



Field Notes

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Why Field Notes ?

While some individuals have asked us why we wanted to go to all this trouble to publish a newsletter, to those who have known SASI for any length of time the answer is quite simple. SASI was conceived as a company that would serve as a resource to the drug testing community, not just a supplier. Prior to 1997 the drug testing community had very few options other than going to the large supply houses for consumables. These companies were primarily designed as medical supply distributors, focusing on the hospital and laboratory community. Their expertise is in the distribution and warehousing of laboratory supplies. Few, if any, have any knowledge of the specific needs and concerns of the drug testing industry.

We here at SASI knew better. The SASI team brings to the table experience in working with both new and existing collection and diagnostic sites whether small on-site facilities or large reference laboratories. We know about the needs of these facilities from the physical sense as well as the educational sense. While there are still a few areas of the country that almost anyone can hang a shingle on the side of a building and open a collection or on-site testing lab with little or no knowledge, state and federal regulations are mandating training and experience. SASI supports these regulations and feels that continuing education is paramount to provid-

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URINE DILUTION:

THE PROBLEM, ITS DETECTION AND POLICY RESPONSES

Leo Kadehjian, Ph.D., Biochemistry

One of drug users' resources in their attempts to thwart detection through drug testing is dilution of their urine specimens through excess fluid consumption. After consumption of 1 liter of fluids shortly before a drug test, urine drug/metabolite concentrations can be reduced several-fold and remain diluted for a few hours. This may allow a drug user to escape detection by reducing the concentration of any drugs/metabolites present in the specimen to levels below the screening assay cut-offs. Current federally-regulated drug testing programs specifically limit the amount of fluids allowed when donating a specimen, in part to minimize opportunities for dilution.

Dilution should not be confused with adulteration, where chemical adulterants are directly added to a urine specimen. Many products intended for oral consumption and claiming to help "rid the body of toxins" are sold over the Internet. Although these "body cleansing" products may claim to "rid the body of toxins" (i.e. help beat the drug tests), they appear to be effective only because of the large amounts of water the user is instructed to consume along with the teas or powders. Consumption of excess fluids is the most effective way to dramatically increase urine production rates and produce dilute urine specimens. Diuretics, prescribed for those with high blood pressure, increase urine production rates to only a few mL/min compared to a typical 1 mL/min urine production rate. The same is true for alcohol, with only a few mL/min increase in urine production rate. However excess water consumption of 1½ liters can lead to dramatic increases in urine production rates to 10 or even 20 mL/min!

Although the consumption of excess fluids to avoid detection is commonly called "flushing", this term is misleading. The excess fluid consumption and increased urine production rates are not causing a more rapid elimination of drugs/metabolites from the body. Rather, the same amount of drug and metabolites are being cleared through the kidneys, but they now are being sent to the bladder with a much greater amount of water, and so diluting the measured concentration. It is also important to understand that although a user may escape detection through dilution, the test results are nonetheless scientifically "accurate" in determining the level of drug in the specimen (that is, drug/metabolite concentrations in dilute specimens may be below the assay cut-offs with the assay giving the scientifically correct below cut-off "negative" result).

Although a drug user may be able to easily dilute their urine by a factor of 5 or more, for many drugs the urine concentrations may be

so high that even a 5×10 fold dilution will not allow a drug user to reduce their urine levels below the established cut-offs. For cocaine users, typical urine levels of cocaine metabolite are on the order of many tens of thousands of ng/mL and even higher, so even a 10-fold dilution will still leave urine levels well above the screening cut-off values (300 ng/mL of cocaine metabolite). The same can be true of opiates and amphetamines, simply because of the large doses of these drugs which are commonly consumed by abusers and the very high resulting urine concentrations. However, after the body has had some time after dosing to metabolize and eliminate these drugs/metabolites and their urine levels are reduced to only a few thousand ng/mL, then dilution may allow a user even of large amounts of drug to escape detection. In contrast, for cannabinoid consumption, the urine levels are typically on the order of only a few hundred ng/mL and accordingly a 5×10 fold dilution of urine may easily allow a user of cannabis to avoid detection with the conventional 50 ng/mL screening cut-off.

Measuring Dilution

There are several methods which can be used to identify and measure the extent of dilution of a urine specimen. Clearly diligent collector observation of the nature of the specimen is important. For objective scientific assessments, the two most common tests are for specific gravity and creatinine. Although some have argued for their preferences between these two, both have been recognized as appropriate markers. Note that such specimen validity testing is currently authorized under federally-regulated workplace drug testing programs, but it is not mandatory.

Specific gravity

Specific gravity measures the density of a urine specimen relative to that of pure water (which by definition has a specific gravity of 1.000). It can be easily and reliably measured on-site using a hand-held refractometer, which provides an indication of the specific gravity by measuring the refractive index of the urine specimen. Urine specimens have specific gravities greater than water because of the many dissolved substances and are typically around 1.025. Current regulations established by the Department of Health and Human Services (DHHS) and the Department of Transportation (DOT) for federally-regulated workplace urine drug testing programs have established 1.003 as the lower cut-off for specific gravity (for DHHS in the National Laboratory Certification Program, Program Document #35, 9/28/98, and for DOT in 54 FR 49854, 12/1/89). This cut-off reflects approximately an 8-fold dilution from typical levels.

Creatinine

Creatinine is a metabolic by-product formed primarily from the breakdown of protein within the body and eliminated in the urine. About the same total amount of creatinine is eliminated each day and so its concentration in urine can be used as a marker for the extent of urine dilution. Typical urine creatinine concentrations are on the order of 150 mg/dL. Current DHHS and DOT regulations have established 20 mg/dL as a cut-off for indicating a dilute specimen. Again, this cut-off reflects an approximately 8-fold dilution

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Dr. Kadehjian is an independent biomedical consultant in Palo Alto, California, lecturing and writing on the clinical, scientific, regulatory, and legal issues in drugs of abuse testing. He has provided consulting services for a wide variety of both private and public sector drug programs. Clients have included IBM, Exxon International, Texaco, General Motors, Amtrak, Pfizer, Syntex, Syva, Dade-Behring, the U.S. Federal Courts, and numerous state corrections agencies and local drug courts. He has special experience with on-site testing programs and provides oversight of the U.S. Federal Courts' on-site drug testing programs. He has earned recognition as an Outstanding Speaker from the American Association of Clinical Chemistry and has provided expert testimony in court and labor arbitration. He has provided judicial education, including teaching at the National Judicial College on the neurobiology of addiction and drug testing issues and has given lectures through the Federal Judicial Center. He has also conducted workshops for occupational physicians and other clinical providers.

Dr. Kadehjian received his Bachelor's degree in Organic Chemistry from M.I.T. and his Ph.D. in Biochemistry from Stanford University in 1977. After several years of bio-organic and toxicological research, he served as Manager of International Medical Affairs for Syva, lecturing extensively around the world, including mainland China and the Soviet Union. Since then he has established his own biomedical consulting business with private and public sector clients worldwide. Dr. Kadehjian joins SASI as a consultant and will be providing additional articles in the future.

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(Field Notes continued)

ing service to the community. Our intentions with **Field Notes** is to support the continuing education of the testing community and we hope the articles and information contained within its contents fulfills that goal.

In working with SASI, you are working with a team that knows the difference between polystyrene and polypropylene. We know what “leaching” means and we understand the difference between a transport container and a collection container. We know what it is like to have to sit on a witness stand in a court of law to testify and be cross-examined by a defense attorney, and we understand what quality customer service is all about. That is the SASI difference — and that is why we are going the extra mile to provide you with this newsletter. We hope that you will find it useful. Please, let us know if we are meeting these goals.

**ARE YOUR SPECIMENS
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**HAVE QUESTIONS
YOU WOULD LIKE TO ASK SOMEONE?**

Coming soon to a newsletter near you, the infamous “Ask the Expert” column. Send us questions that you would like to ask and we will get them answered by someone who is qualified within the field of your inquiry. Topics for future articles are also being solicited. Snail-mail or E-mail your suggestions or questions to customerservice@sas-i.com with “Ask the Expert” as the subject matter. Don’t be bashful, someone else probably wants to know the answer as well!

from typical levels. Creatinine may be roughly measured on-site using specially designed urine dipsticks. More accurate measurements can be made on typical laboratory automated analyzers. Creatinine is to be distinguished from creatine, which is used as a dietary supplement by body builders. The difference between creatine and creatinine is a molecule of water. The urine tests for creatinine do not cross-react with creatine. However, oral loading with significant amounts of creatine (e.g. 5g/10 g/day) can increase urine levels of creatinine, but not significantly so.

Policy Responses

In the DHHS and DOT federally-regulated urine drug testing programs, both creatinine and specific gravity must be below their respective cut-offs before a specimen is considered unacceptably dilute. However the Nuclear Regulatory Commission (NRC) drug testing program specifies that either of these markers is sufficient to indicate a specimen as dilute. (54 FR 24468, 6/7/89).

Under the DOT program, if a specimen is shown to be highly dilute, the only sanction imposed is that the next time a specimen is demanded of that donor, it must be collected under direct observation. Unfortunately, this response does not effectively address the ability of a drug user to again provide a dilute specimen! The NRC has proposed that dilute specimens be subjected to testing at a reduced cut-off, but this has only been published as a Proposed Rule and has not been established as a Final Rule (61 FR 21105, 5/9/96).

Furthermore, there is some discussion surrounding the appropriateness of the specific cut-offs established to indicate dilution. The DHHS has published on its web-site their basis for selecting the cut-offs for creatinine and specific gravity, including the references to the research they reviewed. (www.health.org/workplce/urinesubs.htm).

I recommend that the provision of a dilute specimen be considered unacceptable and should be met with appropriate sanctions. Of course excessively dilute specimens should nonetheless still be forwarded to the laboratory for testing as they may still test positive. An approach like that proposed by the NRC could also be implemented where dilute specimens are tested at a lower cut-off, or even at the limit of detection of the assay. However caution should be exercised whenever different donor specimens are treated differently, ensuring that there is a sound and non-discriminatory basis for doing so. Rather, I recommend that all persons subject to drug testing should be informed at the outset that they will be expected to provide a fresh, clean, unadulterated, and undiluted specimen; that they will be provided a limited amount of time and limited access to fluids in which to provide an adequate specimen; and that any failure to provide an adequate specimen absent a documented medical condition will be considered a failure to comply with the conditions of the testing program, with appropriate sanctions, depending upon the testing context. To conservatively allow for the possibility that a donor simply does not understand their responsibilities, kidney physiology and dilution, and may have innocently consumed excess fluids prior to donating a specimen, perhaps the first time a donor

submits a dilute specimen they may be reminded of the policy regarding excessively dilute specimens being unacceptable. A recurrence would then trigger appropriate sanctions.

Conclusion

Although efforts to reduce urine drug/metabolite concentrations below screening cut-offs through dilution may be effective, there are objective tests to measure dilution, and policy responses to minimize the effectiveness of these efforts.

Selected References

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