kit, or test system) cleared by the FDA as meeting the CLIA requirements for quality control located at §§ 493.1215, 493.1217, and 493.1223, and applicable parts of §§ 493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with the requirements of §§ 493.1204, 493.1213, 493.1219, and 493.1221 and those parts of §§ 493.1205, 493.1211, and 493.1218 that are unique to the laboratory facility and cannot be met by following manufacturer's instructions.

[58 FR 5230, Jan. 19, 1993]

§ 493.1204 Standard; Facilities.

The laboratory must provide the space and environmental conditions necessary for conducting the services offered.

(a) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate.

(b) Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical and electrical hazards and biohazardous materials.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§ 493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.

The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test method as determined under § 493.1213.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.

(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.

(1) These conditions include, if applicable—

(i) Water quality;

(ii) Temperature;

(iii) Humidity; and

(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(2) Remedial actions taken to correct conditions that fail to meet the criteria specified in paragraph (c)(1) of this section must be documented.

(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate—

(1) Identity and, when significant, titer, strength or concentration;

(2) Recommended storage requirements;

(3) Preparation and expiration date; and

(4) Other pertinent information required for proper use.

(e) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that—

(1) Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality. The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and

(2) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§493.1211 Standard; Procedure manual.

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include, when applicable to the test procedure:

(1) Requirements for specimen collection and processing, and criteria for specimen rejection;

(2) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

(5) Calibration and calibration verification procedures;

(6) The reportable range for patient test results as established or verified in §493.1213;

(7) Control procedures;

(8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(9) Limitations in methodologies, including interfering substances;

(10) Reference range (normal values);

(11) Imminent life-threatening laboratory results or ''panic values'';

(12) Pertinent literature references;

(13) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;

(14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;

(15) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be approved, signed, and dated by the director.

(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory.

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued.

§493.1213 Standard; Establishment and verification of method performance specifications.

Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.

(b)(1) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) cleared by the FDA as meeting certain CLIA requirements for quality control, must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision,