Specimen Validity Testing*

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Posted: February 2005

Specimen validity testing refers to the tests conducted by laboratories to determine if a urine specimen is dilute or has been adulterated or substituted. An adulterated specimen is a urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration. A dilute specimen is a urine specimen with creatinine and specific gravity values that are lower than expected for human urine. A substituted specimen is a urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

To report a specimen as dilute, adulterated, or substituted, the laboratory must conduct an initial validity test (the first test used to determine if a urine specimen is adulterated, dilute, or substituted) and a confirmatory validity test (a second test performed on a different aliquot of the original urine specimen to further support a validity test result).

Adulterants detected in urine specimens include: acids, bases, nitrite, chromium (VI), halogens, glutaraldehyde, pyridine, and surfactants.

Adulterated

The following criteria have been established to report a specimen as adulterated:

(1) The pH is less than 3 or greater than or equal to 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration greater than or equal to the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration greater than or equal to the LOD of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in 3 through 7 is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Substituted

A urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

Dilute

A urine specimen is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

* From the Mandatory Guidelines for Federal Workplace Drug Testing Programs published in the Federal Register on April 13, 2004 (69 FR 19644), effective November 1, 2004.