PROCEDURE
Corewell Health East - Blood Storage Coolers - Grosse Pointe

This Procedure is Applicable to the following Corewell Health sites:
*Sites:, Corewell Health Beaumont Grosse Pointe 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. The purpose of this document is to provide staff with instructions on how to validate the coolers used for transporting blood components needing to be kept at refrigerated temperature.

B. The Credo Thermal Packaging Solutions' O.R. container utilizes a reusable, ice-less container to safely and efficiently store blood. The cooler is used to issue red cells and plasma during massive transfusion protocols and has been validated to maintain storage temperature of 1°C to 6°C for up to 4 hours so that unused blood may be returned to inventory.

C. Validation is performed before a new cooler is put into production or annually thereafter. Validation will be performed In June ± 1 month.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Definitions

A. TIC (Thermal Isolation Chamber): A system of reusable ice-less panels (4 large, 2 small) used with an IGLOO® cooler designed to maintain the Food and Drug Administration (FDA) required storage temperature of 1-6°C for up to 24 hours.

4. Reagent/Equipment Needed

A. Credo Thermal IGLOO® cooler
B. TICs
C. Expired Red Blood Cells (RBCs)
D. Expired thawed plasma or liquid plasma
E. Calibrated refrigerator thermometer
F. InfraRed Thermometer
G. Cooler validation form

5. Quality Control

For an acceptable validation,

a. the thermometer temperature should not exceed 10º C at any point during the four hours.
b. each unit temperature should not exceed 10º C at any point during the four hours.

6. Procedure

A. **Pre-Conditioning the TIC System**

1. Place the TIC System panels flat in the plasma freezer (-18ºC or colder) for a minimum of 12 hours, until Phase Change Material (PCM) is frozen hard.

2. Remove from freezer, spread components out on a bench and let the TIC panels stand at room temperature for 25 minutes or until surface frost melts. This lets the component's temperature rise from the freezer temperature into the acceptable temperature range (above 2°C).

3. After preconditioning, the TIC System may be refrigerated up to 48 hours before needing to be reconditioned.

B. **Validation**

1. Obtain 6 outdated units of plasma or packed cells.

2. Assemble a TIC system in a cooler and place the units inside the cooler.

3. Read and record the temperature of a thermometer from a refrigerator, ensuring that it is in 1-6ºC range. Place the thermometer in the cooler in the middle of the units of blood products.

4. Read and record the temperature of each unit from the refrigerator, ensuring that they are in the 1-6ºC range with the IR Thermometer.

5. Place the TIC lid on and close the cooler.

6. Read and record the temperature of the thermometer and each unit 30 minutes after being placed in the cooler and one-hour thereafter. Continue to record the temperature of the cooler and the units hourly for a minimum of 7 hours.

C. **Cleaning the cooler and components**

The TIC panels and Igloo Cooler can be cleaned using warm water and soap or alcohol. Sanitization can be performed using isopropyl alcohol and water mixture (typically 70/30 mix alcohol to water) or other salt-based disinfectants.

Replace damaged labels.

D. **DO NOT:**

1. Autoclave any of the components.
2. Use any organic solvents such as acetone or methyl ethyl ketone (MEK) on any of the components.
3. Expose any of the TIC components or insulator to extreme heat (+75°C or above).
4. Use any abrasive cleaners on any of the components

7. Results/Interpretation

A. For an acceptable validation:
   i. the thermometer temperature should not be less than 1ºC or exceed 10ºC at any point during the seven hours.
   ii. each unit temperature should not be less than 1ºC or exceed 10ºC at any point during the seven hours.

B. For an unacceptable validation:

i. any temperature exceeds the acceptable range:
    a. Place the cooler and tics out of service
    b. Precondition the TICs
    c. Repeat validation after TICs have been condition and expired units have cooled.
        i. If acceptable place TICs and cooler back in service
        ii. If validation fails again, determine the cause of the failure either the cooler, the TICs or thermometer by using different validated TICs with a different validated cooler and different thermometer.
        iii. If failure still exists write a variance and consult the transfusion services medical director

8. Revisions

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

9. References

User Guide, Credo Thermal Packaging Solutions; Series 4-8240R; Minnesota Thermal Science, 2009.

10. Procedure Development and Approval

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11. Keywords

Not Set