

**DukeMedicine****Division of Cellular Therapy****DOCUMENT NUMBER:** ABMT-COLL-010**DOCUMENT TITLE:**

Directed-Donor Granulocyte Collection

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## **ABMT-COLL-010**

### **DIRECTED-DONOR GRANULOCYTE COLLECTION**

#### **1 PURPOSE**

- 1.1 To describe the procedure and supplies required for leukapheresis using the Terumo Spectra Optia Apheresis System (Optia). This procedure is followed for the collection of granulocytes/polymorphonuclear (PMN) cells. For information on using the Optia System, refer to the Spectra Optia® Apheresis System Operator's Manual.

#### **2 INTRODUCTION**

- 2.1 The American Association of Blood Banks (AABB) and Food and Drug Administration (FDA) have established standards for the safe collection of blood products. These standards will be maintained during the care of all donors undergoing granulocyte collection.
- 2.2 Bone marrow (BM) or peripheral blood stem cell (PBSC) transplant patients may become septic during the period of pancytopenia following high dose chemotherapy. If patients remain septic despite the administration of antibiotics, a request may be made to collect granulocytes from a related donor.
- 2.3 Either peripheral veins or central lines will be used for vascular access. Apheresis collections are performed in the Adult Blood and Marrow Transplant (ABMT) Clinic in treatment chairs or beds that are separated by curtains to prevent improper labeling, mix-ups, contamination or cross-contamination of cellular products. Overhead lighting and adequate ventilation is present and cellular products are collected at room temperature in the ABMT Clinic. Sinks are present in each treatment room for hand hygiene.
- 2.4 North Pavilion pharmacy is available to dispense apheresis related medications, if applicable.
- 2.5 Duke Life Flight is available to response to emergencies and to transport patients to Duke North emergency room or 9200 inpatient ABMT. Emergency equipment including code cart, AED, suction and oxygen are available and in close proximity to the apheresis area.
- 2.6 Apheresis supplies in the ABMT Clinic are supplied by Duke Materials Management and stored at room temperature in the ABMT Clinic Storeroom and in the Apheresis Area of the Treatment Room. Refer to the procedures: ABMT-GEN-019 *Adult Apheresis/Photopheresis Supply Management* and ABMT-GEN-021 *Monitoring Temperature and Humidity*.
- 2.7 Labeling the cellular product and plasma bags is completed prior to the end of the apheresis. Refer to COMM-PAS-003 *Labeling Cellular Therapy Products*. Labels will be double checked by two apheresis nurses and documentation will be done on the Apheresis Checklist.

- 2.8 Granulocytes are difficult to separate from Red Blood Cells (RBCs) in a centrifuge because the specific gravity of both cells types are similar. Using hydroxyethyl starch (HES) causes a stacking formation of the RBCs which forces the granulocytes out of the RBC layer, making them easier to collect.
- 2.9 Starch is a volume expander and has different effects on patients depending on their condition. It is not uncommon for the patient's hematocrit (HCT) to decrease during the procedure, not just because of the collection of RBC but because of the effects of volume expansion.
- 2.10 The recommended anticoagulant (AC) ratio for procedure is 13:1, which provides optimal separation of the RBC from the granulocytes.
- 2.11 Granulocytes will be irradiated but **NOT** filtered by leuko-reduction filter for transfusion.
- 2.12 In emergency situation, the granulocyte product may be transfused prior to receiving the results of the infectious disease testing. See APBMT-COMM-001 FRM3 *Summary of Donor Eligibility and Infectious Disease Testing (ABMT)*.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 The apheresis nurse is responsible for the collection of PNC products using the Optia.
- 3.2 The apheresis nurse, ABMT attending apheresis physician, and Advance Practice Providers (APPs) are responsible for patient/donor care during apheresis.
- 3.3 The Stem Cell Lab (STCL) is responsible for processing the granulocytes, red blood cell or plasma depleting as indicated.

### **4 DEFINITION/ACRONYMS**

- 4.1 AABB: American Association of Blood Banks
- 4.2 ABMT: Adult Blood and Marrow Transplant
- 4.3 ABO: Blood groups A, B, O and AB
- 4.4 AC: Anticoagulant
- 4.5 APP: Advance Practice Provider
- 4.6 BM: Bone Marrow
- 4.7 BMT: Blood and Marrow Transplant
- 4.8 CBC: Complete Blood Count
- 4.9 CMP: Complete Metabolic Panel
- 4.10 CVC: Central Venous Catheter
- 4.11 FDA: Food and Drug Administration
- 4.12 G-CSF: Granulocyte Colony Stimulating Factor
- 4.13 HCT: Hematocrit

- 4.14 HES: Hydroxyethyl Starch
- 4.15 IV: Intravenous
- 4.16 Min: Minute
- 4.17 mL: Milliliter
- 4.18 PBSC: Peripheral Blood Stem Cell
- 4.19 PMN: Polymorphonuclear (Granulocyte Collection)
- 4.20 PPE: Personal Protective Equipment
- 4.21 RBC: Red Blood Cell
- 4.22 SOP: Standard Operating Procedures
- 4.23 STCL: Stem Cell Laboratory
- 4.24 SQ: Subcutaneous
- 4.25 WBC: White Blood Cell

## 5 MATERIALS

- 5.1 Optia IDL Set
- 5.2 Anticoagulant Connection Adapter
- 5.3 0.9% sodium chloride injection USP 1000 mL bag
- 5.4 500 mL bag/bottle of 6% Hydroxyethyl Starch
- 5.5 30 mL vial of Trisodium citrate
- 5.6 Blood warmer tubing
- 5.7 Triple lumen extension set, as needed
- 5.8 Alcohol Preps, Gloves, Mask
- 5.9 Heparin flush syringes, as needed
- 5.10 0.9% saline flush syringes, as needed
- 5.11 Paperwork:
  - 5.11.1 ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*
  - 5.11.2 Product base labels, tie tags and tie tag labels
  - 5.11.3 International Society for Blood Transfusion (ISBT-128) bar code labels
  - 5.11.4 APBMT-GEN-001 FRM3 *Physician Leukapheresis Procedure Note FRM3* (if applicable)
  - 5.11.5 APBMT-COMM-003 *Interim Donor History Questionnaire*
  - 5.11.6 APBMT-COMM-002 *Adult Donor Health History Questionnaire* for allogeneic/NMDP donors only (if applicable)
  - 5.11.7 ABMT-COLL-001 FRM2 *Apheresis Checklist FRM2*
  - 5.11.8 STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1*

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- 5.11.9 APBMT-COMM-030 FRM1 *Adverse Event Form* (if applicable)
- 5.11.10 APBMT-COMM-001 FRM3 *Summary of Donor Eligibility and Infectious Disease Testing (ABMT)*
- 5.11.11 STCL-FORM-041 *Doctors Orders Adult Stem Cell Transplant Program*

## **6 EQUIPMENT**

- 6.1 Optia Apheresis System
- 6.2 Astotherm Blood Warmer

## **7 SAFETY**

- 7.1 Follow all safety related Standard Operating Procedures (SOPs) and wear all required Personal Protective Equipment (PPE) when handling blood and body fluids. PPE includes but is not limited to gloves, surgical mask, face shield or goggles. Hand hygiene performed before and after patient contact and prior to tubing set up. All tubing connections will be made using aseptic technique.

## **8 PROCEDURE**

- 8.1 Priming of donors:
  - 8.1.1 Donors may be stimulated prior to donation with Granulocyte colony stimulating factors (G-CSF). G-CSF (cytokines) are administered under the supervision of a licensed physician/designee experienced in the management of persons receiving these agents. G-CSF is used to increase the number of circulating granulocytes. Cytokines are generally administered by the subcutaneous (SQ) route a minimum of one hour to a max of 12-16 hours prior to the next planned procedure. If the patient is healthy and well, with no new issues, administration may be performed by either a home health nurse or the donor/family member. Training will be provided prior to start of procedure.
  - 8.1.2 To further enhance the collection of granulocytes from the donor's red blood cell (RBC) layer, 6% Hydroxyethyl Starch (HES) will be used during the collection. It is metabolized by the body slowly and is also a volume expander. Potential donors should be questioned about a history of headaches, heart disease, and hypertension. A pregnant donor should be deferred from donation.
- 8.2 Donor Screening:
  - 8.2.1 Patients are evaluated to determine whether they are candidates for donation. Donors are evaluated through donor screening questionnaires and donor testing for risk factors. Completion of the APBMT-COMM-002 *Adult Donor Health History Questionnaire*. Donor testing is performed and results will cover the entire donation period of 30 days. Refer to APBMT-COMM-001 *Donor Selection, Evaluation, and Management*.

- 8.2.2 Granulocyte donors have blood counts checked regularly.
  - 8.2.2.1 If the donor hemoglobin (Hgb) is < 10.5 gm/dL, check Hgb the day before the next planned collection. If Hgb is 10 gm/dL, proceed with the collection the next day without waiting for labs that are drawn at the time of collection.
  - 8.2.2.2 If the Hgb is < 10gm/dL, skip collection and recheck the day before the next planned collection.
  - 8.2.2.3 Check labs at the time of each collection to determine future collections.

### 8.3 Pre-Collection:

**NOTE:** Procedural steps prompted by the machine in the order shown on the screen. Exact order of other steps in procedure can vary.

- 8.3.1 Review the STCL-FORM-041 *Doctors Orders Adult Stem Cell Transplant Program*. If the order is not in the patient's chart, contact the Stem Cell Lab.
- 8.3.2 Identify the patient by asking them to state their name and date of birth. Ensure that the name and birthdate on the patient identification wristband match.
- 8.3.3 Patient weight will be obtained daily by ABMT nursing staff. Patient identification labels can be printed from the electronic medical record (EMR) and attached to the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*.
- 8.3.4 Complete the APBMT-COMM-003 *Interim Donor History Questionnaire* and review medication reconciliation on each day of donation. Vital signs taken and recorded pre-, mid-, and post-apheresis on the ABMT-COLL-019 *Optia CMNC Run Sheet* or documented in the EMR. Vital signs may be taken more frequently, as needed.
- 8.3.5 The apheresis nurse collects blood samples from the CVC per hospital policy. For peripheral intravenous (PIV) access and blood draw, refer to ABMT-COLL-011 *Venipuncture Procedure*.
- 8.3.6 Notify the apheresis attending physician of any abnormal values or findings and document the outcome of the decision regarding acceptability of the donor. Refer to the donor selection guidelines above for hemoglobin requirements.

### 8.4 Collection:

**NOTE:** Procedural steps prompted by the machine in the order shown on the screen. Exact order of other steps in procedure can vary.

- 8.4.1 Verify recorded lot numbers and expiration dates of apheresis related supplies on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*. Record any additional supply lot numbers and expiration dates used during the collection in the additional space provided.

- 8.4.2 Attach the base labels to the cellular product bag. Double check all labels for accuracy with a second nurse. Refer to COMM-PAS-003 *Labelling Cellular Therapy Products*. Ensure labeling completion before disconnecting the products from the machine at end of procedure.
- 8.4.3 Select the granulocyte collection procedure (PMN). The Optia Apheresis System will default to use HES on the configuration screen. You may change the values on the run screen to optimize the collection. **NOTE:** You must touch **Confirm** to save the settings.
- 8.4.4 Trisodium citrate is an anticoagulant. Add 30-40 mLs of Trisodium citrate to the HES. Mix the Trisodium citrate very well with the starch.
- 8.4.5 Properly loading the tubing set is one of the most important steps of the procedure. Attach the Anticoagulant Connection Adapter to the Correct Connect apheresis Optia IDL set. Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection* and Spectra Optia System PMN Procedure Handbook.
- 8.4.6 Enter and confirm patient and procedure data. Review and confirm run values. Prime the inlet and return lines, connect the patient, and start the run. Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection* and Spectra Optia System PMN Procedure Handbook.
- 8.4.7 View run information on the main screen. **HES: YES** indicates the use of starch. The default collect pump flow rate is 7.5% of the inlet pump flow rate. This allows for the collection of granulocytes to be maximized at any inlet pump flow rate. The length of the procedure is usually such that one bottle of starch is used.
- 8.4.8 Wait for the interface to be established and then consider changing the collection preference. The default starting collection preference is 60. Lower the collection preference to achieve the appropriate Hct. Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection* and the Spectra Optia System PMN Procedure Handbook.
- 8.4.9 Monitor the collection line and the door for excessive RBC loss.
- 8.5 Completion of the Collection:
  - 8.5.1 Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection* and Spectra Optia System PMN Procedure Handbook for completing the procedure.
  - 8.5.2 Review the procedure summary data.
    - 8.5.2.1 Review the data on page 1 of the procedure summary.
    - 8.5.2.2 Touch **Next Page**.
    - 8.5.2.3 Review the data on page 2 of the procedure summary.
- 8.6 Removing the Tubing Set and Cleaning of Machine



- 8.6.1 Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection* and Spectra Optia System PMN Procedure Handbook for completing the procedure.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 ABMT-COLL-001 FRM2 Apheresis Checklist
- 9.2 ABMT-COLL-011 Venipuncture Procedure
- 9.3 ABMT-COLL-019 Adult Apheresis/Photopheresis Supply Management
- 9.4 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet
- 9.5 ABMT-GEN-019 Adult Apheresis/Photopheresis Supply Management
- 9.6 APBMT-COMM-003 Interim Donor History Questionnaire
- 9.7 APBMT-COMM-002 Adult Donor Health History Questionnaire
- 9.8 APBMT-COMM-001 FRM3 Summary of Donor Eligibility and Infectious Disease Testing (ABMT)
- 9.9 APBMT-COMM-030 FRM1 Adverse Event Form
- 9.10 APBMT-COMM-035 Detection & Management of Adverse Events
- 9.11 APBMT-GEN-001 FRM3 Physician Leukapheresis Procedure Note
- 9.12 COMM-PAS-003 Labelling Cellular Therapy Products
- 9.13 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
- 9.14 STCL-FORM-041 Doctors Orders Adult Stem Cell Transplant Program
- 9.15 Duke Hospital Intravenous (IV) Therapy Protocol (Adult)

## 10 REFERENCE

- 10.1 Spectra Optia System PMN Procedure Handbook.

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	M. Christen	Section 5: Added the Anticoagulant Connection Adapter to the Materials section. Section 8: Added the Anticoagulant Connection Adapter to the Procedure section.



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