CLIA Corner

State Hygienic Laboratory at the University of Iowa

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NOTE: The CLIA regulations and interpretative guidelines are located at www.cms.gov/CLIA. Click on the link for Interpretative Guidelines for Laboratories or CLIA Regulations and Federal Register Documents. The Clinical Laboratory Improvement Amendments (CLIA) can also be found in the Code of Federal Regulations (CFR), Title 42-Public Health, Part 493-CLIA Laboratory Requirements.

Weak D (Rh_0) antigen testing using the ID-Micro Typing System (ID-MTS)™

If your laboratory uses the ID-Micro Typing System (ID-MTS™) Gel Test to perform routine D antigen testing, how does it confirm a D-negative test result in instances in which confirmation is required (e.g. prenatal patients, candidates for Rh immune globin and cord blood testing)?

The manufacturer of the ID-MTS™ Gel Test has in its "Instructions for Use" package insert[1], under the section Interpretation of Results-Negative Result, the following:
Note: In instances where confirmation of D-negative antigen status is required; negative D reactions obtained with the MTS™ Anti-D (Monoclonal)(IgM) Cord should be retested with an Anti-D reagent licensed for antiglobulin phase testing.

The MTS™ A/B/D Monoclonal and Reverse Grouping Card contains anti-D (Monoclonal)(IgM) for D antigen typing. Therefore, laboratories using the MTS for D-antigen typing must select an alternative test method (e.g. tube) that uses an IgG anti-D reagent and includes antiglobulin phase testing to confirm the presence or absence of a weak D antigen type.

[1]Micro Typing Systems, Inc. Instructions for Use, Blood Grouping Reagent, MTS A/B/D Monoclonal and Reverse Grouping Card; Pub. No. J32851_EN; Version 1.1, 2008.

Blood Product Storage Regulations and Requirements

The CLIA regulations for blood and blood product storage are located at 42 CFR 493.1271(C):

§493.1271(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.
(c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.
(c)(2) Inspections of the alarm system must be documented.

Blood and Blood Product Storage Temperature Ranges

The laboratory must establish the acceptable temperature range for the storage of blood and blood products. Whole blood, red cells, fresh frozen plasma, cryoprecipitate and platelet concentrates must be stored at temperatures in compliance with the Food and Drug Administration (FDA) regulations, as detailed in the table below:

Blood Product	FDA Acceptable Storage Temperature Range
Whole blood	1-6°C
Red Blood Cells	1-6°C
Liquid Plasma	1-6°C
Platelets	20-24°C
Fresh Frozen Plasma	-18°C or colder
Cryoprecipitated AHF	-18°C or colder

NOTE: If reagents for immunohematology testing are stored in the same refrigerator as blood and blood products, the laboratory must ensure that the temperature range for both the blood products and reagents are met.

Monitoring Storage Temperature

Actual readings of temperature-controlled storage areas must be recorded during the time that the blood or blood products for transfusion are stored. It is acceptable to monitor temperatures of storage equipment (i.e. refrigerators, freezers, incubators) continuously using a recording thermograph or central monitoring system. The laboratory needs to compare the temperature inside the storage equipment to the recording charts.

Refrigerators and freezers used for blood and blood product storage must be equipped with an audible alarm system. The temperature alarm system needs to be set to activate at a temperature which is still within acceptable limits. For example, if the range for the blood bank refrigerator is 1-6°C, the lower temperature activation should be set at approximately 1.5°C and the upper temperature activation at around 5.5°C. If the laboratory is not staffed 24 hours a day, seven days a week, the laboratory must have a system in place to ensure the prompt response to an activated alarm. Refer to the next section for details on the regular inspection of the alarm system.

The laboratory must have an action plan for storage equipment failure or when temperatures exceed the acceptable range limits, or when the continuous temperature monitoring system or alarm system fails. The plan should include how the laboratory will properly store blood and blood products until the problem is resolved. If the laboratory does not have an emergency power source for the blood storage equipment and temperature alarm system, the laboratory must have a system to ensure that the blood and blood products are maintained at the appropriate temperatures when a power failure occurs.

All temperature readings, including recording charts or central monitoring system recordings, must be documented and retained to ensure that temperatures are maintained within the Food and Drug Administration (FDA) limits. Any unacceptable temperature or abnormal fluctuation in temperature (e.g alarm checks or transfer/handling of blood and blood products) must be documented on the recording chart and in the temperature records.

Blood Storage Equipment and Temperature Alarm System

The laboratory is required to perform any maintenance and/or function checks as defined by the manufacturer. If the manufacturer does not provide guidelines, the laboratory must establish its own maintenance and function check protocols, including the frequency of the maintenance and/or function checks.

As mentioned earlier, refrigerators and freezers used for blood and blood product storage must be equipped with an audible alarm system that is inspected on a regular basis. It is the laboratory's responsibility to define

the protocol for performing the inspection and function check of the alarm system. For determining the frequency, the laboratory should contact its provider of blood and blood products for their requirements and recommendations.

A function check of the alarm system includes the manual activation at high and/or low temperature settings. The laboratory must ensure the following checks are performed and documented:

- Actual temperature reading(s) at which the alarm activates are within the acceptable range;
- Temperature reading on the recording chart or central monitoring system demonstrates a fluctuation; and
- Response time to the alarm activation by nursing service or other department(s) is with acceptable limits.

The laboratory must take and document corrective action if the function check fails to meet its established limits.

Records and Documentation

Immunohematology patient and quality control records related to transfusion testing must be retained for the time frame stated by the FDA regulation, Current Good Manufacturing Practice for Blood and Blood Components, 21 CFR 606.160(d):

§ 606.160 Records.

Records shall be retained for such interval beyond the expiration date for the blood or 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.*

Records include, but are not limited to, the following:

- Storage temperatures, including recording charts or central monitoring system;
- Visual inspection of whole blood and red blood cells during storage and immediately before distribution; and
- Record of reissue, including records of proper temperature maintenance.

FDA Reissue Requirements are as follows:

- ✓ The container must have a tamper-proof seal which remains unbroken;
- ✓ Tamper-proof pilot tube or segment must be attached;
- ✓ Records should indicate that the blood was maintained at 1 – 10 C while outside the control of the establishment; and
- ✓ The unit must be inspected prior to reissue.

Blood issued for transfusion to a ward or operating room and not refrigerated may be reissued if the unit is returned to the blood bank within 30 minutes.

For assistance or additional guidance on proper blood and blood product storage, contact your blood provider or local blood center.

Contact Information:

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