

§ 40.89

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, Aug. 16, 2010; 77 FR 26473, May 4, 2012]

§ 40.89 What is validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you must conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 73 FR 35970, June 25, 2008]

§ 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

49 CFR Subtitle A (10–1–13 Edition)

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 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]

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of the following three categories. However, as a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as appropriate:

(i) Negative, or
(ii) Negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as appropriate:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remark(s);

(iv) Substituted, with confirmatory test values for creatinine and specific gravity; or

(v) Invalid result, with remark(s). Laboratories will report actual values for pH results.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(b) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.*, C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.*, computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;
(B) Employer's name (you may include I.D. or account number);
(C) Medical review officer's name;
(D) Specimen I.D. number;
(E) Donor's SSN or employee I.D. number, if provided;
(F) Reason for test, if provided;
(G) Collector's name and telephone number;
(H) Date of the collection;
(I) Date received at the laboratory;
(J) Date certifying scientist released the results;

(K) Certifying scientist's name;
(L) Results (*e.g.*, positive, adulterated) as listed in paragraph (a) of this section; and

(M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality.