
Appendix D: Definitions and Terms

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A fractional part of a specimen used for testing, representing the whole specimen.

Calibrator. A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a concentration range.

Chain of Custody (COC). Procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from point of specimen collection to final disposition of the specimen and its aliquots.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The decision point or value used to establish and report a specimen as negative, positive, adulterated, substituted, or invalid.

Donor. The individual from whom a specimen is collected.

HHS. The U.S. Department of Health and Human Services.

Initial Drug Test. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.8 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory testing, reporting of results, and recordkeeping is performed under the supervision of a responsible person.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the agency.

Negative Result. The result reported by an HHS-certified laboratory, IITF, or POCT tester to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class and the specimen is a valid specimen.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration.

Sample. A performance testing sample, quality control material used for testing, or a representative portion of a donor specimen.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test. Urine is the only specimen allowed for Federal workplace drug testing programs.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.