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P.C. 8400123

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

RE: FR DOC 04-7984

Dear Dr. Vogl,

In response to the proposal by the U.S. Health and Human Services to establish guidelines for using alternative testing methodologies for federal workplace drug testing programs, Kroll Laboratory Specialists offers the following correspondence outlining our opposition on all counts and respectfully recommends that the proposal be withdrawn.

Since 1989, Kroll Laboratory Specialists has participated in the National Laboratory Certification Program (NLCP) that regulates the laboratories certified to test specimens as part of the federal drugfree workplace program. Our experience with federal testing, and drug testing as a whole, enables us to comment on the proposed changes with a definitive understanding of procedures, protocols, and methodologies. This proposed modification of the Mandatory Guidelines for Federal Workplace Drug Testing Programs to allow alternative testing methods causes us concern. Our apprehension is not a result of our business stake in the drug testing industry but is a result of our clients' stake in a program that must remain universally uniform and reliable. HHS's proposal will modify the federal guidelines in such a way that they no longer resemble the steadfast methods that our clients have depended on to ensure their drug testing programs are consistent and, thereby, accurate and legally defensible.

Consistency is the ability to maintain a particular standard with minimal variation. This is what the federal guidelines have been striving for since their inception; however, several areas within the alternative testing matrix are inconsistent and perforate what has been established as a singularly coherent program for companies to follow.

The first consistency issue lies in the fact that no single alternative testing methodology is recommended for all testing situations. For example, hair testing is not recommended for post accident or reasonable suspicion testing. Drug testing with hair specimens may provide evidence of long term use; however, it cannot detect recent use, i.e. the day or few days before.

Companies are attempting to uncover recent use when the analysis is being performed under post accident or reasonable suspicion circumstances. Hair testing cannot provide definitive proof of recent use and, therefore, requires that another testing methodology be used in post accident and reasonable suspicion circumstances. Using two separate methodologies to test in two separate employment situations could be difficult for company representatives and collectors to coordinate. In relation to testing for all drugs of abuse, the potential for testing positive for marijuana due to passive inhalation is too great with saliva testing. Marijuana is America's most abused drug, and, as such, companies need to know if their employees or potential employees are marijuana users to have an effective program. Saliva testing cannot provide definitive proof of marijuana use and, therefore, requires that another testing methodology be used to test for marijuana. Collecting a urine specimen along with a saliva specimen could be neglected, and, thus, the test performed would not be complete. Finally, regarding separate screening and confirmation requirements, point of collection testing only provides initial test results indicating the qualitative presence of a drug or drug metabolite. Suspect positive specimens from POCT devices must be confirmed with a separate, distinct testing methodology; therefore, companies that utilize POCT devices would have to send all suspect positive specimens to a laboratory for confirmation. Point of collection testing cannot provide definitive proof of the presence of any drug or drug metabolite and, therefore, requires that another testing methodology be used to confirm initial test results. Transporting suspect positive specimens to a separate location for confirmation adds to the complexity of ensuring chain of custody and specimen integrity.

In all of these cases, the companies that elect to use an alternative specimen must combine methodologies to fully meet federal requirements for all testing situations, which would inevitably complicate their testing programs, create inconsistencies, and incur additional costs. The only universally accepted method, which is both convenient and cost effective and meets all requirements, is traditional, laboratory-based urine testing.

In addition to the aforementioned issues, several others fragment the overall coherence that a single methodology drug testing program provides. For the end user – the company required to perform drug testing – opening up the program to other methods, produces sweeping irregularity and unpredictability with regards to employment practices, statistical reporting, and training.

First of all, enabling companies to choose from several "approved" testing methodologies creates inconsistencies in the universal hiring practices employed by federally-regulated companies. Because each testing methodology has a different drug detection period, a potential employee that may be hired by a company using one testing methodology could be denied employment by another that uses a different one. These two companies should be equal, utilizing the same employment practices and hiring from the same applicant pool..

Secondly, various companies using various testing methodologies also leads to a lack of consistency in program monitoring. Positivity rates may vary among the testing methodologies. These variations in positivity rates would complicate the interpretation of industry statistics and would have to be accounted for when performing statistical analyses. Within that, companies that have to use multiple testing methodologies, i.e. those that normally use hair testing and

would have to use urine for a post accident test, would have disparate statistics because of the disparate methods. Again, performing a statistical analysis on the company and comparing it to industry-wide statistics would be imprecise without accounting for the varied positivity rates.

Finally, ensuring consistency in the training of all participants in the drug testing program is a monumental task. As currently available for traditional, laboratory-based urine testing, training programs for each methodology must be outlined for collectors, medical review officers, and company representatives. Collectors will need to be provided with the appropriate collection protocols for each method. Additionally, they will need to be trained on the various points of deviation for each methodology. For example, collectors must be trained to ensure a urine specimen is collected with a saliva specimen so that testing for marijuana can be conducted. Further, they would need to be trained to ensure that urine is collected for those clients that normally use hair testing so that a post accident or reasonable suspicion test can be performed. These exceptions must be clear to the collector, and their collection methods must be agreed upon by all laboratories and deemed legally defensible for companies. Assuming that collecting for alternative testing methods will follow along with the collection requirement for traditional, laboratory-based urine testing, the collectors will need to be certified to perform collections for each methodology. Along with the need to design and implement consistent collector protocols, training and certification programs will need to be developed and enforced. Certification for collectors has been recently implemented to correct the inconsistencies in collection protocols, ensuring the integrity of the collection process and reducing the number of rejected specimens due to collector error. This commitment to consistency must continue with the alternative testing methodologies and, as such, will expand the already overwhelming task of ensuring certification. With the potential for millions of collectors out there, enforcement will be difficult. Add this to the need to educate MROs and company representatives on interpreting results and managing programs, and not enough resources currently exist to design and implement training and certifications programs.

As final commentary on the proposed guidelines for alternative testing methodologies, Kroll would like to address the complicated nature of point of collection testing. Our experience indicates that specific attention should be paid to point of collection testing and the logistical issues that surround implementing this method for the federal drugfree workplace program.

If a company chooses to perform its own collections for a point of collection testing program, an employee of the company will participate in every step of the process – collecting the specimen, testing the specimen, and interpreting the results of the test. Having each individual involved in the testing process employed by the same company conducting the testing will eliminate the checks and balances currently in place to maintain the integrity of the specimen, preserve the donor's privacy, ensure the accuracy of test results, and guarantee the defensibility of test results in a court of law. A step in the process may be inadvertently neglected or the results of the test intentionally misread to the benefit or detriment of the donor. Too many opportunities for errors, omissions, or corruption exist when placing all of these steps in a single location, exposing a company utilizing point of collection testing to be held liable in unfair hiring practices, unfair dismal, or negligent hiring lawsuits.

Point of collection testing also exposes the donor's right to privacy. Confidentiality has always been a large part of the federal drug testing program. Special care was taken to design a chain of custody form to conceal the donor's name from the laboratory, ensuring that donors are only identifiable by their social security numbers and assuring results are not influenced by an employee knowing the individual on whom he/she is performing analysis. Where a laboratory is an objective entity with no history with or knowledge of the donor, in point of collection testing, the donor will encounter with the collector and/or tester. These two individuals may be related, friends, or enemies. In any scenario, the results are subject to falsification to the benefit or detriment of the donor. Even if the donor and collector/tester are not known to each other prior to the point of collection testing process, donor confidentiality and test integrity are still breached. First of all, corruption of the testing process is possible. The donor may attempt to bribe the collector/tester or the collector/tester may attempt to extort money from the donor in exchange for a negative test result. Secondly, potential confrontation issues exist. The donor may be insistent on knowing his/her results immediately or agitated and irate at the prospect of having to be confirmed, putting the collector/tester in awkward and potentially harmful situations. Finally, an individual's positive initial test result could damage his/her reputation within a company, even though that result does not confirm positive in a laboratory setting. Results not yet confirmed by laboratory testing are known to the collector/tester. The collector/tester may tell other employees or form his/her own negative opinion of an employee. The slightest question about breach of confidentiality, specimen integrity, or result falsification can lead to a legal dispute about employment action taken on results of a point of collection test.

Finally, while point of collection testing may appear like an inexpensive alternative to traditional laboratory urine testing, implementing a POCT program under federal guidelines will eventually become a burden on a company. If companies or collection facilities performing point of collection testing are held to the same security standards as laboratories, the areas where the testing is performed, devices are stored, and records are maintained must be secure. Many companies or collection facilities would find meeting these stringent requirements cumbersome. A similar burden would be on companies or collection facilities to ensure that collectors are certified and appropriate procedures are followed. Additionally, ensuring Medical Review Officers are informed of on-site negative test results and maintaining meticulous records would be challenging. Non-regulated clients, who are not held to the high standards of federal testing programs, have difficulty implementing point of collection testing programs, training collectors, managing this training, interpreting results, and addressing issues like shy bladder and adulterant testing. These difficulties will only be magnified when attempting to meet the strict requirements of performing federally-regulated testing.

Thus far, Kroll Laboratory Specialists' response has focused on the "real world" issues created by accepting alternative methodologies for drug testing in the workplace. We have chosen to focus on this area because scientific acceptance of alternative testing is still being debated. Issues of environmental contamination remain, and specimen validity testing and quality control procedures have yet to be determined. With these technical and logistical issues unresolved, Kroll Laboratory Specialists asserts that modifying federal guidelines to include alternative

testing methodologies is simply premature, and we recommend that the HHS's proposal be withdrawn. While we understand the need to "advance" and keep up with "new technology," these technologies must be researched more thoroughly to determine impact on real world scenarios, and the straightforward consistency that has been created through years of evolution in traditional, laboratory urine testing programs must be evenly applied. Let us remember that the initial purpose of the federal drug testing program was to ensure a drugfree workforce nationwide. Accepting other methodologies would expand the program to an unrecognizable, unpredictable state, and this lack of consistency would be in direct opposition to the original mission.

Sincerely,

Kroll Laboratory Specialists