

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, and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

(2) Each laboratory that introduces a new method or device as specified in either § 493.1202(a) or (b), or § 493.1203(a), must, prior to reporting patient test results—

(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

- (A) Accuracy;
- (B) Precision;
- (C) Analytical sensitivity;
- (D) Analytical specificity to include interfering substances;
- (E) Reportable range of patient test results;
- (F) Reference range(s); and
- (G) Any other performance characteristic required for test performance.

(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish calibration and control procedures for patient testing as required under §§ 493.1217 and 493.1218.

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.

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

§ 493.1215 Standard; Equipment maintenance and function checks.

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instru-

ments and test systems, to assure accurate and reliable test results and reports.

(a) *Maintenance of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all maintenance performed.

(2) For methods or devices, as specified in either § 493.1202(a) or (b) or § 493.1203(a), the laboratory must—

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and

(iii) Document all maintenance performed.

(b) *Function checks of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must—

(i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all function checks performed.

(2) For methods or devices, as specified in either § 493.1202 (a) or (b) or § 493.1203(a), the laboratory must—

(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and

(iii) Document all function checks performed.

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