CONTROL PROCEDURES FOR IMMUNOHEMATOLOGY

In 2003, the final CLIA regulations were published. Included were changes designed to streamline the quality control (QC) process. There is no longer a distinction between high complexity and moderate complexity with regard to quality control.

See the general requirements for control procedures (quality control) that are given in *CLIA Facts 16E--Analytic Systems: Control Procedures*. Additional, specific immunohematology control requirements are listed below.

Patient Testing

You must perform ABO grouping, D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided. Standard operating procedures for compatibility testing should include the following:

- A method of collecting and identifying the blood samples of recipients to ensure positive identification.
- The use of fresh recipient serum or plasma samples less than three days old for all pre-transfusion testing if the recipient has been pregnant or transfused within the previous three months.
- Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.
- A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate the presence of agglutinating, coating, and hemolytic antibodies, the recipient's cells will be tested with the donor's serum (minor crossmatch) by a method that will demonstrate any antibodies to recipient antigens.
- Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, and signed by a physician.

It is essential that you determine the recipient ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, you must test the unknown serum with known A1 and B red cells. In addition, you need to determine the recipient D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

Immunohematological Testing and Distribution of Blood and Blood Products

Blood and blood product testing and distribution must comply with all applicable regulations. To read these regulations go to the code of federal regulations (CFR) searchable database listed in resources below and read the following areas in section 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).

Blood and Blood Products Storage

You should store all blood and blood products under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

Your laboratory should have an audible alarm system to monitor proper blood and blood product storage temperature over a 24-hour period. Also, be sure you document inspections of the alarm system.

Retention of Samples of Transfused Blood

According to your laboratory's established procedures, samples of each unit of transfused blood should be retained for further testing in the event of any transfusion reactions. You are required to promptly dispose of blood that is not retained for further testing and has passed its expiration date.

Investigation of Transfusion Reactions

According to established procedures, if your laboratory performs compatibility testing, or issues blood or blood products, you need to promptly investigate all transfusion reactions occurring in facilities for which you have investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

You must document that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

The laboratory must document

all control procedures performed.

Resources

- To search the CFR for the additional regulations referenced above go to: www.gpoaccess.gov/cfr/index.html.