

§ 493.1223

completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).

§ 493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.

The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. Except as specified in § 493.1202(c), the laboratory must meet the applicable general requirements specified in §§ 493.1201 through 493.1221. In addition, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.

[58 FR 5232, Jan. 19, 1993]

§ 493.1225 Condition: Microbiology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and in §§ 493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

§ 493.1227 Condition: Bacteriology.

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

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(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and

(3) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

§ 493.1229 Condition: Mycobacteriology.

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates,

the laboratory must check the procedure each week of use with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

§ 493.1231 Condition: Mycology.

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

§ 493.1233 Condition: Parasitology.

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a

fecal sample control that will demonstrate staining characteristics.

§ 493.1235 Condition: Virology.

To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

§ 493.1237 Condition: Diagnostic immunology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.

§ 493.1239 Condition: Syphilis serology.

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.