

ensure that the information is transcribed or entered accurately.

- We revised the requirement now at § 493.1242(a)(3) (formerly § 493.1105(f)) clarifying that the specimen source requirement, when appropriate, is part of the laboratory's submission, handling, and referral procedures.

- We removed the requirement formerly at § 493.1243, the Condition of Chemistry, as it is a duplicate requirement under the Conditions of Routine Chemistry at § 493.1210, Urinalysis at § 493.1211, Endocrinology at § 493.1212, and Toxicology at § 493.1213.

- We clarified the requirement now at § 493.1251(b)(13) (formerly at § 493.1211(b)(14)) that the procedure manual must include in the test procedure the laboratory's system for entering results in the patient record and reporting patient results including the protocol for reporting panic or alert values, when appropriate.

- We revised the language now at § 493.1251(d) (formerly at § 493.1211(d)) to provide that procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

- We revised the language now at § 493.1252(b) (formerly §§ 493.1202(c)(1) and 493.1205(c)) to specify that the laboratory's criteria for storage of reagents and specimens and test system operations must be consistent with the manufacturer's instructions, when available.

- We revised the language now at § 493.1253(a) (formerly at § 493.1213(a)) to provide that laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

- We revised the language now at § 493.1253(b)(1) (formerly at § 493.1213(b)(2)) by adding the words "FDA-cleared or approved test system" to the requirements regarding verification of performance specifications.

- We revised the heading now at § 493.1254 (formerly § 493.1215) to read "Maintenance and function checks."

- We revised the language now at § 493.1254(a)(2) (formerly at § 493.1215(b)(2)(ii)) regarding function checks by removing the word "laboratory" and adding, in its place, the word "manufacturers."

- We clarified the requirement now at § 493.1254(a)(2) (formerly at §§ 493.1202(c)(1) and 493.1215(b)(2)(ii)) to require that function checks be within the manufacturer's established limits before conducting patient testing.

- We removed the requirement formerly at § 493.1255, the Condition of Pathology, as it is a duplicate requirement under the Conditions of Histopathology, Oral Pathology and Cytology now at §§ 493.1219, 493.1220, and 493.1221, respectively.

- We revised the language now at § 493.1256 by removing the mandatory concurrent control testing requirements formerly at §§ 493.1237 Diagnostic immunology; 493.1239 Syphilis serology; and 493.1241 General immunology. We now require two levels of QC materials once each day of testing.

- We revised the language now at § 493.1256(d) (formerly at § 493.1218(b)) reducing the requirement by removing the specialty-specific control requirements (formerly at § 493.1253(b)) for automated hematology analyzers. We now require two levels of control materials once each day of testing.

- We revised the language now at § 493.1256(d)(3) (formerly at § 493.1218(b)) to clarify that QC materials are assayed or examined each day of patient testing.

- We revised the requirement now at § 493.1256(d)(3) for hematology by reducing the required frequency for control testing (formerly at § 493.1253(b)) from once each 8 hours of operation to once each day of testing.

- We added the requirement now at § 493.1256(d)(3)(v) that the laboratory must use a control system capable of detecting reaction inhibition when performing molecular amplification procedures in which inhibition is a significant source of false negative results.

- We removed the term "drug abuse screening" at § 493.1256(d)(4)(i), and added the term "all known substances or drug groups" identified and reported by the laboratory to accommodate the wider use of the technology.

- We revised the language now at § 493.1256(d)(5) (formerly at § 493.1218(b)(3)) to clarify that the laboratory must for each electrophoretic procedure, include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

- We revised the language now at § 493.1256(e)(2) (formerly § 493.1218(f)(2)) to clarify the use of staining materials.

- We clarified the use of calibration materials now at § 493.1256(d)(9) (formerly at § 493.1218(h)(2)) to provide that calibration material used as a control material must be from a different lot number than that used to establish a cut-off value or to calibrate the test system.

- We revised the requirement now at § 493.1261 by incorporating the bacteriology requirements formerly at § 493.1227.

- We revised the language now at § 493.1261 (formerly § 493.1227), reducing the requirements by removing the reference to specific control requirements in the subspecialty of bacteriology.

- We revised the requirement now at § 493.1262 by incorporating the mycobacteriology requirements formerly at § 493.1229.

- We added a requirement in mycobacteriology now at § 493.1262(a) (formerly § 493.1229(a)) for an acid fast control organism that produces a negative reaction.

- We revised the requirement now at § 493.1263 by incorporating the mycology requirements formerly at § 493.1231.

- We revised the requirement now at § 493.1263(a) (formerly at § 493.1218(f)(2)). We reduced the requirement to QC certain staining materials each day of use to only checking each batch, lot number, and shipment of lactophenol cotton blue when prepared or opened for intended reactivity.

- We revised the requirement now at § 493.1263(b) (formerly § 493.1213(d)) by reducing the requirement for daily testing to merely testing each batch of media and each lot number and shipment of antifungal agents before or concurrent with initial use.

- We revised the requirement now at § 493.1264 by incorporating the parasitology requirements formerly at § 493.1233.

- We revised the requirement now at § 493.1265 by incorporating the virology requirements formerly at § 493.1235.

- We removed the requirement formerly at § 493.1265(a)(10) that required the laboratory to use specific techniques such as mixed lymphocyte cultures to determine HLA Class II incompatibilities.

- We removed the requirement formerly at § 493.1265(a)(13) that required histocompatibility testing personnel to evaluate unknowns on a monthly basis because it is duplicative of the laboratory director responsibilities at § 493.1445(e).

- We revised the requirement now at § 493.1267 by incorporating the routine chemistry requirements formerly at § 493.1245.

- We revised the language now at § 493.1267(b) (formerly at §§ 493.1245(c) and (d)) by removing reference to the words "calibration and calibration material" from the blood gas requirements. However, we allow