Immunohematology and CLIA

The CLIA regulations at 42 CFR §493.1271(a)(1) state “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).”

The laboratory must determine the ABO group by concurrently testing unknown red cells with, at least, 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.

- Does your laboratory have a policy to detect and resolve ABO discrepancies?
- Does your laboratory compare current testing results with past records?

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

- Does your laboratory have a policy specifying when weak D (Du) testing must be performed?

The frequency and the type of quality control to be performed for immunohematology testing are summarized in the following table:

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Positive Control</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO antisera</td>
<td>Each day of use</td>
<td>N/A</td>
</tr>
<tr>
<td>Rh antisera</td>
<td>Each day of use</td>
<td>N/A</td>
</tr>
<tr>
<td>Other anti-sera</td>
<td>Each day of use</td>
<td>N/A</td>
</tr>
<tr>
<td>Anti-human globulin sera</td>
<td>Each day of use</td>
<td>Each day of use</td>
</tr>
<tr>
<td>ABO reagent red cells</td>
<td>Each day of use</td>
<td>N/A</td>
</tr>
<tr>
<td>Antibody screening cells (at least one known antibody)</td>
<td>Each day of use</td>
<td>N/A</td>
</tr>
</tbody>
</table>

If more than one container of the same reagent is used for patient testing, the laboratory must perform quality control testing on each container used for patient testing each day.

The reagent red cell panels used in antibody identification do not require daily quality control testing, but the applicable quality control requirements for new
batch, lot and shipment of identification systems at §493.1256(e)(1) must be performed.

The laboratory should have policies established regarding:

- Compatibility testing for patients with a history of an antibody.
- Retyping, rescreening and/or recrossmatching blood components not transfused at the requested time.
- Action to be take for positive antibody screens and/or incompatible crossmatches.
- Corrective action for any unacceptable QC results.
- Transfusion of non-type specific blood components.
- Testing required for non-RBC components (i.e., platelets or plasma).
- Preparation of blood components for transfusion (i.e., thawing or splitting units).
- Emergency release of uncrossmatched blood.
- Monitoring the proper storage conditions of blood components.
- Release of blood components from the blood bank.
- Monitoring of the blood bank alarm system.
- Identification and investigation of transfusion reactions.
- Look-back procedures for HIV and HCV positive donors (see 21 CFR §610.45).
- Quarantine of blood products if necessary.
- Notification of physician and/or patient if potentially infectious blood products were administered.

The laboratory is required to ensure maintenance of proper centrifuge speed, centrifuge time, incubation temperature, and pipette dispensing volume according to the manufacturer’s instructions or laboratory policy, whichever is more stringent.

Laboratories not performing immunohematology testing but distributing blood products are required to maintain the applicable policies.

Sources for this article: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CLIA Western Consortium Meeting July 2008

Questions and Answers (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q. What are the CLIA requirements for choosing the type of blood product to be administered?
A. CLIA does not have any requirements for choosing the type of blood product to be administered. Choosing the type of blood product is considered a practice of medicine.

Q. What are the CLIA requirements for thawing frozen blood products?
A. CLIA does not have any requirements for thawing frozen blood products. Refer to the “Circular of Information for the Use of Human Blood and Blood Components,” which can be accessed at www.fda.gov/Cber/gdlns/crclr.pdf

Q. Is it acceptable to store non-immunohematology reagents in the Blood Bank refrigerator with blood products?
A. Yes, if the storage area is orderly and labeled. There should be no direct contact with the blood products or leaking of fluids on the blood products. Do not place solid barriers in the refrigerator as this may affect air circulation and maintenance of proper temperature.
State Operations Manual (SOM) Update

The State Operations Manual (SOM) Chapter 6—Special Procedures for Laboratories has been revised effective April 4, 2008. The SOM may be accessed on our website at www.ndhealth.gov/HF/NDCLIA.htm.

Record Retention

Immunohematology records, blood and blood product records, and transfusion records must be retained as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

Other immunohematology patient and quality control records related to transfusion testing—including but not limited to donor processing, compatibility testing, and transfusion reaction investigations—must be retained for the timeframe stated at 21 CFR 606.160(d). This also includes the visual inspection of whole blood and red blood cells during storage and immediately before distribution; record of reissue, including records of proper temperature maintenance; and emergency release of blood, including signature of requesting physician obtained before or after release. 21 CFR 606.160(d) states, “Records shall be retained for such interval beyond the expiration date for the blood and blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.”

Non-transfusion related immunohematology patient testing and quality control records—such as instrument function checks, maintenance and temperature records—must be retained for at least two years.