**DOCUMENT NUMBER:** ABMT-GEN-019

**DOCUMENT TITLE:**
Adult Apheresis/Photopheresis Supply Management

**DOCUMENT NOTES:**

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**Document Information**

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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 personnel 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 a Quality Program for the production of cellular products, the ABMT Clinic must ensure that all apheresis and photopheresis supplies and services used consistently meet specified requirements. This is accomplished by initial qualification and regular evaluation of suppliers, and by continuous monitoring of critical supplies received by the ABMT Clinic. SOP defines the process for assuring and monitoring the quality of critical supplies, from receipt to use.

2.2 The ABMT Apheresis coordinator/designee will document receipt of all supplies in the Apheresis Supply Notebook, which is kept on the Apheresis cart. This record will include stock identification, lot numbers, quantity received, expiration dates and, if applicable, a package insert and a Certificate of Analysis (COA) or Certificate of Conformance (COC).

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

2.4 The ABMT Apheresis coordinator/designee is responsible for ensuring that the supplies are used in a first in, first out order.

3 SCOPE AND RESPONSIBILITIES
3.1 Apheresis coordinator/designee, QSU personnel, Duke Hospital Material Management personnel.

3.2 The Apheresis coordinator/designee is responsible for:
3.2.1 The accurate inspection, documentation, and storage of supplies received for apheresis and photopheresis.
3.2.2 Maintaining current copies of package inserts, Certificates of Analysis (COA), and retaining outdated copies of same.
3.2.3 The QSU personnel are responsible for inspecting and releasing the supplies for use.

4 DEFINITIONS/ACRONYMS
4.1 SOP: Standard Operating Procedure
4.2 ABMT: Adult Bone Marrow Transplant
4.3 COA: Certificate of Analysis
4.4 COC: Certificate of Conformance
4.5 QA: Quality Assurance
4.6 NS: Normal Saline
4.7 ACD-A: Acid citrate dextrose formula A
4.8 PDF: Portable Document File
4.9 QSU: Quality Service Unit

5 MATERIALS
5.1 ABMT Supply Notebook
5.2 Red Sign for Quarantine (do not use)
5.3 Green Sign for Release (OK to Use)
5.4 Green Stickers for release (OK to 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 Clinic supply room by materials management personnel. Supplies shipped directly from the supplier will be delivered directly to the ABMT Clinic.

8.2 The apheresis supplies will be placed in a designated 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 The apheresis and photopheresis kits will be placed in a designated area by materials management personnel. The Apheresis coordinator/designee will unbox and inspect the kits. They will place a red “Quarantine” sign on them.

8.4 The Apheresis coordinator/designee will inspect all delivered supplies for damage, contamination, leakage, abnormal color, cloudiness.

8.5 If there are any unacceptable supplies (see 8.4 above), the Unacceptable Supply Corrective Action Log will be completed.

8.6 The Apheresis coordinator/designee will record the following supply information in the Apheresis Supply Notebook:
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
   8.6.7.1 Product insert included, if applicable
   8.6.7.2 If a product insert is delivered, verify that the revision date of the new package insert is the same as the package insert on file in the Apheresis Supply Notebook, under the appropriate product. Discard the product insert if it is.
   8.6.7.3 If the product insert is a new version, record new version on the Package Insert Review Log.
      8.6.7.3.1 Review the insert for changes. If changes are identified, initiate appropriate revisions to the procedure and staff training.
      8.6.7.3.2 Place the new version in front of old one in the Apheresis Supply Notebook. The supply cannot be used until the procedure change is implemented and staff is trained.
8.6.8 COA, if applicable (NS and ACD-A):
   8.6.8.1 To obtain the COA for ACD-A and Normal Saline from Fenwal/Baxter:
       Go to website http://certificates.freseniuskabiusa.com/pages/CHome.aspx. Scroll to bottom of page. Under Certificates of Analysis, enter the lot#, and hit enter. Print PDF file of the COA and place in Apheresis Supply Notebook, ACD-A and/or Normal Saline, COA section.
8.7 QA personnel will inspect and verify that the supplies are acceptable and that all applicable documentation is complete. After inspection and sign-off, QA personnel will place an “OK to Use” sign on the supplies.
8.8 The Apheresis coordinator/designee will rotate the new stock to ensure “first in first out rotation” of supplies.
8.9 Storage and Disposal
   8.9.1 Apheresis and photopheresis supplies must be stored at appropriate temperature and humidity ranges in a safe, sanitary and orderly manner.
   8.9.2 The ABMT Clinic supply room and apheresis suite are the areas where the apheresis/photopheresis supplies are stored. The temperature and humidity will be recorded each day in these areas by the charge nurse/designee.
8.9.3 Appropriately dispose of all outdated supplies will be disposed of according to Duke Hospital policy.

9 RELATED DOCUMENTS/FORMS
  9.1 ABMT-GEN-019 FRM2 Package Insert Review Log
  9.2 ABMT-GEN-019 FRM3 Unacceptable Supply Corrective Action Log
  9.3 ABMT-GEN-019 FRM1 Material Acceptance Specification/Quality Checklist

10 REFERENCES
  10.1 AABB Standards for Hematopoietic Progenitor Cell Services, current edition
  10.2 FDA Code of Federal Regulations, Title 21
  10.3 FACT-JACIE Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation.

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<tr>
<td>08</td>
<td>M. Christen</td>
<td>Removed Section(s) 8.6.8.1 and 8.6.8.3, which are no longer current practice.</td>
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<td>Updated *New Section 8.6.8.1 to include current practices of obtaining COA from Fenwal/Baxter</td>
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# ABMT-GEN-019 Adult Apheresis/Photopheresis Supply Management

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## Management

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## Medical Director

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