

§ 26.127

10 CFR Ch. I (1–13 Edition)

certification that personnel are proficient in conducting testing in accordance with manufacturer's most recent instructions for the instruments and devices used and tests for color blindness; and appropriate data to support determinations of honesty and integrity required by this part.

§ 26.127 Procedures.

(a) Licensee testing facilities shall develop, implement, and maintain clear and well-documented procedures for accession, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens.

(c) Licensee testing facilities shall develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If a licensee testing facility performs validity screening tests, the licensee testing facility shall develop, implement, and maintain written standard operating procedures for each test. The procedures must include, but are not limited to, detailed descriptions of—

- (1) The principles of each test;
- (2) Preparation of reagents, standards, and controls;
- (3) Calibration procedures;
- (4) Derivation of results;
- (5) Linearity of the methods;
- (6) Sensitivity of the methods;
- (7) Cutoff values;
- (8) Mechanisms for reporting results;
- (9) Controls;
- (10) Criteria for unacceptable specimens and results;
- (11) Reagents and expiration dates; and
- (12) References.

(d) Licensee testing facilities shall develop, implement, and maintain written procedures for instrument and test setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments and validity screening tests;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) Licensee testing facilities shall develop, implement, and maintain written procedures for remedial actions to be taken when systems, and instrumented and non-instrumented tests are out of acceptable limits or errors are detected. Each facility shall maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, each facility shall have systems in place to verify all stages of testing and reporting and to document the verification.

§ 26.129 Assuring specimen security, chain of custody, and preservation.

(a) Each licensee testing facility must be secure at all times. Each licensee or other entity shall have sufficient security measures in place to control access to the licensee testing facility and to ensure that no unauthorized personnel handle specimens or gain access to the licensee testing facility's processes or areas where records are stored. Access to these secured areas must be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times while in the licensee testing facility.

(b) When specimens are received, licensee testing facility personnel shall inspect each package for evidence of possible tampering and shall compare information on the specimen containers within each package to the information on the accompanying custody-and-control forms. Licensee testing facility personnel shall attempt to resolve any discrepancies identified in the information on specimen bottles or on the accompanying custody-and-control forms. When resolving any discrepancies, licensee testing facility personnel shall obtain a memorandum for the record from the specimen collector involved in the discrepancy to document correction of the discrepancy. This memorandum must accompany

the specimen(s) and custody-and-control forms to the HHS-certified laboratory if the specimen(s) must be transferred.

(1) Indications of tampering with specimens in transit from the collection site, or at a licensee testing facility, must be reported to senior licensee or other entity management as soon as practical and no later than 8 hours after the indications are identified. In response to a report, licensee or other entity management personnel shall initiate an investigation to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, licensee or other entity management shall ensure that corrective actions are taken.

(ii) If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying custody-and-control forms that cannot be resolved), the specimen may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and

an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(c) The licensee testing facility shall retain specimen containers within the testing facility's accession area until all analyses have been completed. Testing facility personnel shall use aliquots of the specimen and licensee testing facility chain-of-custody forms, or other appropriate methods of tracking aliquot custody and control, when conducting validity screening and initial validity and drug tests. The original specimen bottles and the original custody-and-control forms must remain in secure storage. Licensee testing facility personnel may discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen appears valid and initial test results for drugs and drug metabolites are negative.

(d) The licensee testing facility's procedure for tracking custody and control of specimens and aliquots must protect the identity of the donor, and provide documentation of the testing process and transfers of custody of the specimen and aliquots. Each time a specimen or aliquot is handled or transferred within the licensee testing facility, testing facility personnel shall document the date and purpose and every individual in the chain of custody must be identified.

(e) Urine specimens identified as positive or of questionable validity at a licensee testing facility must be shipped to an HHS-certified laboratory for testing as soon as reasonably practical.

(f) Licensee testing facility personnel shall take appropriate and prudent actions to minimize false negative results from specimen degradation. If validity screening or initial validity testing indicate that the specimen is of questionable validity, or initial drug test results are positive, or if a specimen has not been tested within 24 hours of receipt at the licensee testing facility, then the facility shall maintain the specimen cooled to not more than 6 °C (42.8 °F) until it is forwarded

to the HHS-certified laboratory for further testing, if required. Split specimens in Bottle B that are associated with positive specimens or specimens of questionable validity in Bottle A must also be maintained cooled (as previously specified) until test results from the HHS-certified laboratory are known to be negative for Bottle A; until the MRO informs the licensee testing facility that Bottle B must be forwarded to an HHS-certified laboratory for testing; or until the specimen is moved to long-term, frozen storage, under § 26.135(c).

(g) Licensee testing facility personnel shall ensure that the original custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the licensee testing facility to the HHS-certified laboratory must be placed in a second, tamper-evident shipping container designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(h) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

§ 26.131 Cutoff levels for validity screening and initial validity tests.

(a) Each validity test result from the licensee testing facility must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen. The licensee testing facility shall forward any specimen that yields a questionable validity screening or initial validity test result to the HHS-certified laboratory for fur-

ther testing. Licensee testing facilities need not perform validity screening tests before conducting initial validity tests of a specimen.

(b) At a minimum, the licensee testing facility shall test each urine specimen for creatinine, pH, and one or more oxidizing adulterants. Licensees and other entities may not specify more stringent cutoff levels for validity screening and initial validity tests than those specified in this section. If tests or observations indicate one or more of the following from either a validity screening test or an initial validity test, the licensee testing facility shall forward the specimen to the HHS-certified laboratory for additional testing:

(1) Creatinine is less than 20 milligrams (mg) per deciliter (dL);

(2) The pH of the specimen is either less than 4.5 or equal to or greater than 9, using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter that is capable of measuring pH to one decimal place (for initial validity tests), or colorimetric pH tests, dipsticks, and pH paper (for pH validity screening tests) that have a narrow dynamic range;

(3) Nitrite or other oxidant concentration is equal to or greater than 200 micrograms (mcg) per mL or equal to or greater than 200 mcg/mL nitrite-equivalents using either a nitrite colorimetric test or a general oxidant colorimetric test;

(4) The possible presence of an oxidizing adulterant (e.g., chromium (VI), pyridine (pyridinium chlorochromate)) is determined using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL);

(5) The possible presence of halogen (e.g., bleach, iodine, fluoride) is determined using a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or equal to or greater than 50 mcg/mL chromium (VI)-equivalents), a halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD)), or the odor of the specimen;