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Beaumont

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Area	Laboratory-Blood Bank
Applicability	Dearborn

Cooler Validation - Dearborn Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To provide technical staff with instructions on how to validate the coolers used for transporting blood components that require refrigerated temperature.

II. PRINCIPLE:

Coolers that are used to transport red blood cells (RBCs) and thawed plasma (FFP) must have the limits of RBCs and/or FFP storage challenged so that the validation shows that the coolers storage environment is maintained between 1°C -6°C for a determined length of time whether packed with minimum amount or maximum amount of any combination of refrigerated products. The minimum and maximum amounts are rotated yearly between the different coolers.

III. DEFINITIONS:

A. Cooler: For the context of this document, cooler refers to any device that is used to transport blood products or tissues at refrigerated temperatures.

B. Glass Thermometer: Thermometers placed in any cooler that uses wet ice as the coolant (e.g., Igloo, Massive, and small Igloo tissue coolers). All glass thermometers used to monitor the temperature of a cooler are placed in a container filled with a glycerol solution.

C. Standard Cooler: a temperature-monitored cooler used for inpatients that has been validated for the transport of blood components, and is intended for the transport of 1 to 4 blood components which require refrigeration.

D. Massive Transfusion Cooler: a large, temperature-monitored cooler that is intended for use during the massive transfusion protocol for the transport of 6 RBCs and 6 FFP, or that is

intended for transport of up to 12 FFP during a therapeutic plasma exchange, and that has been validated for the transport of blood components.

E. Refrigerated blood components: Red Blood Cells (RBCs) and or Thawed Plasma.

IV. POLICIES:

A. Red blood cells (RBCs) and thawed plasma (FFP) that require refrigerated temperatures may be transported to other areas of the hospital in coolers which have been validated to maintain the proper storage temperature of the components.

B. The coolers are validated to transport varying combinations of RBCs and FFP (including warm, recently thawed FFP).

C. The coolers are validated for 6 hours to maintain the RBC temperatures at 1°C -10°C , 1°C -10°C for refrigerated FFP thawed greater than 12-24 hours, and 1°C -37°C for recently thawed FFP.

D. The coolers are validated on a rotating basis, as outlined on the back of the *Cooler Validation Form*.

E. Coolers must be validated before they are put into use and yearly thereafter.

F. The Extech® IR200 thermometers will be calibrated yearly, as described in Transfusion Medicine policy, *Thermometer Calibration*. These thermometers are used to take the temperatures of blood products upon return as described in Transfusion Medicine policy, Taking the Temperature of a Blood Product.

G. The cooler must be packed with coolants as described in Transfusion Medicine policy, Transporting Blood Products in a Cooler.

V. EQUIPMENT:

A. Calibrated thermometers in containers of glycerol

B. Extech® IR200 thermometer

C. Coolers to be validated

D. Calibrated Timer

VI. SUPPLIES:

A. Expired RBCs and FFP (front labels defaced, discarded in biohazard after study)

B. Saline bags (to simulate FFP or RBCs if needed)

C. Coolants to pack the cooler

D. Ice chips

E. Ice scoop

F. Plastic Bags for Ice

G. Towel

H. Hepacide Quant® II Virucidal Disinfectant Cleaner

l. Sani-Cloth Germicidal Disposable Wipes

VII. QUALITY CONTROL:

All thermometers used for this cooler validation must be calibrated before use and yearly thereafter.

VIII. PROCEDURE:

A. Inspection

1. Inspect the coolers for cracks, tears or other physical damage and verify that all the closing mechanisms operate properly.
2. Confirm that all of the labels are secure and legible on each cooler.
3. If a cooler is found to be defective or damaged the cooler, then take the cooler out of service by affixing the *Do Not Use/Out of Service* tag to the cooler and notify the supervisor.
4. Clean coolers (inside and outside) by wiping down with approved hospital disinfectant.

B. Thermometer Preparation

1. Verify that the glass thermometers to be used in the validation have been calibrated.
2. Place the glass thermometers in the blood product refrigerator and allow the temperature to equilibrate and begin the validation at the temperature of the blood product refrigerator (1°C - 6°C).

C. Temperature Maintenance

The *Cooler Validation Form* is used to document the temperatures taken for this cooler validation.

1. Obtain the cooler, thermometers, and blood products required as specified by the rotation schedule on the backside of the *Cooler Validation Form.*
2. Set up the cooler with the appropriate coolant packs as described in Transfusion Medicine policy, Transporting Blood Products in a Cooler.
3. Pack the required number and combination of RBC and Plasma products as specified on the rotation schedule on the back side of the *Cooler Validation Form* .
4. Place the glass thermometer in the bottom of the cooler.
5. The initial temperature of the cooler is taken using this thermometer, and then taken again at 30 minutes, again 30 minutes later (1 hour after the initial temperature) then every hour for 5 additional hours.
6. The blood products' temperatures are taken using the IR thermometer at the same time as the cooler's thermometer readings by mixing well prior to taking product temperature and holding the IR thermometer less than 2 inches away from the blood product, as described in Transfusion Medicine policy, Taking the Temperature of a Blood Product.
7. Record the temperatures of the cooler and the component(s) packed in the cooler on *Cooler Validation Form.*

8. As each temperature is taken for the applicable interval, set a timer for the next required temperature check.
9. Continue to take and record temperatures at each of the intervals listed on the form.
10. At the end of 6 hours take the final temperature of the cooler and each blood product.
11. Perform visual inspection on each unit and indicate Yes/No for acceptability.
12. Repeat the above steps for each of the coolers used to transport blood products.

IX. EXPECTED RESULTS:

A. The temperature of each blood product (as taken with the Extech® IR200 IR thermometer) must be in the range of 1°C - 10°C for at least 6 hours.

B. The temperature of each cooler must be in the range of 1°C - 6°C for at least 6 hours.

C. Any cooler not meeting these requirements may be revalidated one time. If a cooler fails the validation a second time it must be taken out of use and replaced with a new cooler.

X. NOTES:

A. All completed forms should be given to the Supervisor or Lead Medical Technologist for review and approval sign off.

B. Once the supervisor or Lead Medical Technologist signs off on the cooler validation, that cooler may be put back into use.

C. Remove the label from the cooler which indicates when the previous year's validation was done and replace it with a new one (see *Cooler Validation Labels)*.

Attachments

Cooler Validation Form

Cooler Validation Labels

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	6/7/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	5/31/2022

Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	5/31/2022
	Kimberly Geck: Dir, Lab Operations B	5/30/2022
	Kelly Sartor: Supv, Laboratory	5/27/2022
	Kelly Sartor: Supv, Laboratory	5/27/2022

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COOLER VALIDATION FORM

- ☐ Prior To Use
- ☐ Yearly or As Needed

Thermometer Serial # _____

Cooler # being validated: _____ **Thermometer #:** _____ **Date/Tech:** _____

Number of units packed in cooler:

Unit numbers of units packed in cooler:	Temperature (°C)								Visual Inspection	Results	Disposition of cooler
	Initial	30 mins.	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours			
Cooler											

Key:

Inspection Codes: **Y** = Passes Visual Inspection
N = Fails Visual Inspection

Results Codes: **A** = Acceptable results (Cooler thermometer reading is 1°C - 6°C, RBCs thermometer reading is 1°-10°C)
U=Unacceptable results (Cooler thermometer reading < 1°C or > 6°C, RBCs thermometer reading < 1°or >10°C)

Disposition Codes: Acceptable criteria: Cooler is void of crack, rips, or other physical damage; closing mechanism (latch, zipper) is operating properly.
OK = Cooler meets acceptable criteria and can be placed into inventory (new cooler) or continue to be used for blood storage.
D = Cooler does not meet acceptable criteria and must be discarded

Data Review:

Reviewed by:	Date:

PRODUCT ROTATION SCHEDULE

	Year # 1 Rotation		Year # 2 Rotation		Year # 3 Rotation		Subsequent Years
	Cooler Validation Year:	2022	Cooler Validation Year:	2023	Cooler Validation Yea:	2024	
Products	**Cooler Slot#**		**Cooler Slot #**		**Cooler Slot #**		
1 RBC	3		4		5		
2 RBC	4		5		6		
3 RBC	5		6		7		
3 RBC & 1 FFP	6		7		8		Follow the rotation pattern
3 RBC & 2 FFP	7		8		9		
3 RBC & 3 FFP	8		9		1		
1 FFP*	9		1		2		
1 RBC & 1 FFP*	1		2		3		
3 RBC & 3 FFP*	2		3		4		

Directions:

- Coolers will be assigned a slot in the rotation originally based on their cooler # with the lowest cooler # assuming slot # 1, highest cooler # assuming slot # 9 sequentially. Because the numbering scheme will not necessarily remain sequential over time with the loss/discarding of coolers, the coolers it may be necessary to review previous year's validation to determine which cooler will be assigned slot# 1and be validated with 1 product (minimum) and which will be validated with 6 products (maximum) in the current year on a rotational basis.
- All products used will be RBCs, thawed plasma, and/or saline and in any combination thereof. The cooler storage capacity will be further challenged with the use of thawed plasma product previously stored at refrigerated temperatures and those that are at temperatures more indicative of a fresh thaw* (35-37°C).