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

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmation drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Type of drug or metabolite	Initial test	Confirmation test
(1) Marijuana metabolites ..	50	
(i) Delta-9-tetrahydrocannabinol-9-carboxylic acid (THC).		15
(2) Cocaine metabolites (Benzoylecgonine).	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine	.....	500
(ii) Methamphetamine	.....	500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine	.....	2000
(ii) Morphine	.....	2000
(iii) 6-acetylmorphine (6–AM).	.....	10 (Test for 6–AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

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

§ 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 are authorized to conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 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 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 criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

§ 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 tested as one or more of the following:

(1) Negative;

(2) Negative-dilute, with numerical values for creatinine and specific gravity;

(3) Rejected for testing, with remark(s);

(4) Positive, with drug(s)/metabolite(s) noted;

(5) Positive, with drug(s)/metabolite(s) noted—dilute;

(6) Adulterated, with numerical values (when applicable), with remark(s);

(7) Substituted, with numerical values for creatinine and specific gravity; or

(8) Invalid result, 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. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.

(2) Non-negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the