

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

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In This Issue...

- **Requirements for transfusion services**



According to the Red Cross: approximately 29,000 units of red blood cells, 5,000 units of platelets and 6,500 units of plasma are needed every day in the US, and nearly 16 million blood components are transfused each year. Transfusion services plays a critical role in patient care, and in this edition of the CLIA Corner, we will review the CLIA Regulations and Interpretive Guidelines for administering and receiving blood products.

Transfusion Services: CLIA Regulations and Interpretive Guidelines

D3015

§493.1103 Standard: Requirements for transfusion services

- **A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.**

CLIA defines a “facility that provides transfusion services” as an entity that may store and/or administer blood and blood products to patients.

D3017

§493.1103 Standard: Requirements for transfusion services

- **(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.**



The laboratory must have a contract with their blood supplier that specifies which services will be performed by the laboratory and which services will be performed by the blood provider. For example, does that laboratory perform ABO grouping, D (Rho) typing, antibody screens and cross-matches? When there is a positive antibody screen, does the blood supplier perform antibody identification and antigen typing to find compatible units? The transfusion service agreement should clarify these processes.

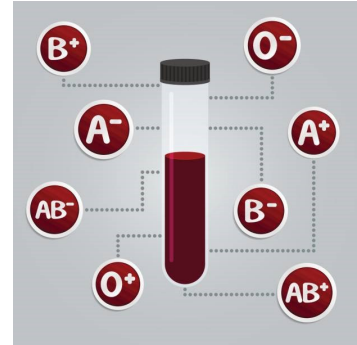
If you would like your name added to our CLIA Corner google group, send an email to:

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D3019

§493.1103 Standard: Requirements for transfusion services

- **(b) Provision of testing. The facility must provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA- certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.**



The laboratory will need to obtain a copy of the current CLIA certificate of any laboratory performing reference testing (ie antigen testing, antibody identification).

How does the laboratory ensure the availability of service on a continuous basis? What happens if the laboratory is unable to perform prompt ABO grouping, D(Rho) typing, unexpected antibody detection, and compatibility testing? The laboratory will need to have a written backup plan should they be unable to perform the testing needed to transfuse blood and/or blood products. The laboratory must also ensure that all staff, including PRN positions, are knowledgeable of the backup plan.

D3021

§493.1103 Standard: Requirements for transfusion services

- **(c) Blood and blood products storage and distribution. (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.**

The laboratory must ensure that all blood stored in refrigerators and/or freezers are being continuously monitored for temperature. This would include areas like operating rooms, nursing stations, pharmacies, and dialysis units. The laboratory must provide documentation ensuring the appropriate temperature is maintained for each of the blood product storage areas. If the blood is temporarily stored in a cooler for transport, the laboratory will also need to ensure the storage conditions are appropriate.

The laboratory must establish acceptable temperature ranges and provide documentation of the temperatures where blood and blood products are stored. Whole blood, red blood cells, and thawed plasma should be stored between 1 – 6°C; platelets and thawed cryoprecipitated AHF should be stored between 20 – 24°C; fresh frozen plasma, frozen plasma within 24 hours after phlebotomy, and cryoprecipitated AHF should be stored at -18°C or colder.

The laboratory must have policies and procedures that include:

- ➔ Policies for the proper storage and transportation of blood or blood products;
- ➔ Policies for how to ensure the proper storage of blood or blood products during a power failure;
- ➔ Procedures to alert the laboratory of blood storage problems;
- ➔ Policies to ensure the positive identification of a blood or blood product recipient;
- ➔ Procedures to identify a possible transfusion reaction; and
- ➔ Procedure to notify the laboratory of a possible transfusion reaction.

For facilities that provide transfusion services, but are not certified for the specialty of immunohematology (i.e. do not perform ABO grouping, D(Rho typing), unexpected antibody detection, and compatibility testing) and perform other nonwaived testing, the requirements for the storage and distribution of blood and blood products must be met. The blood supplier may provide the previously listed policies to the facility receiving the blood and blood products.

The laboratory should ensure that all blood and blood products are stored in a clean and orderly environment in a manner that prevents mix-ups. No expired blood should be in the routine inventory and unacceptable units should be segregated from routine inventory.



D3023

§493.1103 Standard: Requirements for transfusion services

- **(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.**

Upon request, the laboratory will need to be able to provide documentation (written or electronic) of the individual who released the blood and/or blood products and the individual who received the blood and/or blood products. The documentation should mirror the steps that are in the laboratory's procedure.

D3025

§493.1103 Standard: Requirements for transfusion services

- **(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.**

The laboratory will need to provide documentation of all transfusion reaction investigations, including each step in the investigation and the identity of all personnel taking part in the investigation. The transfusion reaction investigation documentation should correspond to the transfusion reaction policies and procedures and be approved by the laboratory director. **The facility must notify the Food and Drug Administration (FDA) of ALL transfusion related fatalities.**

How To Notify FDA of Transfusion Related Fatalities

Section 606.170(b) states that you may report a fatality by telephone, facsimile, express mail, or electronically transmitted mail (email). We recommend that you submit the initial notification by email, if possible, and if you do so, you will receive an email confirmation receipt from us. If email is not feasible, please notify us by telephone or facsimile. We cannot access notification outside of customary working hours unless you use email or telephone. **Similarly, we recommend that you submit 7-day follow up reports by email, facsimile, or express mail.**

- **Email: fatalities2@fda.hhs.gov**
- **Telephone/voice-mail number: 240-402-9160**
- **Fax number: 301-837-6256, Attn: CBER Fatality Program Manager**
- **Express mail address: Office of Compliance and Biologics Quality/CBER**

Attn: Fatality Program Manager

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In summary, the transfusion of blood and blood products is a necessary life-saving measure. Ensuring that your laboratory is following the CLIA Regulations and Interpretive Guidelines for transfusion services will lead to better patient care.