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| **Cooler Validation** | | | | | |
| **Purpose** | This procedure provides instructions for the validation of the transfusion service blood product coolers. | | | | |
| **Policy Statements** | * Blood transport coolers should be validated before initial use and when there is reason to suspect a change or damage to the cooler. Validating coolers ensure that blood products are kept at an optimal temperature when the blood products are not kept in the Blood Bank storage equipment. * Cooler Verification checks will be performed every 6 months. | | | | |
| **Related**  **Documents** | [TS 12.11 Transport of Products in a Cooler](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Alloc/202862.pdf)  [TS 12.12 LogTag Temperature Recorder](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Alloc/202908.pdf) | | | | |
| **Materials** | * Calibrate LogTag data logger * Credo Blood Bank coolers and conditioned liners * Outdated blood products or Gel packs. May use in-date products if other alternatives not   available. | | | | |
| **Quality Control** | Verify the LogTag selected for use as the reference thermometer for this procedure has a current calibration to the NIST calibrated thermometer. | | | | |
| **Procedure** |  | | | | |
|  | **Step** | Action | | | |
|  | 1 | Assign a new identification letter to each Blood Transport Cooler upon receipt. | | | |
|  | 2 | Check cooler(s) for any kind of defect that would affect the ability for the cooler to hold its temperature for the lot time. | | | |
|  | 3 | Prepare the cooler for product issue per procedure [TS 12.11 Transport of Products in a Cooler](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Alloc/202862.pdf). | | | |
|  | 4 | Load the cooler to its maximum blood product volume using outdated red blood cell products, ARC gel packs, or active inventory that have been stored in a BB refrigerator at 1-6°C. | | | |
|  | 5 | Place an activated LogTag datalogger in the cooler according to [TS 12.12 LogTag Temperature Recorder](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Alloc/202908.pdf). | | | |
|  | 6 | Allow recording of the temperature within the cooler for a minimum of 12 hours. | | | |
|  | 7 | Download the datalogger temperature record to the G-drive/BB/Validation folder and print a copy of report designating the cooler identification on the report. | | | |
|  | 8 | Repeat steps 4-8 using a freshly prepared cooler and loading the cooler to its minimum blood product transport volume using gel packs or products that have been stored at1-6°C. | | | |
|  | 9 | Forward the printed LogTag reports to the Transfusion Service Technical Specialist for review and approval.   * The Technical Specialist or Lead will initiated a validation plan using form [QP 5.30](http://khan.childrensmn.org/Manuals/Lab/SOP/Qual/Proc/199354.pdf). The LogTag reports will be attached to the validation plan. | | | |
|  | 10 | Every cooler will go through a verification check every 6 months to check for cracks and excessive wear. Every cooler will be cleaned during the verification check. | | | |
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| **Interpretation** | RBC Coolers to maintain 1-6°C temperature range for a minimum for 12 hours.  Cooler(s) not meeting minimum criteria for 12 hours or fail cooler verification inspection.   1. Immediately remove cooler from service and mark as “Do Not Use”. 2. Notify section technical specialist | | | | |
| **References** | AABB Standards for Blood Banks and Transfusion Services, Current Edition | | | | |
| **Approval**  **Workflow** | Transfusion Service/Medical Director | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | | S. Cassidy | 06/05/2006 | Initial Version |
| 2 | | J. Wenzel | 1/22/2010 | Online Version, replaces TS 16.32  Added minimum and maximum load validation |
| 3 | | J. Wenzel | 05/30/2012 | Removed 6 hour coolers.  Discontinued annual calibration with implementation of calibrated LogTag dataloggers and changed policy to calibration prior to initial use and as needed.  Changed from NIST thermometer to calibrated LogTag as reference device.  Discontinued use of RT coolers. |
|  | 4 | | S. Cassidy | 08/31/2022 | Added policy statement for perform cooler verification every six month. |