

§ 40.91

§ 40.91 What validity tests must laboratories conduct on primary specimens?

As a laboratory, when you conduct validity testing under § 40.89, you must conduct it in accordance with the requirements of this section.

(a) You must determine the creatinine concentration on each primary specimen. You must also determine its specific gravity if you find the creatinine concentration to be less than 20 mg/dL.

(b) You must determine the pH of each primary specimen.

(c) You must perform one or more validity tests for oxidizing adulterants on each primary specimen.

(d) You must perform additional validity tests on the primary specimen when the following conditions are observed:

(1) Abnormal physical characteristics;

(2) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (*e.g.*, non-recovery of internal standards, unusual response); or

(3) Possible unidentified interfering substance or adulterant.

(e) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS certified laboratory would be useful in being able to report a positive or adulterated test result.

[65 FR 79526, Dec. 19, 2000, as amended at 69 FR 64867, Nov. 9, 2004]

§ 40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory, you must consider the primary specimen to be dilute when:

(1) The creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL, and

(2) The specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(b) As a laboratory, you must consider the primary specimen to be substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to

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1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests and on both the initial and confirmatory specific gravity tests on two separate aliquots.

[69 FR 64867, Nov. 9, 2004]

§ 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?

(a) As a laboratory, you must use the cutoff concentrations for the initial and confirmation adulterant testing as required by the HHS Mandatory Guidelines and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, you must report results at or above the cutoffs (or for pH, at or above or below the values, as appropriate) as adulterated and provide the numerical value that supports the adulterated result.

[73 FR 35970, June 25, 2008]

§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines, and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, for a specimen having an invalid result for one of the reasons outlined in the HHS Mandatory Guidelines, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(c) As a laboratory, you must report invalid results in accordance with the invalid test result criteria as required by the HHS Guidelines and provide the numerical value that supports the invalid result, where appropriate, such as pH.

(d) As a laboratory, you must report the reason a test result is invalid.

[73 FR 35970, June 25, 2008]