



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Spectra Optia® Apheresis System Granulocyte (PMN) Collection Procedure

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SPECTRA OPTIA® APHERESIS SYSTEM GRANULOCYTE (PMN) COLLECTION PROCEDURE

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 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 patient remains 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 collection are performed in either the Adult Blood and Marrow Transplant (ABMT) clinic or the Children's Health Center (CHC). All collections are performed in chairs or beds that are separated by at least a curtain to prevent improper labeling, mix-ups, contamination or cross-contamination of cellular products. Overhead lighting and adequate ventilation is present and cellular products are collection at room temperature in the ABMT clinic or the CHC. Sinks are present in each collection area for hand hygiene.
- 2.4 North Pavilion (NP) and/or CHC pharmacy is available to dispense apheresis related medication, if applicable.
- 2.5 Duke Life Flight is available to respond to emergencies and to transport patient to Duke North emergency room if at NP. Duke rapid response teams are available for emergent situations in the CHC. Emergency equipment including code cart, AED, suction and oxygen are available and in close proximity to the collection area.
- 2.6 Apheresis supplies in the ABMT clinic and for CHC procedures are supplied by Duke Materials Management and stored at room temperature in the ABMT Clinic Supply Room. Refer to the procedures: ABMT-GEN-019 *Adult Apheresis/Photopheresis Supply Management*, PBMT-EQUIP-003 *Pediatric Apheresis Supply Management*, PBMT-COLL-015 *Monitoring Temperature and Humidity*, and ABMT-GEN-021 *Monitoring Temperature and Humidity*.
- 2.7 Labeling the cellular product and plasma bag, if needed is completed prior to the end of the collection. Refer to COMM-PAS-003 *Labeling Cellular Therapy Products*. Labels will be double check by either two apheresis nurse, pediatric

care nurse, and/or pediatric physician. Documentation of the double check will be documented on either the ABMT-COLL-001 FRM2 *Apheresis Checklist*, the PBMT-COLL-018 *Pediatric Apheresis Checklist*, and/or the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.

- 2.8 Granulocytes are difficult to separate from Red Blood Cells (RBCs) in a centrifuge because the specific gravity of both cell 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 the patient depending on their condition. It is not uncommon for the patient's hematocrit (HCT) to decrease during the collection, not just because the collection of RBCs but because of the effects of the volume expansion.
- 2.10 The recommended anticoagulant (AC) ratio for the collection is 13:1, which provides the optimal separation of the RBCs from the granulocytes.
- 2.11 Granulocytes will be irradiated but **NOT** filtered by leuko-reduction filters for transfusion.
- 2.12 In emergent situations, the granulocyte product may be transfused prior to receiving the results of the infectious disease testing. See APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The apheresis nurse is responsible for the collection of PMN products using the Optia.
- 3.2 The apheresis nurse, ABMT attending apheresis physician, PBMT attending apheresis physician, and Advance Practice Providers (APPs) are responsible for the patient/donor care during the collection.
- 3.3 The Stem Cell Lab (STCL) is responsible for processing the PMN product, which may include RBC and/or plasma depleting as indicated.

4 DEFINITIONS/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 CBC: Complete Blood Count
- 4.8 CHC: Children's Health Center
- 4.9 CVC: Central Venous Catheter
- 4.10 EMR: Electronic Medical Record

- 4.11 FDA: Food and Drug Administration
- 4.12 G-CSF: Granulocyte Colony Stimulating Factor
- 4.13 gm/dL: Gram per Deciliter
- 4.14 HCT: Hematocrit
- 4.15 HES: Hydroxyethyl Starch
- 4.16 HgB: Hemoglobin
- 4.17 mL: Milliliter
- 4.18 PBSC: Peripheral Blood Stem Cell
- 4.19 PBMT: Pediatric Blood and Marrow Transplant
- 4.20 PMN: Granulocyte/Polymorphonuclear Cell
- 4.21 PPE: Personal Protective Equipment
- 4.22 RBC: Red Blood Cell
- 4.23 SOP: Standard Operating Procedure
- 4.24 STCL: Stem Cell Laboratory
- 4.25 SQ: Subcutaneous

5 MATERIALS

- 5.1 Optia IDL Set
- 5.2 Anticoagulant Connection Adapter
- 5.3 0.9% sodium chloride injection USP 1000 milliliter (mL) bag
- 5.4 6% Hydroxyethyl Starch (HES) 500 mL bag
- 5.5 Trisodium Citrate 30 mL vial
- 5.6 Blood warming tubing, if applicable
- 5.7 Triple lumen extension set, as needed
- 5.8 Paperwork:
 - 5.8.1 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet, if applicable
 - 5.8.2 PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*, if applicable
 - 5.8.3 Product base labels, tie tags, and tie tag labels
 - 5.8.4 APBMT-GEN-001 FRM3 Physician Leukapheresis Procedure Note, if applicable
 - 5.8.5 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
 - 5.8.6 APBMT-COMM-001 FRM3 *Donor Health History Questionnaire*, if applicable
 - 5.8.7 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire

- 5.8.8 PBMT-COLL-018 *Pediatric Apheresis Checklist*, if applicable
- 5.8.9 STCL-GEN-009 FRM1 Cellular Product Chain of Custody
- 5.8.10 APBMT-COMM-030 FRM1 *Adverse Event Form*, if applicable
- 5.8.11 ABMT-COLL-001 FRM2 *Apheresis Checklist*, if applicable

6 EQUIPMENT

- 6.1 Spectra Optia Apheresis System
- 6.2 Astotherm Blood Warmer, if applicable

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, and gowns. 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 factor (G-CSF). G-CSF are administered under the supervision of a licensed physician/designee experience in the management of persons receiving these agents. G-CSF is used to increase the number of circulating granulocytes. G-CSF are generally administered by the subcutaneous (SQ) route a minimum of one (1) hours to a max of twelve to sixteen (12-16) hours prior to the next planned collection. If the patient is health 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 the procedure.
 - 8.1.2 To further enhance the collection of granulocytes from the donor's RBC layer, 6% Hydroxyethyl Starch 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 must 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. Completion of the APBMT-COMM-001 FRM3 *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. Labs are drawn at the time of each collection to determine future collections.

- 8.2.2.1 If the donor's hemoglobin (Hgb) is <10.5 gm/dL, check Hgb the day before the next planned collection.
- 8.2.2.2 If the Hgb is 10 gm/dL, proceed with the collection the next day without waiting for the labs that are drawn at the time of collection.
- 8.2.2.3 If the Hgb is <10 gm/dL, skip the collection and recheck the day before the next planned collection.

8.3 Pre-Collection:

- 8.3.1 Identify the patient by asking them to state their name and date of birth. Ensure that the name and birthdate on the patient's identification wristband match.
- 8.3.2 Patient weight will be obtained daily. Patient identification labels can be printed from the electronic medical record (EMR) and attached to the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* and/or the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.
- 8.3.3 Complete the APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*. Vital signs are taken and recorded on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* and/or the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. Vital signs may also be documented in the EMR.
 - 8.3.3.1 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:

- 8.4.1 Verify recorded lot numbers and expiration dates of apheresis related supplies on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* and/or the PBMT-COLL-016 FRM1 *Optia Leukapheresis 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.
- 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 Spectra Optia System: Granulocyte (PMN) Collection 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 Spectra Optia System: Granulocyte (PMN) Collection 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 the Spectra Optia System: Granulocyte (PMN) Collection 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 the Spectra Optia System: Granulocyte (PMN) Collection 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 the Spectra Optia System: Granulocyte (PMN) Collection Handbook for completing the procedure.

9 RELATED DOCUMENTS/FORMS

- 9.1 ABMT-COLL-001 FRM2 Apheresis Checklist
- 9.2 PBMT-COLL-018 Pediatric Apheresis Checklist
- 9.3 ABMT-COLL-019 Adult Apheresis/Photopheresis Supply Management
- 9.4 PBMT-EQUIP-003 Pediatric Apheresis Supply Management
- 9.5 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet
- 9.6 PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet
- 9.7 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
- 9.8 APBMT-COMM-001 FRM3 Donor Health History Questionnaire
- 9.9 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire

- 9.10 APBMT-COMM-030 FRM1 Adverse Event Form
- 9.11 APBMT-COMM-035 Detection & Management of Adverse Events
- 9.12 APBMT-GEN-001 FRM3 Physician Leukapheresis Procedure Note
- 9.13 COMM-PAS-003 Labelling Cellular Therapy Products
- 9.14 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
- 9.15 STCL-FORM-041 Doctors Orders Adult Stem Cell Transplant Program

10 REFERENCE

- 10.1 Terumo BCT, Inc. (2014). Spectra Optia System: Granulocyte (PMN) Collection Handbook. Lakewood, CO.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	M. Christen	<p>Section 2: Updated and added relevant information regarding standards, collection related data, available resources, and supply management material.</p> <p>Section 3: Further defined the scope and responsibilities.</p> <p>Section 4: Added and defined acronyms.</p> <p>Section 5: Updated material and paperwork needed to complete the collection.</p> <p>Section 8: Added more information regarding priming the donor, donor selection, and pre-collection information. Removed redundant collection and completion of collection information. Added to refer to the Spectra Optia System: Granulocyte (PMN) Collection Handbook as full reference.</p> <p>Section 9: Added related documents that may be used during the collection.</p>

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PBMT-COLL-017 Spectra Optia® Apheresis System Granulocyte (PMN) Collection Procedure**Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		06 Aug 2020, 04:41:01 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		06 Aug 2020, 05:16:40 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		03 Nov 2020, 05:44:42 PM	Approved

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Betsy Jordan (BJ42)		05 Feb 2021, 02:19:50 PM	Approved