§ 493.1253 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.

(5) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(a) Identity and when significant, titer, strength or concentration.
(b) Storage requirements.
(c) Preparation and expiration dates.
(d) Other pertinent information required for proper use.

(6) 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.

(7) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.


(a) Applicability. Laboratories are not required to verify or establish performance specifications for any test system.
§ 493.1254 Standard: Maintenance and function checks.

(a) Unmodified manufacturer’s equipment, instruments, or test systems. The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

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

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

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

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

§ 493.1255 Standard: Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory’s reportable range of test results for the test system. Unless otherwise