

Testimony submitted by Jill F Captain, MD, MPH  
Representative of Drug and Alcohol Testing Industry Association (DATIA)

Regarding: Devices and products used to subvert drug test results

Addendum:

Overview of a typical urine drug screen collection regulated by the Department of Transportation (this scenario does not include every step but outlines the essential elements):

Securing the collection site

- The bathroom has no water supply available to the donor
- Excess equipment such as trash cans are removed from the room (prevents concealment of products placed in the bathroom before the collection takes place)
- The water in the toilet has bluing agent added

Collection process:

- The donor is asked to remove extra outer garments such as jackets, coats or coveralls and heavy boots
- Photo identification is required and checked
- The donor is asked to empty pockets to check for bottles that might contain liquids or containers of substances that might be used to adulterate specimens
- The donor then washes his/her hands
- The collector opens a sealed collection container and hands it to the donor
- The donor is instructed to urinate in the container
- The donor is allowed to enter the bathroom and shut the door, if the donor flushes the toilet, the collection process will start over
- When the donor exits the bathroom, the collection container has a temperature strip and the temperature of the specimen must be within 90 to 100 degrees Fahrenheit (this is to detect the addition of water or other liquid)
- The collector observes the specimen for color and odor (the human check for adulterants)
- The collector then pours the urine into 2 separate containers. Each container is sealed with a label and the donor initials each label. Two containers are used to hold the original specimen. One container is designated bottle A and used for testing. The second container is designated bottle B and reserved if a donor wishes to challenge a result, this challenge is called "split testing".

Paperwork (aka chain of custody):

- The chain of custody form is a multipart carbonless form. Each page is barcoded and the sealing labels of the urine containers (these labels are part of the top page) have the same barcode
- The donor's name and identification number is printed. The donor also signs this form. Additionally, the date of birth and contact telephone numbers are printed.
- The form that goes to the laboratory has only the id number and no other donor identifying information.

- Additional info on the chain of custody includes the collector's name and signature, the date and time of the collection, the company name and contact information and the method of transportation of the specimen to the lab.
- When the paperwork is complete, the specimens and one copy of the form are sealed in a tamper evident bag for shipping.
- The donor is given a copy of the chain of custody.

Laboratory processing (this process can be more properly explained by a representative of a SAMHSA-certified lab):

- When the specimen arrives at the lab, the paperwork and specimen bottles are checked to ensure they match.
- The specimen undergoes validity testing (specific gravity, pH and creatinine) this is to ensure that the specimen is consistent with human urine.
- Adulterant testing is done if requested (not currently required under DOT regulations and costs approximately 10% more).
- If these tests are cleared, then the specimen is subjected to a screening test for 5 drugs: cocaine, opiates, PCP, marijuana, amphetamines.
- If the screening test is positive, the sample undergoes a confirmation test using a different technology that is highly specific. If that test is confirmed, the test is considered positive at the lab level.

Medical Review:

- All test results regulated by DOT must be received in the office of a Medical Review Officer (MRO, who must be a licensed MD with additional certification)
- When a non-negative result is received, the lab result is matched to a copy of the chain of custody to eliminate clerical errors.
- The donor is contacted by the MRO to investigate the possibility of a legitimate medical explanation. For instance, if a donor can a result positive for opiates if he/she took Tylenol with codeine. The donor is required to submit a note from the treating physician documenting the safe and appropriate use of the medication. Our office verifies that the physician has an active license to practice. If all criteria are met, the ultimate result of the test is NEGATIVE. This will be the only result the employer will see.
- If there is no legitimate medical explanation, then the final result is POSITIVE. Under DOT guidelines, donors are offered the process of split testing. With split testing, the second container label bottle B (which is still sealed and labeled) is shipped to a DIFFERENT SAMHSA-certified lab for retesting.

Sources of error: urine drug screen collection is a lengthy, meticulous process. Errors can occur during the collection process by neglecting to prevent obvious attempts at adulteration or substitution (emptying of pockets or a bathroom that hasn't been secured). Human clerical error can occur during the reporting process but there are checks and balances that prevent or ameliorate the effects, such as split testing.

False positive tests: the ultimate security to prevent or identify false positive tests is the process of split testing. If the first lab had a flaw in their testing system and the specimen is retested by a second, independent lab this acts as a check. My experience has been that even people who vehemently deny use, will request split testing. A lab representative can speak to the false positive issue better than I.

Invalid tests: are cancelled but require further investigation. There are some prescription medications that can interfere with the screening test to produce an invalid test. If there is not an adequate medical explanation, the donor is directed to give another specimen under direct observation.

Dilute tests: There are very specific guidelines but basically there are 3 categories of dilute. 1) Mildly dilute which is commonly seen – can be ignored or may require a second unobserved collection. 2) Very dilute – which is rarely seen, requires second observed collection. 3) Extremely dilute – is not considered consistent with human urine and is considered substituted.

Legitimate medical explanation: if a donor has a documented prescription from a licensed physician that ensures safe and appropriate use of medication, there is no requirement for a follow-up drug test. As a physician on the prescribing side and having had to produce such documentation, I feel comfortable as the investigating MRO that this poses a minimal safety risk. Additionally, it is rare for a person to have a legitimate prescription.

Minimal standards for a non-DOT regulated employer. We recommend to all employers that they adhere to the standards set by DOT.

The DOT standards go as far as can be reasonably accepted by a population that is largely innocent.

Comprehensive supervision or observed collection: The DOT does not require observed collections in the absence of evidence that suggests adulteration or substitution. I find it difficult to imagine that the DOT would require observed collections as a standard given that most people are innocent. I think the extra invasion of privacy would be unacceptable.

Recollection of dilute and invalid specimens: My experience has been that when donors are sent back for a recollection after a dilute specimen, there is a higher positive rate. My experience with invalid specimens is that there has been no legitimate medical explanation and , of course, there should be a recollection.

Accuracy of hair and saliva testing: the accuracy of all modes of testing are equally accurate. Hair and saliva testing is theoretically not subject to adulteration or substitution since it is an observed collection.

Window of detection: the period of time a specimen will show a positive result after use of a drug.

- Hair specimens will generally not be positive until about a week after use but will show use for months prior to the collection depending upon the length of the hair.
- Urine specimens will generally be positive roughly 6 hours after use up to about 3 days.
- Saliva specimens can be positive immediately after use for marijuana soon after use for other drugs but can only be detected for about 24 hours after use.

Federal legislation is needed to curtail the use of substances and devices that subvert drug tests. These products pose a safety risk in the transportation industry; they increase employer costs associated with workers compensation, health benefits, impaired productivity; and, they increase employers costs associated with drug testing and the increased need to improve the technology to detect the products.