

§ 40.87

§ 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	15
(i) Delta-9-tetrahydrocannabinol-9-carboxylic acid (THC).		
(2) Cocaine metabolites (Benzoylecgonine).	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	500
(i) Amphetamine		
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	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.)
(i) Codeine		
(ii) Morphine		
(iii) 6-acetylmorphine (6-AM).		

(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