§ 26.167 Quality assurance and quality control.

(a) Quality assurance program. Each HH5-certified laboratory shall have a quality assurance program that encompasses all aspects of the testing process, including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation of procedures must document that carryover does not affect the donor’s specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) Calibrators and controls required. Each analytical run of specimens for which an initial or confirmatory validity test, or an initial or confirmatory drug test, is being performed must include the appropriate calibrators and controls.

(c) Quality control requirements for performing initial and confirmatory validity tests. (1) Requirements for performing creatinine tests:

(i) The creatinine concentration must be measured to one decimal place on both the initial and the confirmatory creatinine tests;
(ii) The initial creatinine test must have a calibrator at 2 mg/dL;
(iii) The initial creatinine test must have a control in the range of 1 to 1.5 mg/dL, a control in the range of 3 to 20 mg/dL, and a control in the range of 21 to 25 mg/dL; and
(iv) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1.0 to 1.5 mg/dL, and a control in the range of 3 to 4 mg/dL.

(2) Requirements for performing specific gravity tests:

(i) The refractometer must report and display the specific gravity to four decimal places, and must be interfaced with a laboratory information management system, or computer, and/or generate a hard copy or digital electronic display to document the numerical result;
(ii) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and
(iii) The initial and confirmatory specific gravity tests must have the following controls:
(A) One control targeted at 1.0020;
(B) One control in the range of 1.0040 to 1.0180; and
(C) One control equal to or greater than 1.0200 but not greater than 1.0250.
(3) Requirements for performing pH tests:
   (i) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Dipsticks, colorimetric pH tests, and pH paper that have a narrow dynamic range and do not support the 2 to 12 pH cutoffs may be used only to determine whether initial validity tests must be performed;
   (ii) At a minimum, pH screening tests must have the following controls:
      (A) One control below the lower decision point in use;
      (B) One control between the decision points in use; and
      (C) One control above the upper decision point in use;
   (iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:
      (A) One calibrator at 4;
      (B) One calibrator at 7;
      (C) One calibrator at 10;
      (D) One control in the range of 2 to 2.8;
      (E) One control in the range of 3.2 to 4;
      (F) One control in the range of 10 to 10.8; and
      (G) One control in the range of 11.2 to 12;
   (vi) An initial colorimetric pH test must have the following calibrators and controls:
      (A) One calibrator at 3;
      (B) One calibrator at 11;
      (C) One control in the range of 2 to 2.8;
      (D) One control in the range of 3.2 to 4;
      (E) One control in the range of 4.5 to 9;
      (F) One control in the range of 10 to 10.8;
      (G) One control in the range of 11.2 to 12.
(4) Requirements for performing oxidizing adulterant tests:
   (i) Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in §26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and
   (ii) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory analytical run must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in §26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.
(5) Requirements for performing nitrite tests: The initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine specimen), one control in the range of 200 to 400 mcg/mL, and one control in the range of 500 to 625 mcg/mL.
(6) Requirements for performing “other” adulterant tests:
   (i) The initial and confirmatory tests for any “other” adulterant that may be identified in the future must satisfy the requirements in §26.161(a);
(ii) The confirmatory test for “other” adulterants must use a different analytical principle or chemical reaction than that used for the initial test; and

(iii) The initial and confirmatory tests for “other” adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(d) Quality control requirements for performing initial drug tests. (1) Any initial drug test performed by an HHS-certified laboratory must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval may not be used for initial drug testing under this part.

(2) HHS-certified laboratories may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part. For example, an HHS-certified laboratory may use immunoassay technique “A” for all drugs using the licensee’s or other entity’s cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique “B” to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique “A” and immunoassay technique “B” is used in an attempt to obtain a valid analytical result.

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s);

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iv) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(e) Quality control requirements for performing confirmatory drug tests. (1) Confirmatory tests for drugs and drug metabolites must be performed using gas chromatography/mass spectrometry (GC/MS) or other confirmatory test methodologies that HHS-certified laboratories are permitted to use in Federal workplace drug testing programs for this purpose.

(2) At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls.

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s);

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff; and

(iv) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(f) Errors in testing. The licensee or other entity shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing, as required under §26.168, in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process.

(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee or other entity, and the HHS-certified laboratory, shall take action to correct the causes of any errors or unsatisfactory
§ 26.168 Blind performance testing.

(a) Each licensee and other entity shall submit blind performance test samples to the HHS-certified laboratory.

(1) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee or other entity shall submit blind performance test samples to each HHS-certified laboratory with whom it contracts in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 blind performance specimens) or 30 blind performance test samples, whichever is greater.

(2) Following the initial 90-day period, the number of blind performance test samples submitted per quarter must be a minimum of one percent of all specimens (up to a maximum of 100) or ten blind performance test samples, whichever is greater.

(3) Both during the initial 90-day period and quarterly thereafter, licensees and other entities should attempt to submit blind performance test samples at a frequency that corresponds to the submission frequency for other specimens.

(b) Calibrators and controls. Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

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