D5551
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1271 Standard: Immunohematology

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

Interpretive Guidelines §493.1271(a)(1)

21 CFR §606.151 requires the following standard operating procedures for compatibility testing:

(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

(b) The use of fresh recipient serum or plasma samples less than 3 days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months. If information on the patient's history of transfusion or pregnancy is not available, then a fresh specimen is to be used.

(c) Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type. These procedures may consist of a serologic crossmatch, or a computer crossmatch. The computer crossmatch is a process of ensuring that a unit of blood is compatible with a specified recipient by means of electronically matching patient pretransfusion test results (ABO/Rh, etc.) with information about the blood donor that is stored in the LIS. The computer crossmatch is not strictly a "test" under CLIA; however, laboratories using this procedure must ensure that the LIS functions as intended. Refer to FDA Guidance for Industry:"Computer Crossmatch" (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type). http://www/fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm25829.htm.

Laboratories using an immediate spin or computer crossmatch should have policies on the use of an antiglobulin crossmatch when warranted.

(d) A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate**.**

A minor crossmatch when the donor unit has not been screened for unexpected antibodies. Because all blood collected in FDA registered facilities is required to be screened for unexpected antibodies, this requirement is rarely applicable.

(e) Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician

The laboratory must maintain complete documentation, signed by a physician, which justifies the emergency action.

When condition-level deficiencies in Immunohematology are identified in any or all phases of testing, use D5026.

Transfusion-related immunohematology testing performed on blood donors and recipients to determine compatibility is considered high complexity testing. When performed on blood donors or recipients, the following analytes are always high complexity: ABO group/ D (Rho) typing/antigen typing, direct antiglobulin tests, tests for unexpected antibody detection and identification, and crossmatch procedures. If personnel do not meet the qualifications or fulfill the responsibilities for high complexity testing, cite under subpart M—Personnel for Nonwaived Testing.

There generally are no daily quality control requirements for reagent red cell panels used in antibody identification. However, we encourage laboratories to follow the manufacturer’s recommendations for QC.

For laboratories using multiple racks of reagent typing sera and cells, laboratories should perform quality control on a representative sample of each lot of reagent in use on each day of testing. In addition, quality control needs to be performed on each new lot of reagent when first used.

When in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available. Under no circumstances, however, should a laboratory adopt policies that would allow for the regular use of expired reagents.

Determine if the laboratory has policies regarding:

- Compatibility testing for patients with a history of a prior antibody;
- Compatibility testing for patients with **no** history of a prior antibody; and
- Course of action to be taken for positive antibody screening and/or incompatible crossmatch.

Probes §493.1271(a)(1)

If the patient has been previously tested, how are results of current testing compared with interpretations of previous testing? When the results of current testing are discrepant with results of previous testing, how has the laboratory resolved the difference? Use D5777.

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(a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

Interpretive Guidelines §493.1271(a)(2)

Determine if the laboratory has a policy to detect and resolve ABO discrepancies. If the laboratory does not have such procedures, use D5401. If the laboratory does not use patient records to confirm ABO group (i.e., current testing compared with historical records when available), use D5777.

(a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

Interpretive Guidelines §493.1271(a)(3)

Determine if the laboratory has established a policy specifying when testing for weak D must be performed.

Probes §493.1271(a)(3)

Is the laboratory following this policy?