

(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.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

§ 493.1241 Condition: General immunology.

To meet the quality control requirements for general immunology, 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) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§ 493.1245 Condition: Routine chemistry.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Condition: Endocrinology.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§ 493.1249 Condition: Toxicology.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—

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(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

§ 493.1251 Condition: Urinalysis.

Except for those tests categorized as waived, to meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221.

[58 FR 5232, Jan. 19, 1993]

§ 493.1253 Condition: Hematology.

To meet the quality control requirements for hematology, 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) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation.

(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation.

(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(d) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(2) Patient and control specimens must be tested in duplicate.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§ 493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1257 through 493.1261 of this subpart for the subspecialties for which it

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is certified under the specialty of pathology. All quality control activities must be documented.

§ 493.1257 Condition: Cytology.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and

(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissues pathology slides examined by a technical supervisor qualified under § 493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§ 493.1449 (b) and (k).);