STEM CELL LABORATORY (STCL)

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Outgoing NMDP Products - STCL Checklist JA2

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STCL-DIST-001 JA2
Outgoing NMDP Products – STCL Checklist

ISBT 128 Barcode Assigned:

Collection Date: _____ **Recipient's Name:** _____

Storage Date: _____ **NMDP Donor #:** _____

Distribution Date: _____ **NMDP Recipient #:** _____

NOTE: Use this checklist as a tool when receiving/ testing / distributing cellular products in the STCL that have been collected by the ABMT Program at DUKE for other Transplant Centers (TC) on behalf of the National Marrow Donor Program (NMDP).

PRE-PRODUCT ARRIVAL IN THE STEM CELL LAB (STCL):

1. Make sure NMDP folder contains the following: Initials _____
   - ☐ Donor's Infectious Disease Markers
   - ☐ Prescription Form
   - ☐ Laboratory Information System Donor's Registration Printout
   - ☐ Laboratory Information System Patient Snapshot Report
2. ☐ Check Prescription form for the requested amount of CD34+ cells. This is needed to give to NMDP Coordinator(s) along with the total CD34+ count obtained from Flow. The Prescription form will also indicate any special instructions required during processing. Be sure to check this form carefully as to not omit any special instructions. Initials _____
3. ☐ Determine whether the product is being picked up or going to be held overnight until a 2nd collection has been collected. Initials _____
   - ☐ If product is being held overnight, contact NMDP Coordinator(s) to see which one should be contacted with the donor's total CD34+ product results. Be sure you have their contact phone # or pager #. Initials _____
4. ☐ For apheresis products, order a HPCA Leukapheresis, HPC Phenotype, HPCA Basic in the Laboratory Information System (LIS); for bone marrow, HPC Harvest, HPC Phenotype, HPCA Basic. Print labels. Initials _____
5. ☐ Assemble the required paperwork (listed below) and complete the requested information; affix barcodes as required. The recipient's weight can be found on the NMDP prescription form. Initials _____

☐ *STCL-GEN-009 (FRM 2) Cellular Product/Sample Chain of Custody Form-* This form is used specifically for cells being collected at Duke University Medical Center by Adult & Pediatric Blood and Marrow Transplant Program.

☐ NMDP Checklist

☐ *Differential Worksheet*

☐ *Peripheral Blood Progenitor Cell Worksheet (STCL-FORM-040)*

☐ STCL Billing Log

☐ *STCL-PROC-022 (FRM1) Stem Cell Laboratory Clinical HPCA Worksheet*

☐ *FLOW-GEN-012 (FRM5) Stem Cell Laboratory Flow Cytometry Worksheet*

☐ MO266 (attach label from product bag to this form and place in lab file)

6. ☐ Assemble the following supplies and label them appropriately. Initials _____

☐ 3-Tubes for ABO/Rh

☐ 2-Tubes for cell count and viability

☐ 1-sterile vial for HPCA (label with Epic Beaker label) (1.0 mls)

☐ 2-sterile vials for cryopreservation (2.0 mls (1 ml/vial)

☐ 1-cytoprep (~ 40 uls/slide)

☐ one set of culture bottles (aerobic / anaerobic) (1.0 mls per bottle)

PRODUCT ARRIVAL IN THE STEM CELL LAB (STCL):

APHERESIS

☐ N/A (Not Applicable)

1. The product will be delivered to the laboratory in a validated cooler (room temperature) by the apheresis nurse or a designee to the STCL processing area. Check the product to ensure that all labeling criteria is accurate and includes: Initials _____

☐ Patient's name

☐ History number

☐ AC (anticoagulant) volume

☐ Recipient's weight

☐ Time/Date Product Collected

☐ ISBT 128 barcode

☐ Inspect the product upon arrival in the STCL to:

- Verify that the product is properly labeled

- Verify that all necessary paperwork accompanied the product
- Ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag (containing) housing the cellular product
- Ensure there is no evidence of microbial contamination
- If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate an event report, non-conforming product form, etc.
- Timely resolution of any problems is imperative since these products are slated to leave the facility via designated courier to be delivered to another transplant center for a patient awaiting transplantation

2. ☐ Perform cell count, trypan blue viability (or equivalent), cultures, flow and HPCA testing. Prepare slides for differential testing (done in HPCA) and save two (2) vials for storage. Refer to internal standard operating procedures (i.e. viability, ABO/Rh testing, etc.) Initials _____

3. ☐ For all NMDP products, tare the collection bag (or use 43.3 correction factor) and then **divide by a factor of 1.06** to obtain the final product volume.

   (**NOTE**: As a general rule, check the weight recorded for the product bag by the collection site to make sure you are in the ballpark for the volume). Initials _____

4. ☐ If the product is being distributed from the STCL to the courier on the same day of collection, be sure to inspect the product before distribution to: Initials _____

   ☐ N/A (Not Applicable)

   - Verify that the product is properly labeled.
   - Verify that all necessary paperwork accompanies the product.
   - Ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag containing the cellular product.
   - Ensure there is no evidence of microbial contamination.
   - If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate an event report, non-conforming product form, etc.
   - Timely resolution of any problems is imperative since these products are slated to leave the facility via designated courier to be delivered to another transplant center for a patient awaiting transplantation.

5. ☐ If **OVERNIGHT STORAGE** is required, see below. Initials _____

   ☐ N/A (Not Applicable)

   - If the cell count exceeds 450 x 10e6 cells/ml, the product should be diluted with Plasmalyte-A and human albumin (or plasma) in an effort to reduce the cell count/ml to maintain a viable product. (Expect overnight storage when a 2nd apheresis product is going to be collected by the Apheresis team). If the product is manipulated before overnight storage, a new set of culture bottles must be labeled and inoculated post-manipulation.

     NOTE: Refer to prescription form for unique requirements requested. Refer to the Donor workup form for request of any special tubes/test/manipulations. Print out any emails that refer to special request or additional information and add to patient folder.

6. ☐ Products being stored overnight must be recorded on the *Blood Product and Cellular Product Log Sheet* located above the under counter monitored refrigerator (1-10° C).

   Initials _____

The product should remain refrigerated until the time of distribution.

7. Before the product is distributed to a designated courier:

   ☐ Fill out the NMDP 0770 form for the product and make a label using the Demand 128 printer designated for NMDP products per COMM-PAS-003 Labeling Cellular Therapy Products section 8.14.

   ☐ Scan barcode into Hematrax Software.

   ☐ Refer to product information provided on NMDP Product Code List (hanging over NMDP label printer) to find appropriate code depending on anticoagulant, storage temperature and product attributes (mobilization, additive(s), concurrent plasma added, 3rd party component, etc).

   - HPC, Apheresis collected for NMDP are always refrigerated and mobilized.
   - A product code containing concurrent plasma attribute must be selected only when concurrent plasma was added after the product has been disconnected from the apheresis instrument.
   - A product code containing 3rd Party Blood Component attribute must be selected when human albumin was added to the product.

   ☐ Select "Investigational Drug" if product being labeled is an apheresis product.

   ☐ Blood type = UNKNOWN.

   ☐ Select donation type as For Use by Intended Recipient(s) Only.

   ☐ Select donor type as Unrelated Donor.

   ☐ Leave Donor Name field blank.

- ☐ Enter NMDP Donor Identification Number in Donor ID field.
- ☐ Enter Recipient Last and First Name in Recipient Name field.
- ☐ Enter Recipient Identification Number in Recipient Field.
- ☐ Leave Collection and Processing Facility blank.
- ☐ Check Collection Date/ Time and enter date/ time product collected
- ☐ Check Expiration time but leave Expiration date and time blank, but then go over to "expiration period" and click "infuse within 48 hours".
- ☐ Enter the quantity of labels needed and click print.
- ☐ Enter the appropriate values in the Print Volumes pop-up window.
- ☐ If a single collection is divided into multiple bags for distribution, select appropriate division codes for each bag e.g. AO, BO etc.
- ☐ Click Update Preview.
- ☐ Review the label for accuracy.
- ☐ Correct any data entry errors if necessary.
- ☐ Select print.
- ☐ Enter volume of product and volume of anticoagulant in product.

Initials _____

- ☐ Re-label bag(s).
- ☐ Verify that **ALL** of the information on the Demand 128 label is accurate.
- ☐ Complete Section A of National Marrow Donor Program® Verification of Product Labeling (F00835).
- ☐ Verify that all necessary paperwork accompanies the product.
- ☐ Inspect the product to ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag (containing) housing the cellular product.
- ☐ Inspect the product to ensure there is no evidence of microbial contamination.
- ☐ If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate an event report, non-conforming product form, etc.
- ☐ Timely resolution of any problems is imperative since these products are slated to leave the facility via designated courier to be delivered to another transplant center for a patient awaiting transplantation.

Initials _____

8. ☐ STCL personnel must distribute the product to the ABMT designated courier (i.e. NMDP Coordinator(s), or other ABMT designee). The *STCL-GEN-009 (FRM 2) Cellular Product/Sample Chain of Custody Form* must be completed at the time the product is distributed to NMDP Coordinator(s). They will issue the product directly to the NMDP-designated courier.

Initials _____

9. ☐ STCL personnel must sign the product out from the refrigerator on the *Blood Product and Cellular Product Log Sheet* at the time it is distributed to the NMDP Coordinator(s) (or other ABMT designee). Initials _____

BONE MARROW

☐ N/A (Not Applicable)

1. Receiving the product from the OR. Initials _____

☐ Have the collecting Dr. sign the chain of custody and make sure they fill out the BMH QA Sheet as soon as they come into the lab with the product.

☐ Make sure all volumes are filled in for plasmalyte, heparin (10,000 units/mL - in case they fill it out in "units"), and marrow.

☐ Check the Demand-128 to see that the volume and collection time are filled in.

☐ Make sure the tie-tag is attached to the product and not at the bottom of the cooler.

2. Splitting Marrow for NMDP outgoing products. Initials _____

☐ Run QC on the marrow when it arrives in the lab to include:

- ☐ Total Nucleated Cell Count
- ☐ Viability
- ☐ 4-5 mL for HPC
- ☐ Perform CD34 testing
- ☐ Cover-slip slides
- ☐ 2 vials to freeze
- ☐ ABO/Rh confirmation
- ☐ Sterility

☐ AFTER running QC on the entire product, split the product into 2 or 3 600 mL transfer bags (depending on the product volume).

Initials _____

☐ For each individual bag.

- ☐ Obtain the volume
- ☐ Perform total nucleated cell count on each bag

Initials _____

3. Before the product is distributed to a designated courier:

☐ Fill out the NMDP 0772 form for each individual bag and make a demand using the Demand 128 printer designated for NMDP products.

- ☐ To calculate volume of plasmalyte and heparin.
  - ☐ Divide the volume of the individual bag by the volume of the OR bag

☐ Multiply that fraction by the total volume of heparin or plasmalyte

Initials _____

☐ Make the Demand 128 label.

☐ Scan barcode into Hematrax Software.

☐ Refer to product information provided on NMDP Product Code List (hanging over NMDP label printer) to find appropriate code depending on anticoagulant, storage temperature and product attributes (mobilization, additive(s), concurrent plasma added, 3rd party component, etc).

- A product code containing 3rd Party Blood Component attribute must be selected when human albumin was added to the product.

☐ Select "Standard" if product being labeled is a bone marrow product.

☐ Blood type = UNKNOWN.

☐ Select donation type as For Use by Intended Recipient(s) Only.

☐ Select donor type as Unrelated Donor.

☐ Leave Donor Name field blank.

☐ Enter NMDP Donor Identification Number in Donor ID field.

☐ Enter Recipient Last and First Name in Recipient Name field.

☐ Enter Recipient Identification Number in Recipient Field.

☐ Leave Collection and Processing Facility blank.

☐ Check Collection Date and Time and enter the date and time the product was collected.

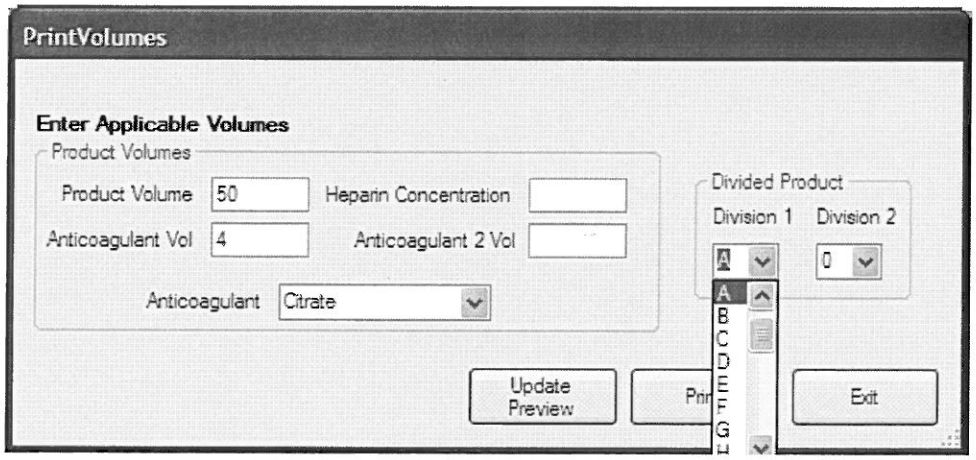
☐ Check Expiration time but leave Expiration date and time blank, but then go over to "expiration period" and click "infuse within 48 hours".

☐ Enter the appropriate values in the Print Volumes pop-up window.

☐ Choose the number of labels to make based off how many bags you split the product into.

☐ Click on down arrow under Divided Product Division 1. The following letter designations will appear.

Initials _____



- ☐ Select the corresponding letter designation for each bag (ie, A, B, C, D, etc). The final product label will be labeled with letter designation on lower left quadrant.
- ☐ Fill in all volumes from each bag and then use the calculated volume of plasmalyte and heparin.

- ☐ Save the Demand-128 from the OR bag on the back of the processing sheet.
- ☐ Make a copy of the flow, diff (if available at the time of pick-up) and Sysmex count for NMDP Coordinator, and 2 copies of the NMDP Form 0772 (1for STCL 1 for courier NMDP Coordinator keeps the original).

PRODUCT DISTRIBUTION FROM THE STEM CELL LAB (STCL):

When the NMDP courier arrives, be prepared to issue the product to NMDP Coordinator(s) (or designee); one or both of them will issue the cellular product directly to the NMDP courier. The STCL employee will not be involved in this transaction. Make sure the NMDP Coordinator(s) signs the *STCL-GEN-010 (FRM 2) Cellular Product/Sample Chain of Custody Form.*

☐ Make sure all pertinent information has been documented on the NMDP checklist prior to distributing the cellular product. Initials _____

☐ Complete the NMDP Product Analysis form and leave it in the designated folder for the NMDP Coordinator(s).

Initials _____

☐ The manual differential can be completed and results provided the next day, if necessary.

Initials _____

☐ Provide ABMT designee with copies of NMDP Form, Flow Cytometry results, etc.

Initials _____

☐ Enter all pertinent laboratory data in Laboratory Information System and STCL EMMES database.

Initials _____

Signature Manifest

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