(1) 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 general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement,

Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b).

or

(2) HHS approves an equivalent procedure that is specified in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) 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. The laboratory must meet the applicable standards in §§ 493.1202 through 493.1221 of this subpart, 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 HHS approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487–4630.

[58 FR 5230, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to December 31, 2000.

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94–295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—(1) Follow the manufacturer's instructions for instrument or test system operation and test performance;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures or check calibration at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing;

(5) Perform and document applicable specialty and subspecialty control procedures as specified under § 493.1223;

(6) Perform and document that remedial action has been taken when problems or errors are identified as specified in § 493.1219; and

(7) Maintain records of all quality control activities for two years. Quality control records for immunohematology and blood and blood products must be maintained as specified in § 493.1221.

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

§ 493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning December 31, 2000.

For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it:

(a) Meets all applicable quality control requirements specified in this subpart when using a standardized method, a method developed in-house, a device not subject to clearance by the

FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94–295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), a manufacturer's product modified by the laboratory, or a device (instrument, kit or test system) not cleared by the FDA as meeting certain CLIA quality control requirements; or

(b) Follows manufacturer's instructions when using a device (instrument, 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