KAISER PERMANENTE

*Kaiser Permanente Medical Center, San Francisco*
*Northern California Region*
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# Work Instruction

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| **Title:** TC Cooler Validation | | **WI Number** SFOWI-0047<br>**Revision:** 14 |
| **Department:**<br>Immunohematology<br>**Area:**<br>2425 Geary Blvd SFO Hospital Lab | ***Document is in the Final Approval Process. 2 - approvals are required*** | |
| **Type of Document:**<br>Work Instruction | | **Review Period -** 340 **Days** |

## PURPOSE

To verify the minimum amount of time that shipping containers used to transport RBC or thawed plasma are able to maintain a temperature of 1-6 °C.

## VALIDATION FREQUENCY

Validation and inspection will be performed before initial use and thereafter, annual inspection will be performed to verify cooler integrity.

## EQUIPMENT

A. Absorbents
B. Calibrated Thermometers / 2 Log Tag Temperature Recorders with Probes or 2 Log Tag Temperature Recorders without probes
C. Coolers
D. Cooler Validation form
E. Frozen Ice Packs (7.5” X 10”)
F. Glycerol Temperature bags, which contain 250-325 ml of 33% glycerol, refrigerated a minimum of 24 hours
G. Timer for manual temperature recording

## CONTROLS

In-date thermometers / temperature recorders that are calibrated to a NIST traceable standard annually.

## PROCEDURE

**A. Prepare Glycerol Temperature Bags (33% Glycerol)**

1. Insert a calibrated thermometer or Log Tag Temperature Recorder into the port of each of two glycerol filled bags (Probe#1 and Probe#2).
2. Refrigerate all glycerol filled bags for 24 hours in 1-6 °C before use.

**B. Initial Cooler Inspection**

1. As part of the initial validation, inspect each new cooler for tears or defects.
2. Use BF0005 Cooler Validation and Initial/Annual Check form to record the inspection.
3. Cooler that does not pass inspection will not be validated and will be replaced.

**C. Prepare Cooler**

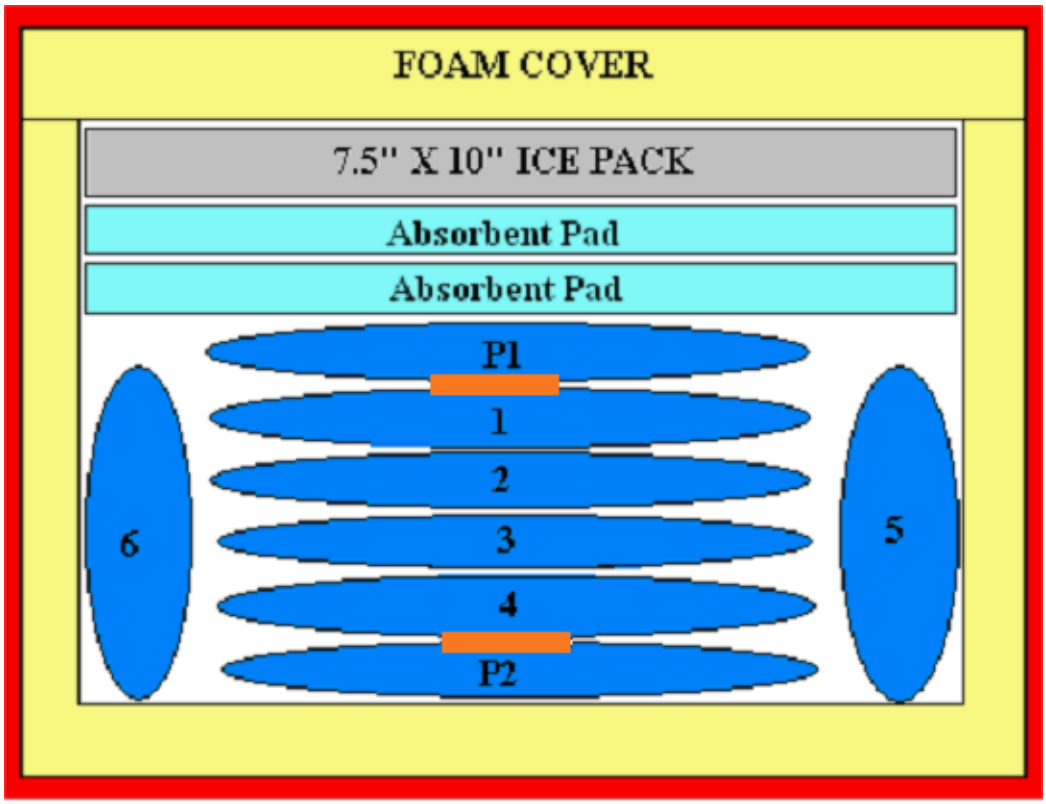
1. **True Pack T3 Transport Cooler (Fabric Foam Cooler)**

   **Note:** Use 8 pre-chilled glycerol filled bags.

   a. Lay Probe#2 bag horizontally on the bottom of the cooler. Position it in the middle of the cooler.
   b. Lay 4 glycerol filled bags on top of the Probe#2 bag.
   c. Place Probe#1 bag on top of the 4 glycerol filled bags.
   d. Lay 1 glycerol filled bag on each side, along the length of the cooler.
   e. Lay 2 absorbent pads (white absorbent sides facing out) on top of the glycerol bags.
   f. Place the frozen icepack on top of the absorbents.
   g. Put the foam cover in place and zip the cooler closed.

   **NOTE:** P1 and P2 can be replaced with glycerols bags without probes. When doing so, place Log Tags without probe (orange bars) as shown in image below. Label the top Log Tag as '1' and the bottom Log Tag as '2'.

**SIDE VIEW OF TRANSPORT COOLER**

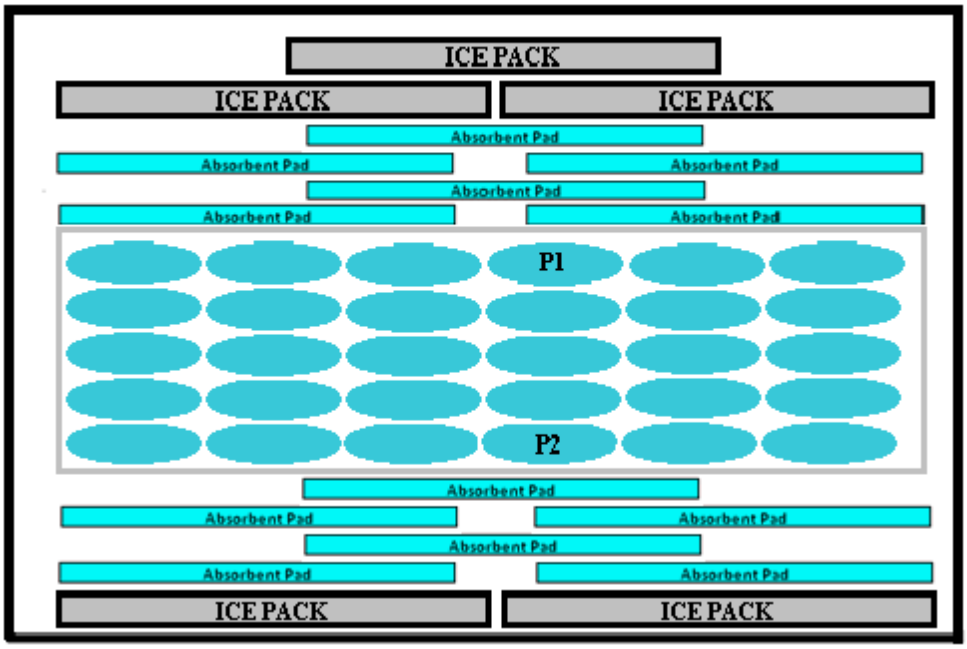



2. **Disaster Cooler (Plastic Wheeled Cooler)**

   a. Lay 2 frozen icepacks on the bottom of the cooler.
   b. Lay 6 absorbent pads (white absorbent sides facing out) overlapping over the icepacks.
   c. Place clear plastic bag on top of absorbent pads.

d. Position Probe#2 in the center of the plastic bag. Place attached wire and thermometer/log tag recorder outside of cooler.
e. Place remaining glycerol bags around and above Probe#2 in layers (see image below).
f. Position Probe#1 on the center top most layer. Place attached wire and thermometer/log tag recorder outside of cooler. Total glycerol bags should be 20-30.
g. Lay 6 absorbent pads (white absorbent sides facing out) overlapping over plastic bag.
h. Place 2 icepacks over pads. Then place another icepack on top center over the first two icepacks. Close cooler.

SIDE VIEW OF DISASTER COOLER




**D. Manual Temperature Recording**

1. Use BF0005 Cooler Validation form to record the times and temperatures.
2. Take temperatures readings every hour for the total amount of time specified below for each type of cooler:
   a. 8 hours total for True Pack T3
   b. 24 hours total for Disaster Cooler
3. Record initial temperatures of Probe#1 and Probe#2.
4. Start timer for 1 hour countdown.
5. When the timer alarms, silence it and restart 1 hour countdown.
6. Record Probe#1 and Probe#2 temperatures.
7. Record temperature readings every hour.

**NOTE:** Stop the recording process if the temperature exceeds 6 $^{\circ}$C at any time.

**NOTE:** Place all glycerol bags including probes into the refrigerator at the conclusion of the validation.

**E. Log Tag Temperature Recording**

**NOTE:** Log Tag Temperature Recorders continuously record temperatures at specified time intervals.

1. Configure Log Tag Recorders to start recording after 30 minutes (1 hour for Disaster Cooler) and to continuously record temperatures every 30 minutes for the total amount of time specified below for each type of cooler:
    a. 8 hours total for True Pack T3 (17 readings)
    b. 24 hours total for Disaster Cooler (49 readings)
2. Match and connect the probes from the Glycerol bags to the Log Tag Recorders. Press START/MARK button.
3. Flashing red then green 'OK' indicates temperature is recording (30 minutes or 1 hour after starting).
4. Wait for the total hours to elapsed. When finished, remove Log Tag recorders and download temperature data to computer.
5. Review and print temperature data and graphs.
6. Hibernate recorders before storing away.

**NOTE:** Place all glycerol bags including probes into the refrigerator at the conclusion of the validation.

**F. Validation Results and Review**

1. **True Pack T3 Transport Cooler (Fabric Foam Cooler)**
    a. The acceptable result is cooler maintains 1 - 6 $^{o}$C for a minimum of 4 hours.
    b. Place completed Cooler Validation form for a supervisor to review.

2. **Disaster Cooler (Plastic Wheeled Cooler)**
    a. The acceptable result is cooler maintains 1 - 6 $^{o}$C for a minimum of 20 hours.
    b. Place completed Cooler Validation form for a supervisor to review.

**G. Attach Cooler Validation Label**

1. If the validation results are acceptable, fill out the Cooler Validation Label with the following information:
    a. Cooler ID:
    b. Validation Date:
    c. CLS Initials:
    d. Next Annual Check: (1 year later)
    e. Maximum Validated Time (amount of time in hours that cooler maintains 1-6 $^{o}$C)
2. Remove the old Cooler Validation Label and replace with the new one.

**H. Annual Cooler Qualification**

1. Each cooler will be inspected annually for wear and tear which may void the initial validation.
2. Use BF0005 Cooler Validation and Initial/Annual Check form to record the inspection.
3. Unacceptable cooler will be removed from use and replaced.
4. If the cooler pass inspection, remove the old cooler label and attach a new label with the following information:
    a. Cooler ID:
    b. Validation Date: (copy the original validation date)
    c. Annual Check: (date of cooler inspection)

d. Next Annual Check: (1 year later)
e. Maximum Validated Time (amount of time in hours that cooler maintains 1-6 °C)

**PROCEDURAL NOTES:**

A. Validated time is the elapsed hours before the temperature exceeds 6 °C.
B. Blood products are not to be kept in the Transport coolers beyond the minimum validated time.
C. During disaster, coolers can be used to store blood products up to the maximum acceptable validated time (number of hours from start to the time right before temperature exceeds 6°C).
D. Recommended 'Recipe' for simulated blood products from Williams Laboratories:

| Blood Product | % Glycerol (by weight in water) | Volume of water per 1 liter of mix | Volume of Glycerol per 1 liter of mix* |
|---|---|---|---|
| **Plasma** | 10% | 900mL | 80mL |
| **Whole Blood** | 22% | 780mL | 176mL |
| **RBCs** | 33% | 670mL | 264mL |

* The density of Glycerol is 1.25 g/mL.

**REFERENCE**


A. AABB Standards for Blood Banks and Transfusion Service, current edition, Bethesda, MD.
B. Simulated Blood Products: 10% Glycerol in water may NOT be “One Size Fits All”. Sept 2012. Ed Sharpless, VP Product Development, Williams Laboratories. 1-800-767-7643.
C. Manufacturer Instructions.


## Associated Documents:

External Documents

Associated Documents:

SFOFCD-0227 -- BF0005 Cooler Validation

Click to Open an Associated Document

## Documents Generated:

## Document Revision History:

| | | |
|---|---|---|
| **Revision:** 14 | **Date Created:** 09/12/2005<br>**Date of Last Revision:** 05/01/2018 | **Last Approval Date:** 01/16/2018 |

| | |
|---|---|
| **Document Author:**<br>Cara H Lim/CA/KAIPERM | **Document Manager:**<br>Richard Chui/CA/KAIPERM |

## Reason for Change:

| Revision: | Sec/Para Changed | Change Made: | Date |
|---|---|---|---|
| 1 | N/A | Initial Issue of Document | |
| 2 | Approver | New Lab Director | 1/7/07 |
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|---|---|---|---|
| 3 | Approver | New Lab Director | 7/29/07 |
| 4 | Control | Blood Bank cooler keeps temperature 1-6 °C for at least 2 hours | 9/21/07 |
| 5 | Procedure | For large Surgery Coolers, remove one temperature bag every hour. | 9/4/09 |
| 6 | Approve<br>Procedure Notes | Change lab director.<br>Validate each cooler annually. | 6/1/11<br>11/11/11 |
| 7 | Approver | New Lab Director | 2/12/13 |
| 8 | Whole Document | Revised. Validate coolers for 8 units using 33% glycerol temp bags with two probes and temp indicators. Added use of Log Tag Recorders as an option. Added notes for acceptable minimum and maximum validated time. | 6/23/14 |
| 9 | Whole Document | New. Added instructions for validating Disaster cooler. | 12/15/14 |
| 10 | Procedure C.1.g.<br><br>Procedure B.2 and C.2.b | Revised emergency cooler packing instructions. Changed from placing 3 to 6 absorbent pads over plastic bag.<br>Added instructions to configure Log Tag recorders and deleted instructions to press START/MARK to stop recording. | 1/20/15 |
| 11 | Procedure B.2. NOTE<br><br>Procedure C.2.b.i.<br><br>Procedure D.2.a. | Changed from configuring Log Tag Recorders to take temperatures for at least 9 hours to 8 hours for Probe#1 and 7 hours for Probe#2.<br>Changed from configuring Log Tag Recorders from 9 hours to 24 hours.<br>Changed from Disaster Cooler maintains 1-6 °C minimum of 8 hours to 20 hours. | 6/3/15 |
| 12 | Whole Document | Reformatted.<br>Added Sonoco Thermosafe Via Blood Transport Cooler and Initial Cooler Inspection.<br>Deleted annual validation and replaced with annual cooler inspection. Annual cooler validation is not required by standards or regulations nor recommended by cooler manufacturers. | 1/2/17 |
| 13 | Procedure G. and H. | Revised the information to be filled on cooler labels. Note: The information for initial validation differs from that of the annual check. | 1/12/18 |
| 14 | Whole document<br><br>Procedure C.1. | Deleted references to Sonoco Thermosafe Coolers because coolers have been removed from use.<br>Added Note that P1 and P2 can be replaced with glycerols bags without probes and validate using probeless Log Tags. | 4/12/18<br><br>4/27/18 |

## Notification List:

## Approvals:

**First Approver's Signature**

**Name:** Maria F Serrano/CA/KAIPERM
**Title:** Transfusion Service Medical Director

**Second Approver's Signature**

**Name:** Eric Suba/CA/KAIPERM
**Title:** Chief of Pathology; CLIA Director

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**Document History Section**

Kaiser Permanente Medical Center - San Francisco
Transfusion Service

# Cooler Validation and Initial/Annual Check

| Thermometer / Temp Indicator | Manufacturer | ID# / Lot# | Calibration Date | Calibration Due Date |
|---|---|---|---|---|
| **Probe#1** | | | | |
| **Probe#2** | | | | |
| | | | | |
| | | | | |

**Year _____**

| **Cooler#** | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Date** | **Time** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** | **P1** | **P2** | **CLS** |
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| **Maximum Validated Time in hours** | | | | | | | | | | | | | | | | | | | | | | |
| **Results Acceptable Y / N** | | | | | | | | | | | | | | | | | | | | | | |

**P1 = Probe#1, P2 = Probe#2, CLS = Performing Technologist**

**Acceptable Results: Cooler maintains 1-6$^{o}$C for (i) 4 hours for True Pack T3 (ii) 8 hours for Sonoco ThermoSafe VIA (iii) 20 hours for Disaster Cooler**

**NOTE: Attach printouts of temperature records if using Log Tag Temperature Recorders.**

**Comments:**

Reviewed by: _____ Date: _____

# Cooler Validation and Initial/Annual Check

Coolers are inspected initially and thereafter, annually for wear and tear which may void the initial validation. Unacceptable cooler should be removed from use.

| **Cooler#** | Any break or tear on exterior (Y/N) | Is zipper or Velcro broken? Y/N/NA | Any break or tear on interior (Y/N) | Is foam insulation broken? Y/N/NA | Acceptable for use Y/N | Removed unacceptable cooler from use Y/N/NA | CLS Initial | Date |
|---|---|---|---|---|---|---|---|---|
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Total coolers unacceptable for use _____

Reviewed by: _____ Date: _____