PROCEDURE
Corewell Health East - Blood Bank Cooler Validation - Troy

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Troy Hospital

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

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1. Principle

A. This document provides Blood Bank staff with instructions on the validation process for the coolers used to transport blood components that require a refrigerated temperature.
B. Red blood cells (RBCs) and thawed plasma (FFP) that require refrigerated temperatures (1°C - 10°C) may be transported to other areas of the hospital in coolers which have been validated to maintain the proper storage temperature of the components.
C. A single platelet pheresis (PPH) that requires room temperatures (21°C -24°C) may be transported to other areas of the hospital in the Maxplus MTP cooler pouch which has been validated to maintain this proper storage temperature.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Definitions

A. PCM: Phase contrast medium used to maintain cold temperatures within the coolers
B. RBC: Red Blood Cells
C. FFP: Fresh Frozen Plasma
D. Designee: Any Blood Bank technologist authorized to act on behalf of leadership
E. MTP: Massive Transfusion Protocol
F. PPH: Platelet pheresis

4. Reagent/Equipment Needed

A. Extech® IR200 thermometers
B. Coolers
C. Expired RBCs (defaced)
D. Expired plasma
E. Saline bags (to simulate FFP or RBCs if expired products are not available)
F. Gel packs (Frozen / Refrigerated)
G. Frozen PCM
H. Timers
I. Silver padding (8.5 x 11 inches)

J. Corrugated plastic sleeves (RBCs and FFP are placed inside of these sleeves, inside of the coolers)
K. Isopropyl alcohol

5. Quality Control

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

6. Procedure

A. Coolers must be validated before they are put into use and yearly thereafter.
B. The coolers are validated to transport varying combinations of RBCs and FFP (including warm, recently thawed FFP). In addition, the Maxplus MTP cooler may also transport one PPH.
C. The coolers are validated for up to 10 hours
    1. RBC temperatures at 1°C -10°C
    2. Thawed FFP (greater than 12 hours) at 1°C -10°C
    3. Recently thawed FFP (less than 12 hours) at 1°C - 37°C
    4. One platelet in Maxplus MTP cooler at 20°C - 24°C
D. The coolers are validated on a rotating basis as outlined in the Transfusion Medicine attachment, Cooler Validation Rotation Schedule Attachment.
E. The Extech® IR2000 thermometers, which are used to take the temperatures of blood products upon return, are used to take the temperature of the blood products during cooler validation.
F. Frozen and refrigerated coolants (gel packs and PCMs) are used as for transporting refrigerated blood products in the coolers.
G. Cooler Inspection
    1. Inspect the coolers for cracks, tears or other physical damage.
    2. Verify that the closing mechanisms operate properly.
    3. Assure that all labels are secure and legible on each cooler.
    4. Clean coolers (inside and outside) by wiping down with isopropyl alcohol.
    5. If a cooler is found to be defective, damaged, etc. take the cooler out of service by affixing a Do Not Use/ Out of Service Tag to the cooler, and notify the supervisor or lead medical technologist.
    6. Verify that the Extech® IR200 thermometers have been calibrated before beginning the cooler validation.
H. Temperature Validation
    1. The coolers are validated on a rotating basis as outlined in the Cooler Validation Rotation Schedule.
    2. Obtain the Transfusion Medicine form, Cooler Validation: Temperature Maintenance to document the temperatures taken for this cooler validation.
    3. Obtain the cooler, thermometers, and blood products as specified by the rotation schedule.
    4. If warm FFP is indicated by the schedule, “thaw” a saline bag in the plasma bath; do not “thaw” (warm) expired FFP for this validation.
    5. Set up the cooler as specified in the schedule, and as instructed on the cooler validation form.
    6. Record the temperature of each unit by mixing well prior to taking its temperature and holding the thermometer less than 2 inches away from the blood product.
    7. Record temperature of units at interval described on Transfusion Medicine form, Cooler Validation: Temperature Maintenance.
    8. As each temperature is taken for the applicable interval, set a timer for the next required temperature check.
    9. At the end of 10 hours, perform visual inspection on each unit and indicate Yes/No for acceptability.
    10. Repeat the above steps for each of the coolers used to transport blood products.

7. Results/Interpretation

A. The temperature of the RBC and FFP (as taken with the Extech® IR200 IR thermometer) must be in the range of 1°C - 10°C.
    1. Note that this requirement does not apply to the saline bags that were thawed immediately before the validation as their initial temperatures will be approximately 37°C.
        a. Acceptable temperatures for recently thawed plasma is 1°C - 37°C.
B. The temperature for PPH must be 20-24°C.
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. A variance will be written to document the failure. Refer to the Transfusion Medicine policy, Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals.

8. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

9. References

1. AABB, Technical Manual, current edition.
2. AABB, Standards for Blood Banks and Transfusion Medicine Services, current edition.
3. Food and Drug Administration, Code of Federal Regulations, current edition.

10. Procedure Development and Approval

Document Owner:
Laura Judd (Operations Specialist)

Writer(s):
Alyssa Malone (Medical Technologist Lead)

Reviewer(s):
Taylor Stencel (Medical Technologist)

Approver:
Brittnie Berger (Dir Sr, Lab Operations), Elzbieta Wystepek (Dir, Laboratory Services), Kelly Sartor (Mgr, Division Laboratory), Masood Siddiqui (Staff Pathologist), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Teresa Lovins (Supv, Laboratory)

11. Keywords

Not Set