DukeMedicine

Division of Cellular Therapy

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Adult Apheresis/Photopheresis Supply Management

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ABMT-GEN-019
ADULT APHERESIS/PHOTOPHERESIS SUPPLY MANAGEMENT

1 PURPOSE

1.1 This standard operating procedure (SOP) describes the steps used by trained apheresis staff to receive, inspect, document, and store supplies for apheresis and photopheresis in the Adult Blood and Marrow Transplant (ABMT) Clinic.

2 INTRODUCTION

2.1 As part of the quality program for the collection of cellular therapy products, the ABMT clinic and the Clinical Quality Program (CQP) must ensure that all apheresis and photopheresis supplies and services used consistently meet specified requirements. This is accomplished by an initial qualification,regular evaluation of suppliers, and by continuous monitoring of critical supplies received by the ABMT clinic. This SOP defines the process for assuring and monitoring the quality of critical supplies, from receipt to use.

2.2 The ABMT apheresis staff will document receipt of all supplies in the Apheresis Supply Management Record, which is kept in the ABMT supply storage room. This record will include product identification, receiver information, receipt date, lot numbers, quantity received, expiration dates, visual inspection, and, if applicable, a package insert and a certificate of analysis (COA) or certificate of compliance (COC).

2.3 The ABMT apheresis staff is responsible for reviewing the manufacturer's package insert for changes. If there are changes that require revisions to the procedure, the Apheresis Coordinator/designee will be notified. The appropriate revisions will be made to the procedures, apheresis staff training will occur, and the changes will be implemented.

2.4 The ABMT apheresis staff is responsible for ensuring that the supplies are used in a first in, first out order.

3 SCOPE AND RESPONSIBILITIES

3.1 Apheresis Staff are responsible for:

3.1.1 Accurately documenting, inspecting, and storing supplies used in the ABMT clinic.

3.1.2 Alerting the Apheresis Coordinator/designee of any discrepancies discovered during this process.

3.1.3 Maintaining current copies of package inserts and COA/COCs, if appropriate.

3.1.4 Retaining outdated copies of these documents and alerting the clinical apheresis coordinator/designee of new reversion of these documents.

3.2 Apheresis Coordinator/designee is responsible for:

3.2.1 Resolving discrepancies that are discovered.

3.2.2 Reviewing revised package inserts, alerting apheresis staff of any changes that affect the use of the supply, and/or initiating revisions to procedures and/or training apheresis staff.

3.2.3 Facilitating the receipt of supplies, required COAs/COCs, and ensuring that certificates are on file.

3.3 Clinical Quality Program (CQP) personnel is responsible for:

3.3.1 Reviewing, inspecting, and approving/rejecting all incoming supplies.

3.3.2 Reviewing all package inserts logs and COAs/COCs.

3.4 Duke Hospital Material Management personnel is responsible for:

3.4.1 Delivering the appropriate supplies, as needed.

3.4.2 Placing delivered supplies in designated area in the ABMT supply room.

3.4.3 Placing a "Quarantine" sign on the supply.

4 DEFINITIONS/ACRONYMS

4.1 ABMT: Adult Blood and Marrow Transplant

4.2 ACD-A: Acid Citrate Dextrose Formula A

4.3 COA: Certificate of Analysis

4.4 COC: Certificate of Compliance

4.5 L: Liter

4.6 mL: Microliter

4.7 NS: Normal Saline

4.8 PDF: Portable Document File

4.9 CQP: Clinical Quality Program

4.10 SOP: Standard Operating Procedure

5 MATERIALS

5.1 Apheresis Supply Management Record

5.2 Green Sign for Release (OK to Use)

5.3 Green Stickers for release (OK to Use)

5.4 Red Sign for Quarantine (do not use)

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Apheresis and photopheresis supplies will be delivered to the ABMT supply storage room by materials management personnel.

8.2 The supplies will be placed in a designated quarantine supply area by materials management personnel. They will place a red "**Quarantine**" sign, which is located on the apheresis cart, to identify the new supplies delivered.

8.3 If the supplies are delivered in a box, apheresis staff will unbox and inspect the supplies. They will place a red "**Quarantine**" sign on them.

8.4 The apheresis staff will visually inspect all delivered supplies for damage, evidence of contamination or leakage, and/or abnormal color/cloudiness that may compromise the contents.

8.5 If there are any unacceptable supplies, notify the Apheresis Coordinator/designee and initiate the ABMT-GEN-019 FRM3 *Unacceptable Supply Corrective Action Log*.

8.5.1 Store the item in the quarantine supply area in the ABMT supply storage room until the problem is resolved (product replaced, credit issued, etc.).

8.6 The apheresis staff will record the following supply information in the Apheresis Supply Management Record using the ABMT-GEN-019 FRM1 *Material Acceptance Specification Quality Checklist*:

8.6.1 Initials of staff signing in supply

8.6.2 Date of receipt

8.6.3 Lot number(s)

8.6.4 Expiration date, if applicable

8.6.5 Quantity received

8.6.6 Matches packing slip, if applicable

8.6.7 Passes visual inspection

8.6.8 Product insert included, if applicable

8.6.8.1 If a product insert is delivered, verify that the version date of the new package insert is the same as the package insert on file in the Apheresis Supply Management Record, under the appropriate product. Discard the product insert if it is.

8.6.8.2 If the product insert is a new version:

8.6.8.2.1 Record that version date and number has been changed on the ABMT-GEN-019 FRM2 *Package Insert Review Log.*

8.6.8.2.2 Notify Apheresis Coordinator/designee.

8.6.8.2.3 Initial and Date.

8.6.8.2.4 The Apheresis Coordinator/designee will review for changes.

8.6.8.2.5 Initiate a procedural change appropriate to the new version to the procedure and train staff.

8.6.8.2.6 Once changes have been implemented, place the new version in front of old one in the Apheresis Supply Management Record.

8.6.8.2.7 CQP will record initials and dates after Apheresis Coordinator/designee confirms required change and/or training are implemented.

8.6.9 Certificate of Analysis (COA) and/or Certificate of Compliance (COC)

8.6.9.1 To obtain the COA for ACD-A **from Terumo BCT**:

8.6.9.1.1 Go to website https://www.terumobct.com/certificates

8.6.9.1.2 Enter the Lot # and press ENTER. The Portable Document File (PDF) will appear. Clink on the PDF and print the document.

8.6.9.1.3 Place the printed copy of the PDF in the Apheresis Supply Management Record under the COA section.

8.6.9.2 To obtain the COA for NS & ACD-A **from Baxter/Fenwal**:

8.6.9.2.1 ACD-A solution available in 500 mL or 1000 mL bags

8.6.9.2.2 NS bags available in 500 mL or 1000 mL

8.6.9.2.3 Go to website http://certificates.freseniuskabiusa.com

8.6.9.2.4 Scroll down to the bottom and enter the lot # under "**Certificate of Analysis**". If there is one, the PDF will appear. If not, you need to follow the steps below:

8.6.9.2.5 Email:

MPCS_COA_Requests@baxter.com and copy the Apheresis Coordinator/designee.

8.6.9.2.6 Provide the supply's name, lot #, and the expiration date.

8.6.9.2.7 Print the supplied COA and place in the Adult Supply Management Record under the COA section.

8.6.9.3 To obtain the COA for Mallinckrodt Pharmaceuticals photopheresis kits:

8.6.9.3.1 Email Mallinckrodt Pharmaceutical's Customer Care Specialist and copy the Apheresis Coordinator/designee.

8.6.9.3.2 Provide the supply's name, lot #, and the expiration date.

8.6.9.3.3 Print the supplied COA and place in the Adult Supply Management Record under the COA section.

8.6.9.4 To obtain the COC for Terumo BCT apheresis kits:

8.6.9.4.1 Go to website https://www.terumobct.com/certificates

8.6.9.4.2 Enter the Lot # and press ENTER. The Portable Document File (PDF) will appear. Clink on the PDF and print the document.

8.6.9.4.3 Place the printed copy of the PDF in the Apheresis Supply Management Record under the COC section.

8.7 CQP personnel will inspect and verify that the supplies are acceptable, and that all applicable documentation is complete. After inspection and sign-off, CQP personnel will place an "**OK to Use**" sign on the supplies.

8.8 The apheresis staff will rotate the new stock to ensure "first in first out rotation" of supplies.

8.9 Storage and Disposal

8.9.1 The ABMT supply storage room and apheresis storage area is where the apheresis/photopheresis supplies are stored.

8.9.2 Apheresis and photopheresis supplies must be stored at appropriate temperature and humidity ranges in a safe, sanitary, and orderly manner. The temperature and humidity will be recorded each day in these areas by the charge nurse/designee. Refer to ABMT-GEN-021 *Monitoring Temperature and Humidity*.

8.9.3 All outdated supplies will be appropriately disposed of according to Duke Hospital policy.

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-GEN-019 FRM1 Material Acceptance Specification Quality Checklist

9.2 ABMT-GEN-019 FRM2 Package Insert Review Log

9.3 ABMT-GEN-019 FRM3 Unacceptable Supply Corrective Action Log

9.4 ABMT-GEN-021 Monitoring Temperature and Humidity

10 REFERENCES

10.1 American Association of Blood Banks (AABB). Standards for Cellular Therapy Services. 9th Edition.

10.2 Food and Drug Administration (FDA). Code of Federal Regulations (CFR), Title 21.

10.3 Foundation for the Accreditation of Cellular Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. 7th Edition.

11 REVISION HISTORY

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12	M. Ritt	• Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP)

Signature Manifest

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Author

Name/Signature	Title	Date	Meaning/Reason
Melissa Ritt (MSR68)	GMP, Quality Assurance Associate I	21 Apr 2025, 11:27:23 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		22 Apr 2025, 04:46:13 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Stefanie Sarantopoulos (SS595)	Professor of Medicine	22 Apr 2025, 06:03:23 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	23 Apr 2025, 01:09:30 PM	Approved

Document Release

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Amy McKoy (ACM93)	Document Control Specialist	24 Apr 2025, 10:14:11 AM	Approved