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SPECIMEN VALIDITY TESTING

IS IT REALLY HUMAN URINE?

Department of Health and Human Services (DHHS) Guidelines for Federal drug testing programs define the gold standard for Specimen Validity Testing that should be applied to all drug testing programs.

Specimen validity testing (SVT) is the name given to the analysis of urine specimens to determine if they are "consistent with normal human urine" (49 CFR Part 40.89 (a)) Notice the wording uses the words "consistent with normal…" That means we cannot absolutely say that any given specimen is normal human urine. This evaluation is intended to indicate the likelihood of whether or not an attempt has been made to adulterate or substitute a urine specimen with an agent or substance of non-human origin that is intended to compromise the testing process. Unfortunately "intent" is not always clear as some byproducts of human physiologic processes and/or bacterial action on the specimen over time may also interfere with the laboratory evaluation of the specimen.

In 2004, the Departments of Health and Human Services and Transportation issued final rules revising the procedures for how drug testing laboratories must conduct SVT on urine specimens for all Federal drug testing programs. The HHS rule sets the analytic standards for determining the validity of specimens.

These procedures apply only to Federally-mandated drug testing in DHHS certified laboratories, but they are considered the gold standard for forensic urine testing today, and should be followed for all forensic urine drug testing. The drug testing laboratories must:

1) Determine the creatinine concentration of every specimen
2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL
3) Determine the pH on every specimen
4) Perform one or more validity tests for oxidizing adulterants on every specimen; and
5) Perform additional validity tests when necessary because of specimen quality, interference, or other atypical results.

The criteria for reporting specimen validity testing results to the MRO are as follows:

- Adulterated Specimen - The pH is less than 3 or greater than or equal to 11; the nitrite concentration is greater than or equal to 500 mcg/mL; chromium, halogen, glutaraldehyde, pyridine or a surfactant are detected at or above DHHS established cut-offs.
- Substituted Specimen - Creatinine less than 2 mg/dL and Specific Gravity less than or equal to 1.0010 or greater than or equal to 1.0200
- Dilute Specimen - Creatinine greater than or equal to 2 mg/dL, but less than 20 mg/dL and Specific Gravity is greater than 1.0010, but less than 1.0030
- Invalid Specimen - Inconsistent creatinine and Specific Gravity results are obtained; pH 3-4.5 or 9-11; nitrite 200-499; possible presence of other adulterants or interferants; interference occurs on the immunoassay screening test on 2 separate aliquots so that a valid result cannot be obtained; interference occurs on the confirmatory test on 2 separate aliquots so that a valid confirmatory result cannot be obtained; if the specimen has an appearance that raises concerns about possible damage to the laboratory testing equipment; or if the 2 specimen bottles look different from each other.

The laboratory must be able to confirm a specific adulterant before it can report an adulterated result to the MRO, and it must give the numerical values for specimens it reports as adulterated or substituted. The MRO must review and interpret every adulterated, substituted and invalid result, including interviewing the specimen donor. If no medical explanation is documented for the laboratory findings, the MRO will verify the results as follows:

- Adulterated - Refusal-to-Test, Specimen Adulterated with <name the substance>
- Substituted – Refusal-t o-Test, Specimen Substituted
- Invalid - Test Cancelled, Invalid Result:

Recollection of Specimen under direct observation required (When the MRO believes there is no acceptable medical reason for the interference),

OR

Recollection of Specimen under direct observation not required (When the MRO believes there is an acceptable medical reason for the interference)

For dilute specimens, the MRO will report the result as Negative-dilute or Positive-dilute. For very dilute specimens where the creatinine is 2-5 mg/dL, the DOT requires that the MRO does not interview the donor, but orders an immediate collection of another specimen under direct observation. For all other negative-dilute results the employer may conduct another specimen collection, however, direct observation procedures are NOT authorized. The employer must accept a second negative-dilute result as final and cannot require a third collection. A positive-dilute result is a positive test and no recollection of a specimen is authorized.

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