permitted on chain of custody forms.

Section 7.2 Subpart G collecttion device: We believe that if the FDA has not cleared a collection device, these devices should not be used for Federal employee testing.

Subpart J Blind samples: We believe that the reduction in blind specimen submissions is warranted and that the recommended percentage will effectively provide the protections required.

Sections 11.26, 11.27, 11.28 and 11.29: We believe that levels should be automatically reported to the MRO. This will increase the effectiveness of the MRO to provide a conclusion to a testing process in a more timely and effective manner.

With respect to POCT's we again believe that only devices approved by the FDA should be allowed when the result of these tests will impact a persons livelihood and reputation.

We believe that the criteria outlined in Section 12.7 will be a good basis for the maintenance of the POCT program.

We are glad that the inclusion of requirdered tests that are negative are being sent to a laboratory for confirmation which is an essential and most important requirement.

Section 14.3, proposal that an individual who works under the direct supervision of an MRO may conduct the review and report of a negative result, we agree with this provision.

For specimens reported as invalid by the laboratory, the Department proposes to allow the MRO to direct the agency to have another specimen collected, we agree with this provision.

Subpart P criteria for rejecting a specimen for testing, we believe that the inclusion of a fatal error on all chain of custody forms regardless of the methodology of testing should be no printed or written signature of the donor, which establishes the inability to connect the donor to the specimen.

We feel that this error should result in the donor returning to continue the collection process until a completed specimen can be tested.

Section 16.3 omissions and discrepancies: The MRO would find tracking discrepancies which are considered by the agency as insignificant and contacting the collector, laboratory of IITF with recommendations of corrections when these discrepancies occur more than once a month would be an undue hardship on the MRO and staff. Instead we propose that anytime the MRO finds a problem, that they immediately contact the collector, laboratory or IITF in order to remedy these situations.

Issues of special interest: With respect to oral fluid and dry mouth we do not believe that adapting specific procedures are necessary. Again, we additionally would like to comment on the fact that oral fluid is a good alternative methodology for the test types as recommended, but we suggest revisiting needing an additional specimen to complete the testing process.

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