Purpose and Regulations

LifeServe Blood Center performs validation on the shipping containers used to transport blood and components. The following regulations apply:

- AABB std 5.1.8.2.1 Containers (eg, portable coolers) used to transport blood and blood components issued for transfusion shall be qualified and the process validated for the appropriate transport temperature and time.
- CFR 606.460(b)(5)(iv) Records shall be maintained that include but are not limited to…periodic test of capacity of shipping container to maintain proper temperature in transit.
- AABB Technical Manual:
  - It is recommended that all red cell transport containers be validated to maintain a temperature of 1 to 6°C for a specified period to ensure compliance with the transport and storage requirements for Red Blood Cells.
  - Validation of all shipping or transport containers is required before they are placed into use. The containers must be able to maintain the proper transport temperature that is appropriate for the component.

Policy

Due to regulatory requirements as stated above, containers used within individual facilities for transport and storage of blood and blood products must also be validated.

LifeServe **will not accept** units that are transported or stored in containers that are not validated even if the temperature is acceptable upon arrival. If we receive units in a container that has not been validated by LifeServe, we will contact your facility to request a copy of your validation of the container. If you are unable to supply it, the blood/components will be discarded and those components will be charged to your facility. If you do not have a container to use when shipping components, please notify the appropriate LifeServe distribution site to ensure that we send one when picking up the shipment.