

(2) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(3) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this subpart).

(4) The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile, and sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

NOTE: A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

**§ 493.1219 Standard; Remedial actions.**

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory's established performance specifications, as determined in § 493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and

(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;

(c) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and

(d) Errors in the reported patient test results are detected. The laboratory must—

(1) Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports promptly to the authorized person ordering the test or the individual utilizing the test results; and

(3) Maintain exact duplicates of the original report as well as the corrected report for two years.

**§ 493.1221 Standard; Quality control records.**

The laboratory must document and maintain records of all quality control activities specified in §§ 493.1202 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of no less than five years. In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been