



STEM CELL LABORATORY (STCL)



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Blood Component Storage and Distribution

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STCL-DIST-001

BLOOD COMPONENT STORAGE AND DISTRIBUTION

1 PURPOSE

- 1.1 To describe the process in which blood components (*ie. granulocytes, apheresis products, packed RBCs, bone marrow, cryopreserved UCB units, etc.*) are stored in the laboratory overnight, if deemed necessary, before those products are processed, cryopreserved, and/or distributed. Temperature-sensitive equipment (*ie. refrigerators, etc.*), as well as the temperature and humidity in the Stem Cell Laboratory, is monitored by the Rees Scientific Monitoring System 24 hours per day, seven days per week.

2 INTRODUCTION

- 2.1 Blood components that are not processed and/or infused/distributed on the same day of collection or receipt will be stored in the laboratory at the appropriate temperature until the product can be processed, cryopreserved or distributed for infusion or transport to another transplant facility (*ie. NMDP collections*). Blood sample tubes, collected from NMDP donors, may also be stored in the refrigerator overnight and will be distributed along with the cellular product or forwarded to the appropriate testing facility as directed.
- 2.2 Products that are stored overnight may require additional manipulation prior to cryopreservation or distribution for infusion.
- 2.3 All products, upon receipt and before distribution, should be inspected to ensure labeling is accurate, there are no visible signs of contamination, and to ensure that the product container is not compromised.
- 2.4 Products distributed for infusion will be transported in a validated shipping container.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Directors, Laboratory Manager, designated laboratory staff, and QSU are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 RBC red blood cells
- 4.2 UCB umbilical cord blood
- 4.3 NMDP National Marrow Donor Program
- 4.4 QSU Quality Systems Unit
- 4.5 OR operating room
- 4.6 STCL Stem Cell Laboratory
- 4.7 C Celsius

- 4.8 DUMC Duke University Medical Center
- 4.9 DOT Date of Transplant
- 4.10 CCBB Carolinas Cord Blood Bank
- 4.11 PICU Pediatric Intensive Care Unit
- 4.12 CHC Children's Health Center
- 4.13 ABMT Adult Bone Marrow Transplant
- 4.14 STCL Stem Cell Laboratory
- 4.15 AABB American Association for Blood Banks
- 4.16 HPC Hematopoietic Progenitor Cell

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 Monitored Refrigerator (*if applicable*)
- 6.2 Transport Container / Cooler (*if applicable*)

7 SAFETY

- 7.1 Wear all appropriate personal protective equipment when handling any/all potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coat, etc.

8 PROCEDURE

- 8.1 Storage temperatures
 - 8.1.1 RBC products are occasionally stored in the Stem Cell Laboratory overnight when there is an early bone marrow harvest case and no courier is available to pick up the cells from the blood bank (*located in Duke North Hospital*) in time for the OR case.
 - 8.1.2 Granulocytes, collected from G-primed family members for pediatric recipients, are stored in a monitored refrigerator between 1-6°C.
 - 8.1.3 Apheresis products and concurrent plasma, when necessary, are stored in the STCL a monitored refrigerator between 1-6°C.
 - 8.1.4 Bone Marrow, when necessary, is stored in the STCL overnight at room temperature, unless otherwise instructed.
 - 8.1.5 Cryopreserved UCB units (*ordered for DUMC recipients coming from the CCBB Laboratory, located in Suite 1400 of the North Pavilion*) are delivered the evening before the recipient's DOT in a charged, validated, monitored (*with data logger*) dry shipper and stored in the STCL overnight. The UCB unit is thawed the following day and a temperature tracing, printed from the data logger, is filed with in the laboratory records to reflect a storage temperature of $\leq -150^{\circ}\text{C}$.

- 8.1.6 Refer to *COMM-PAS-003 (JA1) Storage Temperature and Expiration of Cellular Products* for details regarding storage temperatures and expiration date/times assigned to cellular products.
- 8.2 Visual inspection of the product upon receipt and before distribution should include the following:
 - 8.2.1 Verification that the product is properly labeled.
 - 8.2.2 Verification that all necessary paperwork accompanied the product upon receipt and accompanies the product at the time of distribution (ie. *Summary of Donor Eligibility & Infectious Disease Testing, HPC Infusion Request Form, Infusion Form*, doctor's orders, *Cellular Product/Sample Chain-of-Custody Form*, etc.)
 - 8.2.3 Ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag (*containing*) housing the cellular product.
 - 8.2.4 Ensure there is no evidence of microbial contamination.
 - 8.2.5 If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate an event report, non-conforming product form, etc. Timely resolution of any problems identified is imperative to ensure patient care is not compromised. See *STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition, COMM-QA-042 Deviations and Investigations*.
- 8.3 Refer to the processing and/or infusion orders for each blood component stored to verify what manipulation is required, if any, before that product is processed and/or distributed. Complete the processing required, if applicable, using the appropriate standard operating procedures. Refer to *STCL-DIST-001 (JA1) Incoming NMDP Products – STCL Checklist* and *STCL-DIST-001 (JA2) Outgoing NMDP Products- STCL Checklist* if appropriate.
- 8.4 For products being distributed for infusion, the STCL technologist will coordinate a delivery time with the nursing staff in advance for each cellular products being infused so delays are minimized and patient care is not compromised.
 - 8.4.1 Recipients on N5200 – call 681-5241
 - 8.4.2 Recipients on N5100 – call 681-5151
 - 8.4.3 Recipients on N5600 (PICU) – call 681-5541
 - 8.4.4 Recipients in the CHC Clinic – call 668- 4490
 - 8.4.5 Recipients on N9200 – call 681-9241
 - 8.4.6 Recipients in the ABMT Clinic – call 668-1054 or 668-1052

NOTE: Products that are going to be distributed to an NMDP-designated courier will be coordinated by Janet Adcock, Kim Lynch, Jennifer Suitt, or other designee from the ABMT Program.

- 8.5 The technologist will contact the designated courier (*if applicable*) to alert him/her of the coordinated delivery time so arrangements can be made to pick up the product from the STCL and deliver it to the appropriate destination.
- 8.6 When the courier arrives, a technologist will select the component to be issued and complete the appropriate chain of custody form.
- 8.7 If the product has been refrigerated overnight, the technologist will reflect the date, time, etc. that the product was dispensed to the designated courier on the *Blood Component and Cellular Product Log Sheet* located on the counter top above the monitored refrigerator in the STCL.
- 8.8 If the product is going to be infused after hours, when the courier is not available, the STCL technologist may be required to deliver and distribute the product to the respective infusion.
- 8.9 The technologist will visually inspect the selected component labels for accuracy, irradiation status (*if applicable*), signs of leakage, contamination, and/or clumping. Follow all steps outlined in section 8.2.
- 8.10 A *Cellular Product-Sample Chain of Custody* form (*STCL-GEN-009 FRM2*) should be completed and signed by the STCL employee distributing the product and by the courier who is accepting the product at the time of distribution.
- 8.11 The component will then be placed inside a transport container validated to maintain room temperature, accompanied with *STCL-FORM-056 Cellular Therapy Infusion Request Form*, *STCL-SOP-050 Infusion Form* (except for granulocyte products), and *APBMT-COMM-001 FRM2 Summary of Donor Eligibility & Infectious Disease Testing* and taken to the respective infusion site.
- 8.12 Upon delivery of the cellular product to the infusion site, the courier delivering the product, and the nurse accepting the product, will date, time, and sign (*as the "Delivery Person's Signature" and the "Receipt Person's Signature"*) on the top two lines at the bottom of the *STCL-FORM-056 Cellular Therapy Infusion Request Form*. An original and a copy of this form will be provided to the courier by the laboratory staff. Both copies of the form should be signed by the courier and nurse who accepts the product.
- 8.13 The copy of the form will be left at the infusion site along with the product that was delivered; the **original** signed copy of the form will be returned to the STCL and will serve as documentation reflecting the date/time the product was delivered to the infusion site. This form will be filed in the recipient's laboratory file along with all other applicable documents.
- 8.14 Maintain all laboratory records as outlined in the Records Management procedure and in the Records Retention schedules.

9 RELATED DOCUMENTS/FORMS

- 9.1 Blood Component Storage and Distribution Log
- 9.2 STCL-GEN-015 Records Management
- 9.3 STCL-GEN-009 Packaging and Transporting Non-Frozen Cellular Products Locally

- 9.4 STCL-GEN-009 FRM1 Cellular Product Chain of Custody
- 9.5 STCL-GEN-009 FRM2 Cellular Product-Sample Chain of Custody
- 9.6 COMM-PAS-002 Records Retention Schedule
- 9.7 STCL-DIST-001 (FRM 1) HPC Return from Issue Form
- 9.8 STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition
- 9.9 STCL-QA-007 (FRM 1) Non-Conforming Products form
- 9.10 STCL-DIST-001 (JA1) Incoming NMDP Products – STCL Checklist
- 9.11 STCL-DIST-001 (JA2) Outgoing NMDP Products – STCL Checklist
- 9.12 COMM-PAS-003 Labeling Cellular Therapy Products
- 9.13 COMM-PAS-003 (JA1) Storage Temperature and Expiration of Cellular Products
- 9.14 STCL-SOP-045 (FRM1) Record of Discard
- 9.15 STCL-SOP-050 Infusion Form
- 9.16 STCL-FORM-056 Cellular Therapy Infusion Request Form
- 9.17 APBMT-COMM-001 FRM2 Summary of Donor Eligibility & Infectious Disease Testing
- 9.18 COMM-QA-042 Deviations and Investigations
- 9.19 COMM-QA-042 (FRM1) Deviation and Investigation Report

10 REFERENCES

- 10.1 AABB Technical Manual, *Current edition*
- 10.2 Standards for Blood Banks and Transfusion Services, *Current Edition*
- 10.3 NMDP-related Standard Operating Procedures, *Current Edition*

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
06	Barbara Waters-Pick	<ul style="list-style-type: none"> • Changed temperature range from 1 - 10°C to 1-6°C in Sections 8.1.2 and 8.1.3 • Section 8.4 removed Jackie McPherson's name and added other ABMT contact names in the NOTE. • Section 9.2 removed <i>(FRM2) Cellular Product /Sample Chain-of-Custody Form</i> which was originally listed in 9.6 • Updated 10.1 and 10.2 to reflect “current edition” of AABB Technical Manual, Standards for Blood Banks and Transfusion Services, and NMDP-related SOPs.

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STCL-DIST-001 Blood Component Storage and Distribution**Author**

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