

§ 493.1252

of initial use and discontinuance as described in § 493.1105(a)(2).

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under § 493.1253.

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

- (1) Water quality.
- (2) Temperature.
- (3) Humidity.
- (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.
- (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:
 - (1) Identity and when significant, titer, strength or concentration.
 - (2) Storage requirements.
 - (3) Preparation and expiration dates.
 - (4) Other pertinent information required for proper use.
- (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.
- (e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

42 CFR Ch. IV (10–1–23 Edition)

§ 493.1253 Standard: Establishment and verification of performance specifications.

(a) *Applicability.* Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

(b)(1) *Verification of performance specifications.* Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

- (A) Accuracy.
- (B) Precision.
- (C) Reportable range of test results for the test system.
- (ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

(2) *Establishment of performance specifications.* Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

- (i) Accuracy.
- (ii) Precision.
- (iii) Analytical sensitivity.
- (iv) Analytical specificity to include interfering substances.
- (v) Reportable range of test results for the test system.
- (vi) Reference intervals (normal values).
- (vii) Any other performance characteristic required for test performance.

(3) *Determination of calibration and control procedures.* The laboratory must determine the test system's calibration procedures and control procedures