#04-7984
P.C. 8400103

July 9, 2004

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

Re: Docket Number 04-7984
Comments on SAMHSA' s "Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs" (DOCill:fr13ap04-143)

Dear Dr. Vogl:

We are writing to submit comments on the "Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs" published in the Federal Register on April 13, 2004. On behalf of Varian, Inc., we appreciate the opportunity to comment on these critical proposed guidelines.

We are very pleased that the Department of Health and Human Services has considered the needs and experiences of the drug testing community by proposing to allow the testing of alternative specimen matrices and the use of point of collection test (POCT) devices. However, we strongly disagree with some of the proposed conditions placed on the use of POCT devices given their acknowledged value and suitability for many purposes. We are also concerned that several provisions of these proposed guidelines would lead to significantly more laboratory testing.

We therefore suggest that the proposed guidelines be further reviewed and considered, and that review and consideration include active participation by POCT device manufacturers and users. We believe this would result in guidelines that are both scientifically sound, as well as free from any perceived bias.

Please accept our specific comments on the attached pages. We thank you in advance for considering our comments.

Respectfully yours,

Stephen K. Schultheis
General Manager
Varian, Inc.
Consumable Products

We agree with the provision for the testing of alternative types of specimens for the reasons provided in the Proposed Guidelines:

Preamble, 2004 FR Page 19675: Alternative Specimens

"Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to suborning drug testing through adulteration, substitution, and dilution."

Preamble, 2004 FR Page 19676: Oral Fluid

"Testing methods for drugs in oral fluid have been developed in recent years and have been extensively used in some tested populations (e.g., therapeutic drug monitoring, risk assessment in the insurance industry, and non-Federal workplace testing).

Many studies support the use of oral fluid as a specimen for forensic drug testing. Oral fluid offers some advantages over other types of specimens. Oral fluid is readily accessible and its collection is perceived as less invasive than a urine specimen collection. Oral fluid collections can easily be observed and, therefore, the specimen is less susceptible to adulteration or substitution by the donor. Drugs can be detected in oral fluids within one hour of use making oral fluids useful in detecting very recent drug use."

- **We do not agree with the proposed requirement that a urine specimen be collected when an oral fluid specimen is collected.**

(Reference: Subpart B, Section 2.3, which proposes that a urine specimen must also be collected from a donor when an oral fluid specimen is collected.)

We strongly believe that this proposed requirement is not scientifically supported, and would discourage or eliminate the use of oral fluids as an alternate matrix altogether, despite the usefulness and advantages acknowledged in other parts of the proposed guidelines.

Because of the differences in detection window, a urine test would not be reliable for confirming recent marijuana use, i.e., there is a strong possibility that the THC or THC-COOH will not yet be present in the urine specimen, therefore the negative urine test result would only cause confusion. On the other hand, analytical technology now exists that can easily detect and quantify THC in oral fluid so the quantitative confirmation step on the oral fluid specimen is all that need be performed.

Please refer to the graph on page 6 of Attachment 1 (Michael Peat, Ph.D., "A brief Introduction to Oral Fluid Testing") that shows that for detection of recent use, THC can be detected in oral fluid long before the THC or metabolite is present in urine.

Please also note the following quote from an article titled "Drugs of Abuse in Saliva: A Review," (David A. Kidwell, Naval Research Laboratory, and Willfried Schramm, et al, BioQuant, Inc.) – Attachment 2.

"Therefore, for the determination of 'past use,' urine is more suitable than saliva. However, for the indication of current intoxication or specific time of use, urine is inadequate and saliva has been recommended as the body fluid of choice."

You have also expressed concern with the possibility that THC from passive inhalation, rather than

from direct use, would be detected, and that testing a urine specimen would allow for differentiation because it would not be detected in urine. Again, we would like to emphasize that THC or THC-COOH from actual recent use may not yet be detectable in urine, so a negative result from urine is still not conclusive and would be misleading or erroneous.

We also are not aware of any scientific studies that prove this to be a definite concern.

The extra step of a urine test would therefore add cost without a reliable benefit, and would potentially cause agencies to simply abandon the oral fluid test because the urine test is mandatory. The proposed guidelines would, therefore, inappropriately promote urine testing and limit oral fluid testing.

- **We do not agree with the proposed requirement that each oral fluid specimen be tested to determine validity.**

  (Reference: Subpart C, Section 3.1(c), which proposes that each specimen must be tested to determine if it is a valid specimen.)

  As mentioned in the preamble, 2004 FR, page 19676:

  "Oral fluid offers some advantages over other types of specimens. Oral fluid is readily accessible and its collection is perceived as less invasive than a urine specimen collection. Oral fluid collections can easily be observed and, therefore, the specimen is less susceptible to adulteration or substitution by the donor."

  The collection procedure proposed in Subpart H states that the collection of the specimen must be *directly observed.* Since this is the case, the validity test should not be necessary, would add no value, and would therefore result in unnecessary costs. The above statement quoted from the preamble further supports this.

- **We do not agree with the proposed minimum required volume for the oral fluid specimen, as well as with the proposed limitations on the collection container and collection procedure.**

  (Reference: Subpart B, Sections 2.4 and 2.5 which propose that all specimens, regardless of specimen type, be collected as a split specimen and the Minimum Quantity of Specimen To Be Collected for Each Type of Specimen

  Reference: Subpart G, § 7.1(c) which describes collection device for oral fluid as the single-use plastic specimen container and Subpart G, Section 7.2 which proposes which collection devices may be used)

  We agree that the oral fluid specimen for POCT should be undiluted, however, the required volume should be left to the capability of the POCT devices and laboratories' confirmation procedures. Analytical technologies continue to advance and quantitative procedures are possible and reliable even now, with very small specimen volumes that are much less than the proposed minimum. For example, in the article referenced below, an LC-MS-MS procedure required only 50 µL of oral fluid to achieve limits of detection of 2 µg/L (2 ng /mL) of the analytes tested. We believe that technological advancements will continue to lower the detection limits for all drugs in any matrix.

  It is also possible that manufacturers may devise novel approaches for collecting an adequate volume of uncontaminated specimen for POCT testing, confirmatory testing, as well as for the purpose of a split specimen. We therefore disagree with the proposed restrictions and suggest more flexibility.

  It may also be extremely difficult to collect 2 mL of oral fluid from certain individuals, and forcing them to "spit" this volume of fluid could also result in a diluted specimen.

Literature references:

Attachment No. 3: G. De Boeck et al, "Recent Applications of LC-MS in Forensic Science," *Recent Applications in LC-MS*, November 2002, 2-8.

Attachment No. 4: List of additional references

- **We do not agree with the proposed collection procedure that would require the collector to confirm that the donor has not had anything in his or her mouth for ten minutes prior to the collection.**

  (Reference: Subpart H, Section 8.3(a)(4) which proposes that the collector must confirm with the donor that the donor has not had anything in his or her mouth for 10 minutes prior to providing the oral fluid specimen. If the donor has had anything in his or her mouth within the last 10 minutes, wait 10 minutes prior to beginning the collection process.)

  We do not believe that inquiry alone is a reliable method for the collector to confirm this. We suggest that all donors wait for ten minutes under the collector's observation before beginning the collection procedure.

- **We do not agree with the proposed collection procedure requiring subjects to "spit" into a specimen container.**

  (Reference: Subpart H, Section 8.3(a) 5-17b which proposes collection procedures Used To Collect an Oral Fluid Specimen)

  The proposed collection procedure requiring the subject to "spit" into a specimen container, is unnecessarily limiting. We agree that the collected oral fluid specimen should not be added to diluents, which could cause inaccuracy in the test result, but there are equally effective alternative methods for collecting a specimen. We do not believe that other proven oral fluid collection devices and techniques should be eliminated.

  The proposed guidelines suggest that a stimulated oral specimen should not be used. This suggestion relates to a publication that a lower drug concentration was found in the stimulated specimens.

  Collection of un-stimulated oral fluid is not practical, nor ideal, for the following reasons:

  Oral fluid is highly variable among individuals in viscosity, secretion rate, pH and components. Factors such as age, autoimmune diseases, drugs or medication, physiological status, food habits, etc. all contribute to the variability.
  Un-stimulated oral fluid often has high viscosity that may prevent lateral flow immunochromatography tests from running properly or to completion.
  Seniors, smokers, drug users and many autoimmune patients often have "dry mouth." For these populations, collecting 2 mL of un-stimulated oral fluid in a given circumstance is often unsuccessful. The samples from these individuals are also more viscous.
  Spitting into a collection tube also contributes to the "yuck" factor for the donors and collectors.
  Saliva secreted from different salivary glands is different in viscosity. Saliva from the sublingual gland has much higher viscosity than saliva from submandibular or parotid glands.

  On the other hand, note this point in favor of stimulated oral fluid collection:

Using optimized mild stimulation for oral fluid collection will reduce the viscosity, thus overcoming the problem of running to completion, and increasing the collectable volume, which is imperative for the collections from the "dry mouth" individuals.

We also believe that, in reality, it is not possible to control the amount of oral fluid stimulation from natural causes (visual, olfactory, or by mere suggestions), and therefore it is not possible to be assured of collecting an un-stimulated oral fluid specimen.

This can be related to the issue of "shy bladder" in urine testing, where donors may be allowed to drink water prior to collection.

2. **We agree with the proposed provisions for the use of Point of Care Testing (POCT) devices and with the related comments published in the Federal Register:**

Preamble, 2004 FR Page 19677

Non-instrumented POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories. These tests were conducted on both spiked and donor specimens with and without drug analytes. Little difference in the performance of these devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedures for conducting and reading the tests.

POCTs could potentially be employed almost anywhere, with hundreds, if not thousands of testing sites possible. The value and utility of the POCT is that it provides quick, negative drug results and validity test results and has the added benefit of not requiring a fixed facility, expensive test equipment, and highly trained testing personnel; moreover, POCTs could be run in low numbers, infrequently, and at any given location, as needed.

- **We do not agree with several of the provisions for POCT testing:**

(Reference: Subpart L which proposes guidelines for use of point-of-collection tests (POCT), proposes that POCTs be FDA cleared, and approved by the Secretary and placed on a list of SAMHSA certified POCTs, and proposes how to have POCTs reviewed and placed on list of approved devices.)

The proposed regulations would result in redundant regulatory clearances in requiring that a POCT device be both FDA cleared and DHHS certified.

The current SAMHSA guidelines require FDA premarket clearance. The FDA has viewed workplace drugs of abuse tests as medical devices and fully regulates them as such. They have, in fact, established several guidance documents applicable to drugs of abuse tests. The FDA is highly regarded and already viewed as a capable and strict overseer with regulations that require establishment registration, device listing, premarket clearance, truthful labeling, mandatory quality system management and corrective action system, as well as mandatory reporting for product corrections and removals (recalls) for products that violate established claims. The system for inspections, both random and directed, with strict regulatory requirements to respond to observations and warnings, along with possible severe consequences for unsatisfactory response, already serve to ensure responsible manufacturing and safe and effective devices.

We also do not agree that the FDA premarket clearance system, i.e., the requirement to prove substantial equivalence to a legally marketed device, is unable to ensure that the devices are reasonably accurate and reliable. The requirement to compare a new device with another established device not only establishes a baseline, but also provides incentive to improve performance. Manufacturers

therefore continually strive to improve the technology in order to provide improved performance characteristics. This trend for continual improvement can be seen with all types of devices.

We therefore do not agree with the requirements proposed in these subsections because they are unnecessary and duplicative in addition to being burdensome, complicated and impractical.

- **We do not agree with the proposed provisions of Section 12.13 and 12.14 because they are confusing and problematic.**

(Reference: Subpart L, Section 12.13 which proposes that if, after reviewing the information from the Federal agency and all other agencies using the same device as well as the circumstances of the failure, the Secretary determines that there is a problem with the device the Secretary may suspend the use of the device throughout the Federal drug testing program by informing the agencies through the Federal Register and notifying the manufacturer of the problem. The manufacturer then has 30 days to reply. Section 12.14 proposes that if the Secretary determines that there is a problem with the device, the Secretary shall notify the FDA so that the FDA can evaluate whether any action under the Food, Drug, and Cosmetic Act is necessary.)

The conditions that would constitute a "problem with the device" are not specifically defined or adequately described in the proposed guidelines. We are therefore concerned that such a determination could be based on judgment that is highly subjective or inconsistently applied. We recommend the guidelines promote consistent determinations. In any case, errors reported on a specific POCT device should be properly investigated and evaluated for any statistically significant trends before any action is taken.

We are also concerned that there would be potential confusion between the Department's actions and FDA regulation. FDA's actions are based, for example, on compliance issues with the Quality System Regulation, and/or issues involving product correction and removal activities and reporting. We would like to know how the Secretary's determination would affect manufacturers with regard to FDA regulation. Correction and removal decisions are based on compliance with performance claims, as stated on manufacturers' package inserts. We would like to know if the Secretary's decision would be similarly based. If they were not based on the same criteria, what would be FDA's basis for investigation or follow-up? We would also like to know if and how the Secretary's determination will impact Quality System issues and compliance determinations with 21 CFR Part 820. Would they, for example, prompt a Quality System inspection, in which case, we are concerned that the action may extend beyond the scope of the "problem" that the Secretary has determined.

We do not agree with the proposed requirement for PT testing at DHHS.

(Reference: Subpart L, Section 12.6 which proposes criteria based on Proficiency Test results that the Secretary would use to place a POCT device on the List of SAMHSA-Certified POCTs)

This would add tremendous, and in our opinion, unnecessary cost.

Based on calculations involving our product line, the requirement for sending 100 devices of each lot of each product available for sale could cost more than $1,000,000 for the products alone. We suggest that the Department reconsider this requirement in terms of the cost burden to manufacturers. Will receipts be issued for these test samples, as is the case with FDA in their sample collection procedures? Will there also be any consideration for payment?

There is also a tremendous amount of work and cost involved in actual PT testing. In our opinion, it would be unrealistic to expect that the quality of the program could be maintained due to the huge management and financial support that would be required. We do not believe that such costs could be

supported on an ongoing basis, and we believe that the quality of the program would eventually suffer and reliability of the results would come into question if the program is not continuously well funded. There are a number of questions we have about the "quality systems" that would be required to implement SAMHSA-dictated Proficiency Testing. For example:

1. What would be the turn-around-time to complete the testing on each lot number?
2. Will POCT companies be restricted in selling these lot numbers until this testing is completed? If so, how will companies be notified that their lots are "released for sale"?
3. How many "expert" readers will be employed by SAMHSA to perform these tests? How will they be trained? Will there be on-going training, especially for new products and/or product improvements?
4. How will all of these POCT samples be sequestered, inventoried and stored? How will the PT samples be sequestered, inventoried and stored?
5. What/Who will be the source of the PT samples? What are the quality requirements for manufacturing these PT samples? What will be the matrix (synthetic or "natural" urine/saliva)? Will this matrix for PT samples be tested for all POCT manufacturers products before being implemented to ensure that there are no false results due to matrix-effects?
6. If these product lots passed in-house QC testing before being sent to SAMHSA, how will conflicts be settled if they fail the PT testing? Who at SAMHSA will be the referee of these conflicts?
7. Finally, what is the anticipated budget for such a PT program at SAMHSA?

We would therefore like to know how the quality of the testing laboratory/facility would be ensured.

Again, we propose that FDA oversight should be sufficient as long as the published claims for cut-off values meet the SAMHSA cut-off values. Adopting this very expensive PT testing regimen adds no value, and in our opinion, would waste taxpayer dollars.

- **We do not agree with suggestion in the proposed guidelines that POCT devices are unproven or unreliable.**

  Numerous governmental agencies and other institutions have been successfully using POCT for drugs of abuse screening for many years. The adoption of the proposed guidelines for these agencies and institutions would add a huge amount of cost to their program – costs that are not warranted and not required. We do not believe that it is the intent of the Department to add additional costs and burden to processes that are already productive and producing required results. We suggest that SAMHSA research the processes and procedures used by institutions that are already using POCT devices, as our experience is that they are satisfied with their use.

  POCT devices have been used in the criminal justice arena since the early 1990s. They have been proven reliable and effective in qualitative determinations of drug use for probation/parole, prisons, and community corrections environments. POCT products have withstood legal challenges.

We do not agree with the proposed requirements for PT samples for POCT purposes.

(Reference: Section 12.9 which proposes qualitative and quantitative specifications for PT samples that are used to evaluate test devices submitted by manufacturers or for a federal agency to evaluate a POCT site and tester and Section 9.5 which proposes the qualitative and quantitative specifications of a performance test (PT) sample for laboratories)

The standard applied for Proficiency Testing sample requirements for POCT devices appears to be more stringent than those used for laboratories.

We propose that specifications for PT samples for POCT be the same as those for labs, i.e., the positive sample should be at least 20% above than the cut-off, and the negative sample should contain no drug (a true negative) as stated in Section 9.5, rather than as currently proposed in Section 12.9, i.e., the samples should be at least 20 % above the cutoff, and between 50 and 75 percent of the cutoff concentration for the initial test, and contains no measurable amount of a target drug and/or metabolite (i.e., a negative sample).

- **We do not agree with the proposed frequency of running controls for POCT testing.**

  (Reference Section 12.19 (a) (1) which proposes that, as quality control requirements when conducting POCTs for devices with visually read endpoints, each individual performing drug tests using these devices must test at least one negative control and one positive control before donor specimens are tested. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.)

  It is adequate to run positive and negative control samples only when changing to different manufacturers' lot of the POCT device. Running them more often is wasteful. These are not instruments to be re-calibrated; they are one-time use devices that use variable samples.

- **We do not agree with the proposed specifications for PT samples.**

  There is a difference in standards between laboratories and POCT users. The requirement for SAMHSA-certified labs is a correct answer on better than 90% of all PT challenges (Section 9.9). In section 12.9, if a POCT device is not 100% correct on all PT challenges, the device is subject to be removed from the "approved list." If POCT devices are equivalent to lab tests as indicated in the preamble, then POCT devices should be subject to the same failure criteria.

- **We do not agree with the proposed requirement to send one of every ten negative samples to a HHS-certified laboratory to be tested for quality control purposes.**

  (Reference Section 12.21 which proposes that A POCT tester must send one of every 10 negative specimens together with its split to an HHS-certified laboratory to be tested for quality control purposes. Other negative specimens must be discarded.)

  Sending one of every ten negative samples for confirmation will not improve the overall testing accuracy and will result in a huge increase in end user costs for the redundant laboratory drug testing.

  While the section proposes that 10% of all negative POCT results be sent to a SAMHSA-certified lab for confirmation that the result is a true negative, this same requirement is not being proposed for laboratories. In order to be consistent and fair, laboratories should also be required to send 10% of negative samples to another SAMHSA-certified lab to confirm "true negatives." This requirement for both POCT users and laboratories would add no real value for the unnecessary cost and burden it would impose.

  Proficiency testing adequately ensures the quality of the system.

3. **We do not agree with statements that POCT for urine specimens may be least suited for pre-employment, return to duty and follow-up:**

   Reference: Preamble, 2004 FR, page 19678: Advantages of POCTs

   POCT products could potentially be employed almost anywhere. The value and utility of the FDA-cleared and SAMHSA-certified POCT is that it will provide quick, negative drug and specimen

validity test results. Those specimens that test presumptively positive for drugs or indicate that additional specimen validity testing is necessary would then be referred for confirmatory testing. POCT testing of urine is most suited for situations that require quick, negative drug and specimen validity test results such as in emergency/crisis management. It may be least suited for pre-employment, return to duty and follow-up testing.

POCT testing on urine samples has been performed for over a decade in the area of pre-employment, return to duty and follow up testing. POCT testing on urine samples is the most documented and proven testing protocol and has, in fact, become the gold standard in these areas. On the contrary, POCT testing on urine samples for this area is very well suited.

(Reference: Preamble, 2004 FR page 19679, Subpart B, Urine

This reference states:

"Laboratory based urine testing has traditionally been used for pre-employment, random, reasonable suspicion/cause, post-accident, return-to- duty, and follow-up testing. Drug ingestion for a 3–5 day interval preceding the specimen collection can usually be identified in urine. Based on the detection window, urine is most suited for random, return to duty and follow-up testing. Because of the increasingly evident potential that Federal agency workplace urine-based drug testing has the potential for being seriously compromised by clandestine products and procedures intended to mask current drug use, especially when given sufficient time to obtain these products, urine drug testing may be least suited for pre-employment."

The knowledge of products and procedures to mask current drug use and the laboratories or POCT sites methods to prevent or detect their use is very well documented. This is not a concern that would make urine drug testing least suited for pre-employment testing.

4. We do not agree with some of the proposed changes in Subpart C.

(Reference: Subpart C which proposes to lower cutoff concentrations for cocaine and amphetamines, proposes validity testing requirements for all types of specimens, as well as how and when to report the various types of specimens as adulterated, dilute, or invalid.)

- **We do not agree that the cutoff concentrations for cocaine and amphetamines should be lowered.**

In the past, the cutoffs for other drugs, e.g., for THC and opiates, has instead been increased for this very reason, i.e., that the low cutoff resulted in too many false positives from cross-reacting or allowable forms or sources of the analyte. We are therefore confused with the intent of this proposed provision.

While we agree that the reduction in initial and confirmatory cutoffs for most drugs in urine will increase the time period in which those drugs will be found and produce an increase in the number of urine specimens that identified as containing cocaine metabolites and amphetamines, lowering initial screen cutoffs for any drug will also increase the possibility of more non-negative results due to cross-reacting substances. Thus, lowering the cutoffs will only increase the number of specimens requiring confirmation without improving the detection window significantly.

We are unaware of any evidence to support that current cutoffs are inadequate.

We do not agree that the only sensitive and specific method for performing the initial

test for methamphetamine, amphetamine and MDMA is to use two separate initial tests, i.e., one for methamphetamine and amphetamine, and a second for MDMA.

MDMA and other amphetamine analogs have a high degree of cross-reactivity with most amphetamine or methamphetamine initial tests and would result in a positive test result. Therefore, the criteria for specific detection of MDMA should remain at the confirmation, and need not be a requirement of the initial test.

- **We do not understand the proposed guideline on saliva cocaine/benzoylecgonine confirmation levels. The second table in Section 3.5 indicates the cocaine cut-off is 8 ng/mL with a superscript notation, while the footnote indicates "Cocaine or Benzoylecgonine."**

Should this be indicated as "and/or," "the addition of both"? To illustrate the confusion, if the confirmation analysis indicated 7 ng/mL for each analyte (since cocaine can breakdown in the saliva), would the lab still report a negative result even though the total is 14 ng/mL?

We do not understand the proposed guideline on the oral fluid initial test cutoff concentration for marijuana.

Reference: Section 3.5 What Are the Cutoff Concentrations for Oral Fluid Specimens?

In the table under the section identified above titled "Initial Test Cutoff Concentration" "THC Parent drug and metabolite" is identified as the target. However, the literature overall does not support the metabolite is found in an oral fluid specimen, only the parent drug. This was also identified in the Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004 / Notices in column 2 paragraph 1.

The Walsh Report (published in Journal of Analytical Toxicology (JAT), Vol 27, Oct 2003) on page 438 states "that THC-acid metabolite is rarely ever detected in the oral fluid of a marijuana smoker." This is also reflected in the Niedbala et al. JAT article (JAT, Vol 25, July/August 2001, pp. 289 - 303) on page 290 where the author states that "There appears to be only a single report of detection of marijuana metabolites in oral fluids." The authors then continue to indicate that another study of "revealed no evidence by gas chromatography-mass spectrometry (GC-MS, detection limit = 0.5 ng/mL) " of metabolite.

The discussion continues in the Letters to the Editor (JAT Vol 28 January/February 2004, pp 75-76) between Dr Vina Spiehler and Drs. Walsh and Crouch further indicating the complexity of the discussions.

5. We do not agree with certain proposed requirements in Subpart K.

- **We do not agree with the proposed requirement that a HHS-certified laboratory test the specimen in the same manner as a specimen that had not been previously tested.**

(Reference: Subpart K, Section 11.10)

POCT test devices are simple, visual read devices that do not require extensive training. A duplicate initial screen to confirm the POCT initial screen is simply a duplicated effort, redundant, and of no value because the specimen will be subjected to confirmation. When a sample has been tested by POCT, the analyte drug yielding a non-negative result is included in a request for confirmation. It is sufficient that HHS-certified laboratory perform the GC/MS or LC/MS confirmation. The proposal only adds an additional laboratory cost for the duplicate screen.

- **We do not agree that an initial drug test must be an immunoassay test or a test that combines a chromatographic separation with an appropriate detector.**

  (Reference: Section 11.12 "What Are the Requirements for an Initial Drug Test? (a) An initial drug test must be an immunoassay test or a test that combines a chromatographic separation coupled with an appropriate detector.")

  The analytical methodology for an initial drug screen should be up to the laboratory as long as the laboratory can show satisfactory performance in the proficiency program.

- **We do not agree that, if the laboratory uses a second initial drug test, the second initial drug test should be subject to the same requirements as the first initial drug test.**

  (Reference: Subpart K, Section 11.12 ***(d) "A laboratory may conduct a second initial drug test on a specimen prior to the confirmatory drug test. If the laboratory uses a second initial drug test, the second initial drug test is subject to the same requirements as the first initial drug test.")***

  First, we must point out the poor wording of this section, specifically on the use of the terms "first initial" test and "second initial" test.

  The use of a second "initial" drug test on a specimen prior to the confirmatory drug test would add value only if the second "initial" drug test adds significantly more specificity.