Centers for Medicare & Medicaid Services, HHS § 493.1271

§ 493.1271 Standard: Immunohematology.

(a) Patient testing. (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).

(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.

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

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

(c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(2) Inspections of the alarm system must be documented.

(d) Retention of samples of transfused blood. According to the laboratory’s established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

(e) Investigation of transfusion reactions. (1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical