DukeMedicine

Division of Cellular Therapy

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Optia Continuous Mononuclear Cell (CMNC) Collection

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ABMT-COLL-019
OPTIA CONTINUOUS MONONUCLEAR CELL (CMNC) 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 Peripheral Blood Progenitor Cells (PBPC), T- Lymphocytes (DLIs), and other mononuclear cells (MNC). For information on using the Optia System, refer to the Spectra Optia® Apheresis System Operator's Manual.

2 INTRODUCTION

2.1 The collection of PBPC by apheresis allows patients to be treated with high dose chemotherapy. Autologous patients will donate PBPCs following stimulation with chemotherapy and/or colony-stimulating factors (CSFs). Other Autologous MNC collections, such as chimeric antigen receptor T cells (CAR-T), may not require chemotherapy and/or CSFs. Allogeneic donors are HLA tested and stimulated with CSFs prior to donation. Allogeneic T-Lymphocytes are collected with or without CSFs being administered.

2.2 Peripheral or Central Venous Catheters (CVC) are inserted prior to the apheresis collection performed in the Adult Blood and Marrow Transplant Clinic (ABMT). Apheresis collections are performed in treatment chairs or beds, separated by curtains to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular products. Overhead lighting and adequate ventilation are present and cellular products are collected at room temperature in the ABMT Clinic. Sinks are present in each treatment room for hand hygiene. North Pavilion pharmacy is available to dispense apheresis related medications. Duke Life Flight is available to respond to emergencies and to transport patients to Duke emergency room or inpatient ABMT. Emergency equipment including a code cart, AED, suction, and oxygen is available and close to the apheresis area.

2.3 Apheresis supplies in the ABMT Clinic are supplied by Duke Materials Management and stored at room temperature in the ABMT Clinic Storeroom and the Apheresis Area of the Treatment Room. Refer to the procedures: ABMT-GEN-019 *Adult Apheresis Supply Management* and ABMT-GEN-021 *Monitoring Temperature and Humidity*.

2.4 The Duke Stem Cell Lab will freeze cells as ordered within 48 hours of collection.

2.5 Labeling the cellular product and plasma bags is completed prior to the end of the apheresis using a validated indelible pen. 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 ABMT-COLL-001 FRM2 *Apheresis Checklist*.

2.6 During a continuous mononuclear cell (CMNC) collection, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 4.5. The Automated Interface Management (AIM) system adjusts the flow rate of the plasma pump to control

the concentration of cells that flow through the collect port, based on the collection preference (CP).

2.7 Optia has been configured to collect 75 mL of plasma during the start of the RUN if needed. Once the plasma is collected, the collection of cells begins. Optia has been configured to rinse the blood warmer with 45 mL of saline at the end of RUN, per Terumo BCT recommendations.

2.8 Vital signs are taken and recorded pre-, mid-, and post-apheresis on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* unless collection time is less than (<) 4 hours. If < 4 hours, pre-and post-apheresis vital signs should be taken and recorded. Vital signs may be taken more frequently, as needed.

3 SCOPE AND RESPONSIBILITIES

3.1 The apheresis nurse is responsible for the collection of PBPCs, DLIs, and/or other MNC products using the Optia.

3.2 The apheresis nurse, ABMT attending apheresis physician, and Advanced Practice Providers (APPs) are responsible for patient/donor care during apheresis.

3.3 Non-tunneled CVC will be removed following completion of donation by an ABMT physician or APP. Peripheral access lines will be removed after the donation by the apheresis nurse.

4 DEFINITIONS/ACRONYMS

4.1	ABMT	Adult Blood and Marrow Transplant
4.2	AC	Anticoagulant
4.3	ACD-A	Acid Citrate Dextrose Formula A
4.4	AED	Automated external defibrillator
4.5	APP	Advanced Practice Provider
4.6	CAR-T	Chimeric Antigen Receptor T Cells
4.7	CBC	Complete Blood Count
4.8	CMNC	Continuous Mononuclear Cell Collection
4.9	CMP	Complete Metabolic Panel
4.10	CP	Collection Preference
4.11	CPT	Collection Preference Tool
4.12	CSF	Colony Stimulating Factor
4.13	DLI	Donor Lymphocyte Infusion
4.14	ECV	Extracorporeal Volume
4.15	EMR	Electronic Medical Record
4.16	Hct	Hematocrit
4.17	HLA	Human Leukocyte Antigen
4.18	ISBT	International Society for Blood Transfusion

4.19	IV	Intravenous
4.20	mL	Milliliter
4.21	MNC	Mononuclear Cells
4.22	NaCl	Sodium Chloride
4.23	NMDP	National Marrow Donor Program
4.24	PBPC	Peripheral Blood Progenitor Cells
4.25	PIV	Peripheral Intravenous
4.26	PST	Plasma Separator Tube
4.27	PPE	Personal Protective Equipment
4.28	RBC	Red Blood Cells
4.29	SOP	Standard Operating Procedures
4.30	T&S	Type and Screen
4.31	WBC	White Blood Cell
4.32	WBV	Whole Blood Volume

5 MATERIALS

5.1 Optia IDL Set

5.2 0.9% sodium chloride injection USP 1000ml bag

5.3 ACD-A (Anticoagulant Citrate Dextrose Solution A) 750 mL bag

5.4 Blood warmer tubing

5.5 Triple lumen extension set, as needed

5.6 Alcohol Preps, Gloves, Mask

5.7 Heparin flush syringes, as needed

5.8 0.9% saline flush syringes, as needed

5.9 Blood tubes

5.9.1 Daily lab draws include:

5.9.1.1 Lavender tube for complete blood count (CBC), manual or auto differential.

5.9.1.2 Lavender tube for hematopoietic progenitor cell (HPC) phenotype, if applicable. An HPC phenotype with an expression of CD-34 is used in stem cell collections. An HPC phenotype with an expression of CD-3 may be used for CAR-T collections.

5.9.1.3 Light green plasma separator tube (PST) for complete metabolic profile (CMP) and Magnesium.

5.9.1.4 Lavender tube for Type & Screen (T&S) drawn on the first day of apheresis. T&S is drawn on each day of collection for NMDP donors.

5.9.1.4.1 If a Type and Screen sample has been sent to Transfusion Service within forty-eight hours of the first day of apheresis an "Apheresis Day #1 T&S Needed" tag should be placed in the bag with the blood sample to prevent the T&S from being canceled.

5.9.1.5 Research tubes, as ordered

5.10 10 mL syringe for blood collection and blood transfer device

5.11 Paperwork:

5.11.1 Blood specimen requisitions and/or labels

5.11.2 ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*

5.11.3 On-demand printed product base labels, tie tags, and tie tag labels

5.11.4 International Society for Blood Transfusion (ISBT-128) bar code labels

5.11.5 APBMT-GEN-001 FRM3 *Physician Leukapheresis Procedure Note FRM3* (If applicable)

5.11.6 APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*

5.11.7 APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* for allogeneic/NMDP donors only, if needed

5.11.8 ABMT-COLL-001 FRM2 *Apheresis Checklist FRM2*

5.11.9 STCL-GEN-009 FRM1 *Cellular Product Chain of Custody*

5.11.10 APBMT-COMM-030 FRM1 *Adverse Event Form*, if applicable

5.11.11 ABMT-COLL-001 FRM5 *CD-34 Telephone Log*

5.11.12 APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*

5.11.13 APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Products*

5.11.14 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 is performed before and after patient contact and prior to the tubing set up. All tubing connections will be made using aseptic technique.

8 PROCEDURE

8.1 Patient Identification and Assessment

8.1.1 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.

8.1.2 Patient weight will be obtained daily by ABMT nursing staff.

8.1.3 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 APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire.*

8.1.4 For the National Marrow Donor Program (NMDP) and related allogeneic donors, check for the presence of an APBMT-COMM-001 FRM3 *Donor Health History Questionnaire.* The form is completed in a private ABMT clinic room during the donor evaluation visit. The donor physical assessment will be done by a physician or APP **not** caring for the transplant recipient

8.1.5 Complete the APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire* and review medication reconciliation on each day of donation.

8.2 Blood Draw

8.2.1 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*.

8.2.2 The apheresis nurse will review and record CBC and CD-34 (if applicable) results on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet.*

8.2.3 Notify the apheresis attending physician of any abnormal values or findings, refer to APBMT-COMM-001 *Donor Selection, Evaluation, and Management* for collection criteria. As a secondary check, abnormal parameters are listed on ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*. Document the outcome of the decision regarding the acceptability of the patient or donor. For related or unrelated donor abnormal medical history findings, contact the donor coordinator and refer to the APBMT-COMM-001 JA1 *Medical History Exclusion Criteria*.

8.2.3.1 Contact the patient's attending physician and/or apheresis attending physician for a plan of care for patients when the CD-34 count is less than (<) 10/microliter. The attending and/or apheresis attending physician may decide to start the collection if the CD-34 count is less than (<) 10/microliter if the patient has had difficulty in mobilization or defer

apheresis until an alternate mobilization plan is made which may include Mozobil® (Plerixafor) and/or chemotherapy.

8.2.4 ABMT-GEN-001 *Electrolyte Supplementation Protocol* is used to replace electrolytes and supplement blood products for autologous patients during apheresis. The apheresis attending physician and/or APP may decide not to follow the supplementation protocol depending on the patient's condition. Allogenic donors do not receive blood supplementation. The apheresis attending physician and/or APP may decide to provide electrolyte supplementation to an allogenic patient using oral medications, rarely using intravenous (IV) supplementation.

8.3 Documentation and Labelling

8.3.1 Review the STCL-FORM-041 *Doctors Orders Adult Stem Cell Transplant Program* and/or the electronic order located in the patient's electronic medical record. If STCL-FORM-041 *Doctors Orders Adult Stem Cell Transplant Program* is not in the patient's apheresis packet, contact the Stem cell Lab.

8.3.2 Complete all items listed on the ABMT-COLL-001 FRM2 *Apheresis Checklist*. Notify the apheresis attending physician and/or patient's attending physician if any results are not within the expected limits.

8.3.3 Visually inspect each supply and reagent used to collect cellular therapy products for damage or evidence of contamination. Record on ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet.* If a supply product does not pass visual inspection, refer to ABMT-GEN-019 FRM3 *Unacceptable Supply and Corrective Action.*

8.3.4 Record 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 on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*.

8.3.5 Record the current temperature and humidity on the ABMT-COLL-019 FRM 1 *Optia CMNC Run Sheet* and if the temperature is within an acceptable range. Refer to ABMT-GEN-021 *Monitoring Temperature and Humidity* and ABMT-GEN-021 FRM 1 *Temperature and Humidity Log* for details.

8.3.6 Confirm CVC documentation by chest x-ray or Vascular Radiology note. Contact the patient's transplant coordinator to obtain placement documentation for CVCs placed outside of Duke System.

8.3.7 Record contact phone number for the patient on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* for follow-up calls, if needed.

8.3.8 Calculate extracorporeal whole blood volume (WBV) and record on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*. Contact the apheresis attending physician if the extracorporeal WBV is greater than (>) 15%.

8.4 Selecting the Procedure

NOTE: Procedural steps are prompted by the machine in the order shown on the screen. The exact order of other steps in the procedure can vary.

8.4.1 Confirm that the Optia power cord is attached to the system and plugged into a red power outlet. Turn the power switch ON, located on the upper right side of the system. The system performs a series of self-diagnostic tests to validate the functionality of the hardware and software before you begin the procedure. Once the tests are complete, the buttons on the screen are enabled and you may begin the procedure.

8.4.1.1 Touch **Select Procedure**. The procedure selection screen appears.

8.4.1.2 Touch **CMNC** Collection.

8.4.1.3 Touch **Confirm**. The system loads the procedure software.

8.5 Loading the Tubing Set

8.5.1 Verify that the IDL filler is installed in the centrifuge. The IDL filler has a black square on it.

8.5.2 Verify the selection of the correct tubing set and the expiration date on the package cover.

8.5.3 Verify recorded lot numbers and expiration dates of all supplies used during collection on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet.*

8.5.4 Touch **Prepare Tubing Set.** The screen appears instructing you to prepare the set.

8.6 Unpacking the Lines and Bags

8.6.1 Put the IDL tubing set package on top of the centrifuge cover with the package label upright and facing you, and remove the cover from the package.

8.6.2 Take the product bags and vent bag out of the package and hang the bags on the IV pole. Hang the bags right to left in this order: Collection bag, Plasma bag, and Vent bag.

8.6.3 Take out the replace line and put the line over the right side of the front panel between the two sides of the IV pole.

8.6.4 Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

8.6.5 Take out the AC line (orange luer connection) and the saline line (green spike) and hang the lines over the left side of the system.

8.6.6 Take out the cassette and the channel, and put them on top of the centrifuge cover.

8.7 Snapping the Cassette into the Cassette Tray

8.7.1 Take the cassette out of the package and put the bottom of the cassette in the bottom edge of the tray.

8.7.2 Ensure that there is nothing lodged behind the cassette or the tray that could interfere with the loading.

8.7.3 Hold a finger behind the tray to avoid excess pressure which might cause the cassette to load manually. Press the top corners of the cassette to snap the cassette into the tray.

8.8 Loading the Channel in the Centrifuge

8.8.1 Take the channel out of the package and put it on top of the centrifuge cover.

8.8.2 Open the centrifuge door.

8.8.3 Locate the pin on the filler latch. Raise the latch by pushing the pin toward the center of the filler while pulling up the latch.

8.8.4 Turn the centrifuge so that the loading port faces you

8.8.5 Extend the lines between the cassette and the channel and ensure that they are not twisted.

8.8.6 Pull the channel up through the loading port and then through the opening in the center of the filler.

8.8.7 Lower the filler latch and lock it in place.

8.8.8 Position the lower collar holder on the filler latch so that the inlet line (pink line) is not obstructed by the other lines. Ensure that the base of the pink line aligns with the space between the two screws or that it is adjacent to the indentation on the filler latch.

8.8.9 Grasp the centrifuge loop below the lower collar and gently pull the collar down until you hear the “click” of the locking pin as it pops out and locks the collar in place. Ensure that the notch at the base of the locking pin is visible. If the collar is locked, you can see the notch

8.8.10 Starting with the connector, insert the channel into the groove in the filler, finishing with the inlet port. Run your finger over the groove and push down any section of the channel that is not completely inserted in the groove. The channel must sit flush with the groove.

8.9 Loading the Lower and Upper Bearings, and Upper Collar

8.9.1 Insert the narrow part of the lower bearing into the lower bearing holder, and the narrow part of the upper bearing into the upper bearing holder. Ensure that the braided section of the loop is not twisted.

8.9.2 Position the upper collar below the upper collar holder and insert the line into the holder. Pull the line up to secure the upper collar in the holder.

8.9.3 Spin the centrifuge clockwise to ensure that it rotates freely.

8.9.4 Close the centrifuge door.

8.9.5 Touch **Load.** The system lowers the cassette. Watch the cassette carefully to ensure that there are no objects or tubing caught under the cassette.

8.10 Testing the Tubing Set

8.10.1 Follow the instructions on the screen to perform the following steps:

8.10.1.1 Clamp the line to the diversion bag. Heat seal the line and remove the bag if blood will not be collected using the diversion bag.

8.10.1.2 Heat seal and remove the Replace line if it will not be used.

8.10.1.3 Close the roller clamps on the inlet saline line and the return saline line.

8.10.1.4 Clamp the line to the sample bulbs on the collection bag.

8.10.1.5 Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.

8.10.1.6 Clamp the Replace line if it has not been heat-sealed and removed.

8.10.1.7 Touch **Continue**.

8.10.1.8 Follow the instructions on the screens to clamp the inlet and return line.

8.10.1.9 Touch **Continue**.

8.11 Priming the Tubing Set

8.11.1 Follow the instructions on the screen to perform the following steps:

8.11.1.1 Aseptically connect the fluid containers

8.11.1.2 Fill the drip chambers

8.11.1.3 Insert the AC line in the AC fluid detector.

8.11.1.4 Touch **Start Prime**. The system primes the AC line. After the AC line is primed, the system sounds a tone.

8.11.1.5 Follow the instructions on the screen to open the inlet saline line and the return saline line.

8.11.1.6 Touch **Continue**. The system primes the return line, the inlet line, and the RBC line. Before the system primes the channel, it performs a test to verify that the correct filler is installed. When the prime is complete, the system sounds a tone and the patient data screen appears.

8.12 Entering and Confirming Patient and Procedure Data

8.12.1 Entering patient data

8.12.1.1 Touch the buttons on the screen to enter the following patient information:

a. Sex

b. Height

c. Weight

d. Hematocrit (Hct)

8.12.1.2 The Spectra Optia system uses sex, height, and weight to calculate the patient/donor's total blood volume (TBV). Record this TBV on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*.

8.12.1.3 The Hct is used in two ways

8.12.1.3.1 To calculate the limits for plasma and collect volumes.

8.12.1.3.2 To calculate the initial plasma pump flow rate before the AIM system starts managing the concentration of the cells through the port.

8.12.1.4 Touch **Confirm**. The run values screen appears.

8.12.2 Reviewing and confirming run values

8.12.2.1 Review the run values that appear on the screen and confirm that they are correct. A black border appears around the button of the primary run target. (Whole blood processed, TBV processed, Run Time, Collect volume: Target)

8.12.2.2 Optia has been configured to collect 75 mL of plasma at the start of the run.

8.12.2.3 To collect additional plasma during the run, enter the volume that you want to collect. A screen will appears asking with instructions for indicating whether the additional volume should be collected now or at the end of the run.

8.12.2.4 To change a value, perform the following steps:

8.12.2.4.1 Touch the button on the screen that corresponds to the value you want to change. The data entry pad appears.

8.12.2.4.2 Enter a new value.

8.12.2.4.3 If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

8.12.2.4.4 Touch **Confirm**.

8.13 Emptying the Saline Drip Chamber

8.13.1.1 Follow the instructions on the screen to perform the following steps:

8.13.1.1.1 Empty the saline drip chamber.

8.13.1.1.2 Rehang the saline container.

8.13.1.1.3 Touch **Confirm**.

8.14 Priming the Inlet Line and the Return Line

8.14.1.1 If not already done, place the blood warmer tubing around the blood warmer and aseptically connect the return line to the blood warmer tubing. Ensure that the tubing connection is tight. Prime the blood warmer tubing set and triple extension set (if applicable) by opening the return clamp and allowing saline to enter the line. You may squeeze the saline bag if needed. At completion, inspect the blood warmer tubing to ensure that all the air has been removed.

8.14.1.1.1 The connection of the tubing set to the blood warmer tubing should be no higher than 20 inches above the return access to prevent the possibility of air entering the tubing.

8.14.1.2 Be sure to perform the steps in the order indicated below and on the screen.

8.14.1.2.1 Prime the inlet line. If you are using the diversion bag to collect a blood sample, prime the inlet line to the inlet line manifold only. If you prime the line to the needle, you will dilute the sample with saline.

8.14.1.3 Clamp the inlet line and the return line.

8.14.1.4 Close the inlet saline line.

8.14.1.5 If you are not using the diversion bag, clamp and seal the line to the bag, and then remove the bag if not done earlier.

8.14.1.6 Touch **Confirm**. The screen appears instructing you to connect the patient.

8.15 Connecting the Patient and Starting the Run

8.15.1 Follow the instructions on the screen.

8.15.1.1 If using a CVC remove the needle on the inlet line and discard it in a sharps container. Connect the patient lines using aseptic technique and remove the central line catheter caps and/or IV extension caps to maximize blood flows.

8.15.1.2 If you are performing a peripheral venipuncture, refer to the ABMT-COLL-011 *Venipuncture Procedure*.

8.15.1.3 Unclamp the inlet line and close the red inlet saline roller clamp.

8.15.1.4 Touch **Start Run**. The system diverts the saline used to prime the tubing set to the saline container (approximately 40mL).

8.15.1.5 Double-check that the red inlet saline roller clamp is closed.

8.15.1.6 Follow the instructions on the screen to close the return saline line.

8.15.1.7 Touch **Continue**.

8.15.1.8 Follow the instruction on the screen to unclamp the return line.

8.15.1.9 Touch **Continue**.

8.15.1.10 Follow the instructions on the screen to empty the saline drip chamber and rehang the saline container.

8.15.1.11 Touch **Continue**. The system begins drawing the patient's blood into the tubing set, and the main run screen appears.

8.15.1.12 Confirm that the connection of the tubing set to the blood warmer tubing is no higher than 20 inches above the return access to prevent the possibility of air entering the tubing.

8.16 Monitoring the Run

8.16.1 Attach the base label to the cellular product bag and plasma 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 the procedure.

8.16.2 View run information on the main screen. To return to the main screen after viewing a different screen, touch to go back button, or the tab for the current screen.

8.16.2.1 To access additional screens, touch the tab for the screen you want to view.

8.16.2.2 To access the collection status screen, touch the Collection Status tab. Use this screen to monitor the progress of the run and to adjust the collection preference.

8.16.2.3 Increase the inlet flow rate to maximize the collection. Inlet flow rates may range from 50 to 90 mL/min depending on patient height and weight and symptoms of citrate toxicity. At times it is appropriate to run inlet flow rates less than (<) 50 mL/min due to patient access issues.

8.16.2.4 Monitor and record run parameters on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* every 30 minutes to hourly. Verify that volumes displayed on the screens are consistent with the actual volumes in the fluid containers and the bags.

8.16.2.5 Calcium gluconate IV is given as a precaution for citrate toxicity. The dosage and rate are dependent on the patient's size and any additional symptoms experienced during the procedure.

8.16.3 The collection preference (CP) is a reference number the plasma pump uses to adjust the flow rate, which affects the concentration of cells that flow through the collect port.

8.16.3.1 Place the Collection Preference Tool (CPT) under the collect line to monitor the color of the cells.

8.16.3.2 To change the collection preference to match the color in the collect line with the color on the CPT, use the up/down arrows. The default collection preference for CMNC is 50. If you do not change the CP, the system targets a CP of 60. If you change the CP, the system targets a CP that is 10 points higher than the number that you selected but is not less than a preference of 20.

8.16.3.3 The collect line color should have an Hct of approximately 3% to 4% for stem cell collection. A lower Hct may be used depending on the type of product requested.

8.16.3.4 To darken the color in the collect line, decrease the CP. This increases the concentration of cells that flow through the collect port.

8.16.3.5 To lighten the color in the collect line increase the CP to decrease the concentration of cells that flow through the collect port.

8.16.4 Buffy coat accumulation or a high white blood cell count can be a result in frequent alarms that cause the pumps to stop. To minimize buffy coat accumulation, refer to the Optimizing the Run section of the Spectra Optia Apheresis System Operator's Manual.

8.16.4.1 The connector should be monitored for buffy coat accumulation throughout the run.

8.16.4.2 The collect pump can be increased by increments of 0.1mL/min up to 1.5 until the buffy coat stops accumulating.

8.16.4.3 Lower the CP if the interface is not high enough to allow the system to collect the buffy coat.

8.16.5 Managing platelet clumping in the connector.

8.16.5.1 Clumping can affect collection efficiency by interfering with the separation in the connector. The potential for platelet clumping does not always correlate with the patient's platelet count.

8.16.5.2 If visible platelet clumping in the connector, decrease the inlet AC ratio to 8:1 until the clumping disappears and until the system has processed at least 1000 mL of inlet volume. Adjust the inlet pump to the desired rate and instruct the patient to report citrate toxicity symptoms.

8.16.5.3 If clumping has resolved, consider increasing the inlet AC ratio to 10:1. Allow the system to process 500 mL to 1000

mL of inlet volume before you consider increasing the ratio again. Do not increase the ratio by more than 2.0 for every 500 mL to 1000 mL of inlet volume processed.

8.16.5.4 If clumping persists, leave the inlet AC ratio at 8:1 until the clumping disappears or for the remainder of the run. Some clumps may become clots that are difficult to eliminate. Maintaining the 8:1 ratio will help minimize the impact on collection efficiency.

8.17 Changing the patient data

8.17.1 Touch the **Data** menu button. The data tabs appear.

8.17.2 Touch the **Patient Data** tab. The patient data screen appears.

8.17.3 Adjust the data, as necessary:

8.17.3.1 To adjust the Hct, touch Hct and enter the new hematocrit.

8.17.3.2 Touch **Confirm** to save the change.

8.18 Plasma Collection

8.18.1 Automatic Collection

8.18.1.1 Optia is configured to automatically collect 75 mL plasma into the plasma bag at the start of the run.

8.18.1.2 Additional plasma can be entered by pressing the Plasma Bag plasma button on the Run Values screen

8.18.2 Concurrent plasma

8.18.2.1 Concurrent plasma can also be collected into the MNC collection bag using an MNC collection set with a T-connecter on the collection line

8.18.3 Direct Collection Method

8.18.3.1 Enter the desired amount of plasma to be collected into the MNC collection bag by pressing the Collect Bag plasma button

8.18.4 Gravity Plasma Transfer Method

8.18.4.1 To transfer plasma into the collection bag, manually lower the MNC collection bag so that it is below the plasma bag.

8.18.4.2 Press the yellow Start Transfer button to start the gravity drain from the plasma bag into the MNC collection bag

8.18.5 Plasma Transfer

8.18.5.1 Plasma may be transferred into the collection bag during the run before you confirm rinseback. It cannot be transferred during the collection phase.

8.18.5.2 To initiate a transfer, touch the End Run menu button and then touch the Plasma tab. The instructions for plasma transfer will appear on the screen.

8.18.5.3 Place the collection bag lower than the plasma bag and press Start Transfer. The plasma valve will move into the neutral position allowing plasma to flow by gravity from the plasma bag into the collection bag.

8.18.5.4 Once the plasma transfer is completed, press Resume Run. If the plasma transfer is done at the end of the run the screen will say End Transfer Patient/Donor.

8.19 Adding Anticoagulant to the Collection Bag, if necessary

8.19.1 Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.

8.19.2 Completely break the frangible connector by bending the tubing back and forth.

8.19.3 Using aseptic technique, remove the cap from the luer connector below the sterile barrier filter, and attach a syringe containing the desired amount of anticoagulant to the connector.

8.19.4 Unclamp the line above the frangible connector.

8.19.5 Slowly inject the anticoagulant through the sterile barrier filter into the collection bag.

8.19.6 Clamp the line above the frangible connector.

8.19.7 Remove the syringe from the luer connector.

8.19.8 To ensure that you delivered all of the anticoagulant in the syringe into the collection bag, perform the following steps:

8.19.8.1 Attach a syringe containing at least 2.3 mL of saline to the luer connector. (The volume of the accessory line and sterile barrier filter is approximately 2.3 ml.)

8.19.8.2 Unclamp the line above the frangible connector.

8.19.8.3 Slowly inject the saline through the sterile barrier filter to flush the anticoagulant in the filter into the collection bag.

8.19.8.4 Clamp the line above the frangible connector.

8.20 Using the Sample Bulbs to Obtain a Product Sample

8.20.1 Ensure that the line between the collection bag and the manifold on the sample bulb assembly is clamped.

8.20.2 Clamp one of the lines between the manifold and the sample bulb.

8.20.3 Thoroughly mix the product in the bag to ensure that you obtain a representative sample.

8.20.4 Unclamp the line between the collection bag and the manifold on the sample bulb assembly.

8.20.5 Gently squeeze the sample bulb attached to the line that is not clamped to withdraw the sample.

8.20.6 To express any excess sample back into the collection bag, perform the following steps:

8.20.6.1 Invert the sample bulb, and hold it above the fluid level of the collection bag.

8.20.6.2 Gently squeeze the sample bulb to express the excess sample into the bag.

8.20.6.3 To use the residual air in the sample bulb to clear the fluid from the line between the collection bag and the sample bulb, perform the following steps:

8.20.6.4 Hold the sample bulb upright and below the collection bag.

8.20.6.5 Gently squeeze the sample bulb. The residual air in the bulb pushes the product from the line into the collection bag.

8.20.6.6 While maintaining pressure on the sample bulb, clamp the line between the manifold and the sample bulb.

8.20.7 Before you remove the sample bulb containing the product sample, permanently seal the line between the clamp below the manifold and the sample bulb.

8.20.7.1 Disconnect the sample bulb at the seal on the line.

8.21 Ending the Run before a Run Target is Attained

8.21.1 Touch the **End Run** menu button.

8.21.2 Do one of the following:

8.21.2.1 To discontinue the run and perform rinseback, touch the **Rinseback** tab, and follow the instructions in ending the run with rinseback.

8.21.2.2 To discontinue the run and skip rinseback, touch the **Disconnect** tab, and follow the instructions in ending the run without rinseback.

8.21.2.3 Touch the button on the screen to proceed with your selection, then touch **Confirm.**

8.22 Ending the Run after the Run target is Attained

8.22.1 Ending the run with rinseback

8.22.1.1 Touch **Rinseback**. The screen appears instructing you to confirm your selection to perform rinseback.

8.22.1.2 To proceed to rinseback, and touch **Confirm**.

8.22.1.3 Follow the instructions on the screen to clamp the inlet line.

8.22.1.4 Touch **Continue**. The system tests the pressure in the inlet line.

8.22.1.5 Follow the instructions on the screen to open the inlet saline line, and to clamp and then seal the lines to the plasma and collection bags.

8.22.1.6 Touch **Continue**. The screen appears that shows the status of the rinseback.

8.22.1.7 When rinseback is complete, follow the instructions in the section titled "Completing the Procedure"

8.23 Extending the run after the Run target is Attained

8.23.1 Touch the button for the run target that you want to increase, and use the data entry pad to enter a new value for the target. The run values screen appears.

8.23.1.1 Review the run value and touch **Confirm**

The system will continue the run. When the new target is attained, the run targets screen appears and the system sounds a tone.

8.24 Ending the run without Rinseback

8.24.1 Touch the **End Run** menu button.

8.24.2 Touch the **Disconnect** tab. The screen appears asking you to confirm your selection to disconnect the patient.

8.24.3 Touch Proceed to Disconnect and then touch **Confirm**.

8.25 Completing the Procedure

8.25.1 Following a six-hour leukapheresis, the platelet count is typically lowered 50%. A post-platelet count after the procedure may be needed depending on the initial platelet count prior to collection. The post-platelet count in allogeneic donors should not be less than (<) 50,000. The post-platelet count for NMDP donors should be greater than or equal to (≥) 80,000. The apheresis attending physician and/or patient's attending physician/APP can be contacted for questions regarding the donor's post-platelet count. Arrangements for follow-up lab draws following donations are made by the Donor Coordinator, if needed.

8.25.2 Disconnecting the patient

8.25.2.1 Follow the instructions on the screen to perform the following steps:

8.25.2.2 Close the inlet saline line.

8.25.2.3 Clamp the inlet line and the return line.

8.25.2.4 Disconnect the patient lines. Replace caps on the CVC and flush the lines per Duke Hospital IV Therapy (Adult) Protocol. Flush PIV with normal saline and remove as ordered. Place dry gauze bandage over the site.

8.25.2.5 Seal the AC line, the saline line, and the lines to the bags.

8.25.2.6 Touch **Unload**. The system confirms that the saline lines are closed, and the inlet and return lines are clamped. Then it raises the cassette. The procedure summary screen appears.

8.26 Reviewing the procedure summary data

8.26.1 Review the data on page 1 of the procedure summary.

8.26.2 Touch Next Page.

8.26.3 Review the data on page 2 of the procedure summary.

8.27 Removing the Tubing Set

8.27.1 If Rinseback was not done, the channel will be full of fluid when the set is unloaded. After the cassette is raised, empty the channel by putting the cassette and the bags at a level below the channel, allowing the fluid n the channel to drain into the vent bag.

8.27.1.1 Open the centrifuge door

8.27.1.2 Remove the upper collar holder by grasping the lines above and below the collar, and pulling the lines downward.

8.27.1.3 Remove the upper and lower bearings from the bearing holders.

8.27.1.4 Remove the chamber from the bracket.

8.27.1.5 Gently pull the channel from the filler

8.27.1.6 Push in the locking pin on the centrifuge collar holder and remove the collar from the holder by grasping the tubes above the collar and pulling upward.

8.27.1.7 Push the filler latch pin toward the center of the centrifuge, and raise the filler latch.

8.27.1.8 Fold the channel in half, and pull the channel through the loading port and out of the centrifuge chamber.

8.27.1.9 Lower the filler latch and close the centrifuge door.

8.27.1.10 Remove the lines from the fluid detectors.

8.27.1.11 Remove any bags from the IV pole.

8.27.1.12 Press the latch on the upper right corner of the cassette tray, and lift the cassette from the tray.

8.27.1.13 Discard the tubing set in the Biohazard Trash bins.

8.28 Documentation

8.28.1 Record pre and post vital signs on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* in the spaces provided.

8.28.2 Notify the apheresis physician of any untoward side effects or abnormal findings.

8.28.3 Record final Run values and end time on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* in the spaces provided.

8.28.4 Record final fluid balance on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* in the spaces provided.

8.29 Cleaning of Machine

8.29.1 If a blood spill occurs, inspect the system surface, front panel, and centrifuge chamber. Clean the blood with the Duke Hospital approved disinfecting wipe.

8.29.2 After each use clean the system surface and front panel with the Duke Hospital approved disinfecting wipe. Refer to ABMT-EQUIP-001 FRM10 *Optia Apheresis Machine Quality Control Record.*

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-COLL-001 FRM2 Apheresis Checklist

9.2 ABMT-COLL-001 FRM5 CD-34 Telephone Log

9.3 ABMT-COLL-011 Venipuncture Procedure

9.4 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet

9.5 APBMT-COMM-001 FRM3 Donor Health History Questionnaire

9.6 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire

9.7 APBMT-COMM-001 JA1 Medical History Exclusion Criteria

9.8 APBMT-COMM-030 Recording and Reporting of Adverse Events

9.9 APBMT-COMM-030 FRM1 Adverse Event Form

9.10 ABMT-GEN-001 Electrolyte Supplementation Protocol

9.11 APBMT-GEN-001 FRM3 Physician Leukapheresis Procedure Note

9.12 COMM-PAS-003 Labelling Cellular Therapy Products

9.13 STCL-FORM-041 Doctors Orders Adult Stem Cell Transplant Program

9.14 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form

9.15 ABMT-EQUIP-001 FRM10 Optia Apheresis Machine Quality Control Record.

9.16 Duke Hospital Intravenous (IV) Therapy Protocol (Adult)

10 REFERENCES

10.1 *Spectra Optia Apheresis System Operator's Manual*. Terumo BCT, Inc. Lakewood, CO, 2015.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
06	M. Christen	Update Section 5.11 with correct MC document names and numbers. Update Section 8 with correct MC document names and numbers. Formatting performed throughout the document.

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