

calibration material as a control material provided it is from a different lot number than that used to calibrate the test system or establish a cut-off.

- We revised the requirements now at § 493.1269 by incorporating the hematology requirements formerly at § 493.1253.

- We revised the requirement now at § 493.1271 by incorporating the immunohematology requirements formerly at §§ 493.1239(e), 493.1241(d), 493.1269, 493.1273, 493.1275, 493.1283, and 493.1285.

- We revised the requirement now at §§ 493.1271(a)(1) and (b) (formerly §§ 493.1269(a) and 493.1273) to cite the specific 21 CFR requirements that must be met under the CLIA regulations.

- We revised the requirement now at § 493.1273 by incorporating the histopathology requirements formerly at § 493.1259.

- We added a requirement at § 493.1273(a) (formerly at § 493.1259) that the laboratory must check immunohistochemical stains for positive and negative reactivity each time of use in order to be consistent with the general QC requirements at § 493.1256(e)(3).

- We revised the language now at § 493.1273(c) (formerly at § 493.1259(b)) to add that an individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

- We revised the requirement now at § 493.1274 by incorporating the cytology requirements formerly at § 493.1257.

- We revised the language now at § 493.1274(d)(2)(iii) (formerly at § 493.1257(b)(2)) by removing the reference to gynecologic slides from the 200-workload limit that applies only to nongynecologic slides.

- We revised the language now at § 493.1274(e)(1) (formerly at 493.1257(c)(1)) by removing the requirement that a technical supervisor review cases categorized as reactive and reparative changes.

- We revised the requirement now at § 493.1276 (formerly at § 493.1267) by incorporating the clinical cytogenetics requirements.

- We clarified the requirement at § 493.1276(a) (formerly §§ 493.1107 and 493.1267(c)) by specifying that the laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification for karyotypes.

- We revised the requirement now at § 493.1276(b)(2) (formerly at § 493.1267(b)) to specify that the laboratory must have records that

document that the resolution used was appropriate for the type of tissue or specimen, and the type of study required based on the clinical information provided to the laboratory.

- We revised the language now at § 493.1276(c) (formerly at § 493.1267(a)) by removing the requirements pertaining to the performance of X and Y chromatin counts for sex determination and requiring full chromosome analysis for sex determination.

- We revised the language now at § 493.1276(d) (formerly at § 493.1267(d)) by removing the reference to the words “appropriate nomenclature” and specifying that the laboratory report must use the International System of Cytogenetic Nomenclature.

- We revised the requirement now at § 493.1278 by incorporating the histocompatibility requirements formerly at § 493.1265.

- We added the requirement now at § 493.1278(a)(3) that reagent specificity is required when reagent typing sera inventory is prepared in-house.

- We added requirements now at § 493.1278(b)(1) that the laboratory must use a technique that is established to optimally define, as applicable, HLA Class I and II specificity.

- We added requirements at § 493.1278(d)(1) and (d)(2) to specify that the laboratory must use a technique that detects HLA specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay, and use a method that distinguishes antibodies to HLA class II antigens from antibodies to Class I antigens.

- We revised the language now at § 493.1278(d)(4) and (d)(5) (formerly at 493.1265(a)(2)(ii) and (a)(8)(i)) to require laboratories to make a reasonable attempt to have available monthly serum specimens for periodic antibody screening and crossmatch, and have available and follow a written policy consistent with clinical transplant protocols for the frequency of performing antibody screening.

- We added the requirement now at § 493.1278(d)(7) to specify that for antibody screening, the laboratory must, as applicable, have available, and follow criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

- We revised the language now at § 493.1278(e)(1) (formerly § 493.1265(a)(1)(ii)) to clarify that the techniques for crossmatching must be documented to have increased sensitivity in comparison to the basic complement-dependent microlymphocytotoxicity assay.

- We revised the requirement now at § 493.1278(f)(1) (formerly at § 493.1265(b) and (c)) that requires specific testing protocols to be less prescriptive and allow laboratories to define testing policies and protocols for each type of cell, tissue, or organ to be transfused or transplanted.

- We clarified the requirement now at § 493.1278(f)(3) (formerly at § 493.1265(b)(3)) that the laboratory must have available, and follow, policies that address when HLA testing and final crossmatches are required for presensitized non-renal transplant recipients.

- We clarified the requirements now at § 493.1291(a) (formerly at § 493.1109(a)) to provide that the laboratory must have adequate systems in place to ensure test results and other patient specific data are accurately and reliably transmitted from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.

- We clarified the requirement at § 493.1291(c)(3) (formerly at §§ 493.1109 and 493.1109(a)) to specify that the date of the test report must be identified on the report.

- We clarified the requirement now at § 493.1291(c)(5) (formerly at § 493.1109) to indicate that the test report must include the specimen source, if applicable.

- We added language relevant to interpretation to the test report requirements now at § 493.1291(c)(6) (formerly § 493.1109(b)) for those test results that require supplemental information.

- We revised the language now at § 493.1291(j) (formerly § 493.1109(h)) by removing the words “exact duplicate” and clarified the language by specifying that all test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

#### *Subpart M—Personnel for Nonwaived Testing*

- We revised the heading of subpart M to read “Personnel for Nonwaived Testing” to conform with the names of the new subparts J and K.

- We revised § 493.1359(a)(3) by removing the reference to “subpart P.”

- We revised § 493.1407(e)(5) by removing the word “assurance” and, adding in its place, the word “assessment.”

- We revised § 493.1443(b)(3) to allow individuals with a doctoral degree who are serving or have served as directors of laboratories performing high complexity testing before February 24,