| ADVOCATEHEALTH | | |
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| **Title: Product Labeling Procedure (NCBH)** | | **Document Number: 55139** |
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| **Content Applies to Patient Care: (Select all that apply)**<br>☒ Adults<br>☐ Pediatrics (Under 18) | **Content Applies to: (Select One)**<br>☒ Clinical<br>☐ Administrative | **Effective Date: 06/06/2023** |
| **Scope:** ☐ Enterprise ☐ MW Region ☐ SE Region<br>☐ WI ☐ IL ☐ Greater Charlotte Market ☐ Navicent Market ☐ Wake Market ☐ Floyd Market<br>☒ Entity Only (Entity Name): NCBH ☒ Department Only (Department Name): SCTCT | | |

## I. PURPOSE

Regulatory agencies require that products be labeled in a very specific way, including labels, tags, and stickers that serve to identify the eligibility and suitability of the product's donor. Labeling of products also serves to correctly identify the product donor and recipient, and any product attributes. The International Society of Blood Transfusion (ISBT) provides a common labeling system for all stem cell products. The SCTCT Lab has adopted this labeling system to replace handwritten labels. This procedure gives directions on printing labels for products.

## II. SCOPE

This document applies to the Stem Cell Transplant and Cellular Therapy Laboratory at AHWFBH. This procedure applies to all cryopreserved products infused by the SCTCT Lab.

## III. DEFINITIONS/ABBREVIATIONS

A. FDA: Food and Drug Administration
B. FACT: Foundation for the Accreditation of Cellular Therapy
C. GRID: Global Registration Identifier for Donors
D. IDM: Infectious Disease Marker
E. SOP: Standard Operating Procedure
F. HHQ: Health History Questionnaire
G. NMDP: National Marrow Donor Program
H. ISBT: International Society of Blood Transfusion
I. SCTCT: Stem Cell Transplant and Cellular Therapy
J. DIN: Donor Identification Number
K. NMDP: National Marrow Donor Program
L. HPC: Hematopoietic Progenitor Cells
M. BM: Bone Marrow
N. CT: Cellular Therapy
O. OR: Operating Room
P. PE: Physical Exam

## IV. POLICY

A. The Collection label is applied to the product bag by the Apheresis staff. Any label applied to the product by the Processing Lab staff after collection is a Processing label.
B. All data fields should be completed on labels; any empty fields should have "n/a" entered.
C. All labeling shall be clear, legible, and completed using black ink that is indelible to relevant agents.
D. Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials.
E. Labels shall be validated as reliable for storage under the conditions in use.
F. Transfer bags should be labeled and checked before product is disconnected from mother bag.
G. Labels should be checked by at least two technologists before final distribution of the product.
H. The source document for the check should be the EPIC electronic order. The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
I. Always retain any labels removed when a product label is changed.
J. Each cell therapy product collection shall be assigned a unique alphanumeric identifier by which it will be possible to trace any cell therapy product to its donor, its recipient, or final disposition and all records.
K. Label the cellular therapy product, product samples, concurrent plasma and concurrently selected samples with the same identifier.
L. Because the donor Health History Questionnaire (HHQ) is not completed for autologous donors, all autologous products are labeled: "Not Evaluated for Infectious Substances".
M. Products with additives (Plasmalyte-A or Human Serum Albumin) will have an additional sticker placed on the bag indicating the volume of any additive.
N. These protocols apply to products designated 361 by the FDA as of May 2005. Any product collected prior May 2005 might be labeled according to laboratory SOP at that time.
O. All products processed by the SCTCT laboratory will be labeled with ISBT compliant labels.
P. Some products may arrive from outside institutions with non-ISBT labels, in which case the product will be relabeled upon receipt with an ISBT compliant label; the original label shall be retained.
Q. In downtime, complete blank ISBT labels by hand. A stock of blank labels is maintained in the SCTCT lab in the bottom drawer below the HP printer.
R. The source document for completing labels should be the EPIC electronic order.
S. As the DIN is assigned, two technologists must check the DIN in the Patient Index and record their initials for documentation.
T. Two technologists shall check any additions or changes to labels.
U. Do not reprint labels for frozen products infused at bedside.
V. Additional tags may be required in addition to ISBT labels because of donor eligibility. See Quick Reference Guides, page 25-26.
W. Retain any unused printed labels in the patient chart.
X. If original collection label is replaced with the processing label, leave the DIN# attached to the product bag; There is a perforated DIN# cutout on the label that allows for this transfer.

**Refer to charts on page 23-24 of procedure for quick reference guides.**

## V. PROCEDURE

### A. AUTOLOGOUS HPC: BEFORE PROCESSING

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 1.5 x 0.75 inches cryolabels (CT-15x75-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches, and 1.5x 0.75 inches.
Specimen Requirements: n/a

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop.
    a. Login box will appear.

2. Log in to the HematraxCT software.
    a. Main screen will appear at login.

3. Click on Label Design Tab.

4. Print Full Face Label: Click on Select Label.
    a. 4.1 Select 4x4 Full Face from the drop down box. Click Generate DIN.
    b. Record DIN in the Patient Index, have another technologist check as in protocol bullet S. Electronic Patient Index is at G:/Lab Shared/BMT Common/BMT Processing Lab/Electronic Patient Index. Select S1128 - HPC,Apheresis|Citrate|xx|refg|Mobilized (or appropriate code)from the Product Code drop-down box. Refer to Code descriptions, linked to procedure in Title21.
    c. Select the Standard button.
    d. Select correct blood type from the Blood Type drop down box.
    e. Select For Autologous Use Only from the Donation Type drop down box.
    f. Complete Donor Name and ID from the source document.
    g. EPIC electronic order from the Nurse Coordinators is the source document.
    h. Select Wake Forest Baptist Health from the Collection Facility and Processing Facility drop down boxes.
    i. Leave the Collection Date/Time and Expiration Date/Time boxes unchecked.
    j. Select Label qty: 1
    k. Select 4x4 label from the Printer drop down box.
    l. Click Print. Print Volumes box will appear.
    m. Leave all Product Volumes blank and all Division codes 0.
    n. Click Print.

5. Print cryolabels: Click Print Log.
    a. Highlight the line that corresponds to the printed DIN on the Print Log.
    b. Click Get Data and the label design screen appears.
    c. Click Select Label, highlight 1.5 x 0.75 cryo label.
    d. Select Label Quantity: 26 (Or greater number if indicated or requested by the medical director).
    e. Select 1.5 x 0.75 cryo label from the Printer drop down box.
    f. Click Print.
    g. Ensure that both Division Codes are 0.
    h. Click Print once for each cryo label.

6. Have a second technologist check the 4x4 and the cryo labels.

    a. The source document for the check must be the EPIC electronic order.

   b. The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
   c. The checking technologist must initial on the Patient Index to document the check.

7. Place the 4x4 label and 5 cryo labels in a biohazard Ziploc bag and send in tube system to apheresis, tube station 127.
   a. Apheresis will apply the label to the product.
8. Use the remaining cryo labels for tubes, samples, and processing transfer bags.

EXPECTED OUTCOME RESULTS: Autologous ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## B. AUTOLOGOUS HPC AFTER CONCENTRATION

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None
Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 3.75 x 1.5 inches (CT-375x15-FOLD-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 3.75 x 1.5 inches
Specimen Requirements: n/a

1. Print 4x4 inch Full Face Labels for freezing bags:

1.1 Click Print Log
1.2 Highlight the line that corresponds to the DIN# you are working with on the Print Log.
1.3 Click Get Data.
1.4 Label design screen appears.
1.5 Select S1475 – HPC,Apheresis|Citrate|xx|≤-120C|10% DMSO|Other Additives:Yes|Cryopreserved|Mobilized|Plasma Reduced in the Product Code drop down box.
1.6 Press Tab to update the label preview.
1.7 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
1.8 Check the box for Expiration Date/Time.
a. Enter the Expiration Date and Time.
1.9 Click Select Label.
1.10 Ensure that 4x4 Full Face label is selected.
1.11 Change label quantity to the number of labels needed depending on the cell concentration per bag.
1.12 Ensure 4x4 label is selected in the Printer drop down box.
1.13 Click print.
1.14 Print Volumes box will appear.
a. Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box.
b. Product volume is total volume (product + ACDA)
1.15 Select A from the Division 1 drop down box.
1.16 Leave 0 in the Division 2 drop down box.
1.17 Click Print.
1.18 The Print Volumes Box will reappear based on the quantity of labels printed.
a. Select the next alphabetic division in the Division 1 drop down box for each label printed.
Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0
1.19 Attach each label to a freezing bag.
1.20 Calculate amount of Plasmalyte-A in product according to SOP; Record amount on Plasmalyte-A sticker and attach to product label. Label Master can be accessed at G:/Lab Shared/BMT Common/BMT Processing Lab/For Review/mL Plasmalyte Added Label

## B. AUTOLOGOUS HPC AFTER CONCENTRATION, CONTINUED

2. Print Partial Labels:
   2.1 Click Print Log.
   2.2 Highlight the line that corresponds to the Auto DIN on which you are working on the Print Log.
   2.3 Click Get Data and the label design screen appears.
   2.4 Select S1475 - HPC,Apheresis|Citrate|xx|≤-120C|10% DMSO|Other Additives:Yes|Cryopreserved|Mobilized|Plasma Reduced in the Product Code drop down box.
      a. Press Tab to update the label preview.
   2.5 Select Label Quantity: 2 (or greater is more freezing bags)
   2.6 Click Select Label, highlight 3.75 x 1.5 label.
   2.7 Select 3.75 x 1.5 label from the Printer drop down box.
   2.8 The Print Volumes Box will reappear based on the quantity of labels printed.
      a. Select the next alphabetic division in the Division 1 drop down box for each label printed.
         Example: Bag 1 = A0
         Bag 2 = B0
         Bag 3 = C0
         Bag 4 = D0

   2.9 Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box
   2.10 Click Print once for each label printed.

3. Have a second technologist check the 4x4 and the partial labels.

   3.1 The source document for the check must be the EPIC electronic order.
   3.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
   3.3 The checking technologist must initial on the Processing Worksheet to document the check.

4. Fold the label in half and insert in the pocket of the freezing bag.

EXPECTED OUTCOME RESULTS: Autologous ISBT labels for freezing bags are generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## C. RELATED ALLOGENEIC HPC- COLLECTED AND INFUSED AT WFUBMC

Chemical Risk Assessment: None

Biological Risk Assessment: Low
Protective Equipment: None

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 1.5 x 0.75 inches cryolabels (CT-15x75-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 1.5 x 0.75 inches.
Specimen Requirements: n/a

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop and Login box will appear.

2. Log in to the HematraxCT software.
   2.1 Main screen will appear at login.

3. Click on Label Design Tab.

4. Print Full Face Label: Click on Select Label.

   4.1 Select 4x4 Full Face from the drop down box.
   4.2 Click Generate DIN.
   4.3 Record DIN in the Patient Index have another technologist check as in protocol bullet 18.
   4.4 Electronic Patient Index is at G:/Lab Shared/BMT Common/BMT Processing Lab/Electronic Patient Index.
   4.5 Select S1128 - HPC,Apheresis|Citrate|xx|refg|Mobilized (or appropriate code) from the Product Code drop-down box.
      a. Refer to Code descriptions, Attachment 1.
   4.6 Select the Standard button.
   4.7 Select correct blood type from the Blood Type drop down box.
   4.8 Select For Use By Intended Recipient Only from the Donation Type drop down box.
   4.9 Select Related Donor, 1st or 2nd Degree from the Donor Type drop down box.
   4.10 Complete Donor Name and ID and Recipient Name and ID from the source document.
      a. EPIC electronic order from the Nurse Coordinators is the source document.
   4.11 Select Wake Forest Baptist Health from the Collection Facility and Processing Facility drop down boxes.
   4.11 Leave the Collection Date/Time and Expiration Date/Time boxes unchecked.
   4.12 Select Label qty: 1
   4.13 Select 4x4 label from the Printer drop down box.
   4.14 Click Print and Print Volumes box will appear.
   4.15 Leave all Product Volumes blank and all Division codes 0.
      a. Click Print

## C. RELATED ALLOGENEIC HPC - COLLECTED AND INFUSED AT WFUBMC, CONTINUED

5. Print cryolabels: Click Print Log.

5.1 Highlight the line that corresponds to the printed DIN on the Print Log.
5.2 Click Get Data and the label design screen appears.
5.3 Delete Recipient Name and ID from Recipient Information.
a. Hit TAB to update label preview.
b. Only the W number and the S code should appear on the cryo label.
5.4 Click Select Label, highlight 1.5 x 0.75 cryo label.
5.5 Select Label Quantity: 20 (Or greater number if indicated or requested by the medical director).
5.6 Select 1.5 x 0.75 cryo label from the Printer drop down box.
5.7 Click Print.
5.8 Ensure that both Division Codes are 0.
5.9 Click Print once for each cryo label.

6. Have a second technologist check the 4x4 label and the cryo labels.

6.1 The source document for the check must be the EPIC electronic order.
6.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
6.3 The checking technologist must initial on the Patient Index to document the check.

7. Place the 4x4 label and 5 cryo labels in a biohazard Ziploc bag and send in tube system to apheresis, tube station 127.
7.1 Apheresis will apply the label to the product.

8. Use the remaining cryo labels for tubes, microbiology samples, and processing transfer bags.
9. If any product is to be frozen for backup use, continue to Frozen Allogeneic Products on Page 17 Section H.
10. If product is to be red cell or plasma depleted prior to infusion, continue to Reprinting Labels, and enter appropriate Product Code.

10.1 Refer to Code descriptions, linked to SOP in Title21.

EXPECTED OUTCOME RESULTS: Related Allogeneic ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## D. OUTGOING NMDP

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 1.5 x 0.75 inches cryolabels (CT-15x75-1A)

Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 1.5 x 0.75 inches.
Specimen Requirements: n/a

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop.
   1.1 Login box will appear.
2. Log in to the HematraxCT software.
   2.1 Main screen will appear at login.
3. Click on Label Design Tab.

4. Print Full Face Label for Apheresis: Click on Select Label.

   4.1 Select 4x4 Full Face from the drop down box.
   4.2 Click Generate DIN.
   4.3 Record DIN in the Patient Index have another technologist check as in protocol bullet S.
   4.4 Electronic Patient Index is at G:/Lab Shared/BMT Common/BMT Processing Lab/Electronic Patient Index.
   4.5 Select S1128 - HPC,Apheresis|Citrate|xx|refg|Mobilized (or appropriate code) from the Product Code drop-down box.
      a. Refer to Code descriptions, Attachment 1.
   4.6 Select the Investigational New Drug Button.
      For Related transplants through the NMDP, select the Standard button.
   4.7 Select Unknown in the Blood Type drop down box.
   4.8 Select For Use By Intended Recipient Only from the Donation Type drop down box.
   4.9 Select Related or Unrelated Donor according to the EPIC electronic order from the Donor Type drop down box.
   4.10 Complete Donor Name and Donor MR#, Recipient ID from the source document.
      a. EPIC electronic order from the Nurse Coordinators is the source document.
   4.11 Leave Donor and Recipient DOB boxes unchecked.
   4.12 Leave Collection Facility and Processing Facility as Not Selected.
   4.13 Check box for Expiration Date/Time.
   4.14 Select Infuse Within 48hrs.
   4.12 Select Label qty: 1
   4.13 Select 4x4 label from the Printer drop down box.
   4.14 Click Print and Print Volumes box will appear.
   4.15 Leave all Product Volumes blank and all Division codes 0, Click Print.

**D. OUTGOING NMDP, CONTINUED**

5. Print cryolabels: Click Print Log.

   5.1 Highlight the line that corresponds to the printed DIN on the Print Log.
   5.2 Click Get Data and the label design screen appears.
   5.3 Delete Recipient Name and ID from Recipient Information.

a. Hit TAB to update label preview.
b. Only the W number and the S code should appear on the cryo label.

5.4 Click Select Label, highlight 1.5 x 0.75 cryo label.
5.5 Select Label Quantity: 20 (Or greater number if indicated or requested by the medical director).
5.6 Select 1.5 x 0.75 cryo label from the Printer drop down box.
5.7 Click Print.
5.8 Ensure that both Division Codes are 0.
5.9 Click Print once for each cryo label.

6. Have a second technologist check the 4x4 label and the cryo labels.

6.1 The source document for the check must be the EPIC electronic order.
6.2 The labeling technologist must read and spell the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
6.3 The checking technologist must initial on the Patient Index to document the check.

7. Place the 4x4 label and 5 cryo labels in a biohazard Ziploc bag and send in tube system to apheresis, tube station 127.
7.1 Apheresis will apply the label to the product.

8. Once the product has been picked up and sampled for analysis, print Full Face Label for Outgoing Product. Click on Select Label.
8.1 Click Print Log.
8.2 Highlight the line that corresponds to the just printed DIN on the Print Log.
8.3 Click Get Data.
a. Label design screen appears.
8.4 Select the Investigational New Drug Button.
8.5 Change Donation Type to Related or Unrelated Donor according to the Physician Order Form.
8.6 Remove Donor Name and MR#.
8.7 Type Donor GRID# in Donor ID space; Barcode should display when GRID# is typed correctly.
8.8 Add Recipient Name and NMDP ID#
8.9 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
8.10 Check the box for Expiration Date/Time.
a. Expiration should read Infuse within 48 hours or as soon as feasible.
8.11 Click Select Label.
8.12Ensure that 4x4 Full Face label is selected.
8.13 Select Label qty: 1
8.14 Select 4x4 label from the Printer drop down box.
8.15 Click print.

## D. OUTGOING NMDP, CONTINUED

8. Print Full Face Label for Outgoing Product, continued.
8.16 Print Volumes box will appear.
a. Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box.
b. Product volume is total volume (product + ACDA)

8.17 Click Print.
8.18 Remove the DIN cutout from the printed label and place over the current product label that was applied by apheresis.

9. Print cryolabels: Click Print Log.

9.1 Highlight the line that corresponds to the printed DIN on the Print Log.
9.2 Click Get Data and the label design screen appears.
9.3 Click Select Label, highlight 1.5 x 0.75 cryo label.
9.4 Select Label Quantity: 10 (Or greater number if indicated or requested by the medical director).
9.5 Select 1.5 x 0.75 cryo label from the Printer drop down box.
9.6 Click Print.
9.7 Ensure that both Division Codes are 0.
9.8 Click Print once for each cryo label.

10. Have a second technologist check the 4x4 label using the Verification of Product Labeling Form.

10.1 The source document for the check must be the EPIC electronic order.
10.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
10.3 The checking technologist must initial on the Processing Form to document the check.

11. Continue with Releasing Products to the NMDP,SCT-SOP-0194.

EXPECTED OUTCOME RESULTS: Outgoing NMDP ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## E. CONCURRENT PLASMA

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printer 4x4 inches
Specimen Requirements: n/a

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop.

1.1 Login box will appear.
2. Log in to the HematraxCT software.
   2.1 Main screen will appear at login.
3. Click on Label Design Tab.
4. Print 4x4 inch Full Face Label for apheresis:
   4.1 Click Print Log
   4.2 Highlight the line that corresponds to the DIN# you are working with on the Print Log.
   4.3 Click Get Data.
   4.4 Label design screen appears.
   4.5 Have another technologist check as in protocol bullet S.
   4.6 Select S1185 – Concurrent Plasma, Apheresis|Citrate|xx|refg|For further processing:donor cell prod in the Product Code drop down box.
      a. S1179 - Concurrent Plasma, Apheresis|Citrate+Heparin|xx|refg|For further processing:donor cell prod is used if heparin is added to the concurrent plasma.
   4.7 Select the Standard Button.
   4.8 Select Unknown in the Blood Type drop down box.
   4.9 Select For Use By Intended Recipient Only from the Donation Type drop down box.
   4.10 Select Unrelated Donor in the Donor Type drop down box.
   4.11 Complete Donor NMDP ID and Recipient NMDP ID from the source document.
   4.12 Leave Donor and Recipient DOB boxes unchecked.
   4.13 Leave Collection Facility and Processing Facility as Not Selected.
   4.14 Check box for Expiration Date/Time.
   4.15 Select Process As Soon As Possible.
   4.16 Ensure 4x4 label is selected in the Printer drop down box.
   4.17 Click print.
   4.18 Print Volumes box will appear.
      a. Leave Product, Anticoagulant, and Heparin Volumes blank.
   4.19 Leave 0 in the Division 2 drop down box.
   4.20 Click Print.

5. Have a second technologist check the 4x4.
   5.1 The source document for the check must be the EPIC electronic order.
   5.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
   5.3 The checking technologist must initial on the Processing Form to document the check.

## E. CONCURRENT PLASMA, CONTINUED

6. Place the 4x4 label in a biohazard Ziploc bag and send in tube system to apheresis, tube station 127.

   6.1 Apheresis will apply the label to the product.
   6.2 When product comes back, reprint label with volumes printed.
   6.3 Remove Donor Name and MR#.
   6.4 Add Donor GRID #
   6.5 Add Recipient Name and NMDP #.
   6.6 Add collection and expiration date and time.

EXPECTED OUTCOME RESULTS: Outgoing NMDP ISBT label for concurrent plasma will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## F. INCOMING NMDP PRODUCTS

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None
Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 1.5 x 0.75 inches cryolabels (CT-15x75-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 1.5 x 0.75 inches.
Specimen Requirements: n/a

1. If no processing of product will occur, no new label shall be printed.
   1.1 Continue with Related Allogeneic HPC,A, SCT-SOP-0199.
2. Open HemaTraxCT software, current validated version from the ISBT computer desktop.
   2.1 Login box will appear.
3. Log in to the HematraxCT software.
   3.1 Main screen will appear at login.
4. Click on Label Design Tab.

5. Print new Full Face Label for Product with updated S code:
   5.1 Click on Select Label.
   5.2 Select 4x4 Full Face from the drop down box.
   5.3 Use bar code scanner to scan the DIN from the product label.
   5.4 Select appropriate code from the Product Code drop-down box.
   a. Refer to code descriptions, Attachment 1.
   5.5 Select the Standard button.
   5.6 Select For Use By Intended Recipient Only from the Donation Type drop down box.
   5.7 Select Related or Unrelated Donor according to the Physician Order Form from the Donor Type drop down box.
   5.8 Complete Donor ID and Recipient Name and ID from the source document.
   a. Electronic EPIC order from the Nurse Coordinators is the source document.
   5.9 Select Not Selected from the Collection Facility and Processing Facility drop down boxes.
   5.10 Check the box for Collection Date/Time.
   a. Enter the Collection Date and Time.

## INCOMING NMDP PRODUCTS, CONTINUED

   5.11 Check the box for Expiration Date/Time.
   a. Enter the Expiration Date and Time.
   5.12 Select Label qty: 1
5.13 Select 4x4 label from the Printer drop down box
   5.14 Click Print.
   a. Print Volumes box will appear.
   5.15 Enter Product Volumes from original bag label (that was applied by the donor center).
   a. Total volume is concentrated HPC + freezing medium.
   5.16 Click Print.

6. Print cryo labels: Click Print Log.

6.1 Highlight the line that corresponds to the printed DIN on the Print Log.
6.2 Click Get Data and the label design screen appears.
6.3 Click Select Label, highlight 1.5 x 0.75 cryo label.
6.4 Select Label Quantity: 20 (Or greater number if indicated or requested by the medical director).
6.5 Select 1.5 x 0.75 cryo label from the Printer drop down box.
6.6 Click Print.
6.7 Ensure that both Division Codes are 0.
6.8 Click Print once for each cryo label.

7. Have a second technologist check the 4x4 and the cryolabels.

7.1 The source document for the check must be the EPIC electronic order.
7.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
7.3 The checking technologist must initial on the Processing Form to document the check.

8. Remove the DIN cutout from the printed label, and place over the current product label (that was applied by the donor center).

8.1 The original DIN must be clearly visible when the printed label is applied.
8.2 If donor center does not use ISBT terminology, remove the entire label and retain.

9. Place a label on each cryovial.
9.0 Use remaining cryovial labels to label sample tubes and micro samples.

10. Continue with Related Allogeneic HPC,A,SCT-SOP-0199.
11. Calculate amount of Plasmalyte-A in product according to SOP; Record amount on Plasmalyte-A sticker and attach to product label. Label Master can be accessed at G:/Lab Shared/BMT Common/BMT Processing Lab/For Review/mL Plasmalyte Added Label

EXPECTED OUTCOME RESULTS: Incoming NMDP ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

**G. BONE MARROW PRODUCTS COLLECTED AT WAKE FOREST BAPTIST MEDICAL CENTER**

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop.
   1.1 Login box will appear.
2. Log in to the HematraxCT software.
   2.1 Main screen will appear at login.
3. Click on Label Design Tab.
4. Print Full Face Labels:
   4.1 Click on Select Label.
   4.2 Select 4x4 Full Face from the drop down box.
5. Click Generate DIN.
   5.1 Record DIN in the Patient Index and have another technologist check as in protocol bullet S.

5.2 Electronic Patient Index is at G:/Lab Shared/BMT Common/BMT Processing Lab/Electronic Patient Index.
5.3 Select S1288 – HPC,Marrow|Heparin|xx|refg|Other Additive:Yes (or appropriate code) from the Product Code drop-down box.
5.4 Refer to In-house code descriptions, Attachment 1.
5.5 Select the Standard button.
5.6 Select Not Selected in the Blood Type drop down box.
5.7 Select For Use By Intended Recipient Only from the Donation Type drop down box.
5.8 Select Unrelated Donor or Related Donor in the Donor Type drop down Box according to the Physician Order Form.
5.9 Complete Donor Name and MR# and Recipient NMDP # from the source document.
a. Physician Order Form from the Nurse Coordinators is the source document.
5.10 Leave Donor and Recipient DOB boxes unchecked.
5.11 Leave Collection and Processing Facilities Not Selected.
5.12 Check box for Expiration Date/Time.
5.13 Select Infuse Within 48hrs.
5.14 Ensure 4x4 label is selected in the Printer drop down box.
5.15 Select Label qty: 4.
5.16 Click print.
a. Print Volumes box will appear.
5.17 Leave Product, Anticoagulant, and Heparin Volumes blank in the Print Volumes Box.
5.18 Select A from the Division 1 drop down box.
a. Leave 0 in the Division 2 drop down box
5.19 Click Print.
a. The Print Volumes Box will reappear based on the quantity of labels printed.
5.20 Select the next alphabetic division in the Division 1 drop down box for each label printed.
Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0
5.21 Click print.
a. Print Volumes box will appear.
b. Click Print again to print label.

**G. BONE MARROW PRODUCTS COLLECTED AT WAKE FOREST BAPTIST MEDICAL CENTER, CONTINUED**

6. Print cryo labels: Click Print Log.

6.1 Highlight the line that corresponds to the printed DIN on the Print Log.
6.2 Click Get Data and the label design screen appears.
6.3 Click Select Label, highlight 1.5 x 0.75 cryo label.
6.4 Select Label Quantity: 20 (Or greater number if indicated or requested by the medical director).
6.5 Select 1.5 x 0.75 cryo label from the Printer drop down box.
6.6 Click Print.
6.7 Ensure that both Division Codes are 0.
6.8 Click Print once for each cryo label.

7. Have a second technologist check the 4x4 and the cryo labels.
   7.1 The source document for the check must be the EPIC electronic order.
   7.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
   7.3 The checking technologist must initial on the Patient Index to document the check.

8. Obtain four labels indicating volume of Plasmalyte-A added.
   8.1 Label Master can be accessed at G:/Lab Shared/BMT Common/BMT Processing Lab/For Review/mL Plasmalyte Added Label
9. Place the four 4x4 labels, 10 cryo labels, and four mL Plasmalyte added labels in a biohazard Ziploc bag in the OR collection basket with one 1000mL bag of Plasmalyte-A and 3 vials of 10,000 unit/mL heparin.
   9.1 Check to ensure lot numbers and expiration dates of heparin and Plasmalyte are logged on the OR Package Log.
   9.2 Use the remaining 10 cryolabels to label any sample tubes.
10. When marrow product arrives from the OR in SCTCT lab, Print new Full Face labels for the product bags:
   10.1 Highlight the line that corresponds to the just printed DIN on the Print Log.
   10.2 Click Get Data and the label design screen appears.
   10.3 Check the box for Collection Date/Time.
      a. Enter the Collection Date and Time.
   10.4 Check the box for Expiration Date/Time.
      a. Change Expiration Period to Custom.
      b. Enter the Expiration Date and Time.
   10.5 Click Select Label.
   10.6 Select 4x4 Full Face label.
   10.7 Remove Donor Name and MR#.
   10.8 Add Donor GRID#.
   10.9 Add Recipient Name and NMDP#
   10.10 Change label quantity to the number of labels needed.
   10.11 Ensure 4x4 label is selected in the Printer drop down box.
   10.12 Click print.
   10.13 The Print Volumes Box will reappear based on the quantity of labels printed.
      a.Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box.
   10.14 Click Print.
      a. Print Volumes box will appear.

**G. BONE MARROW PRODUCTS COLLECTED AT WAKE FOREST BAPTIST MEDICAL CENTER, CONTINUED**

11. Remove the DIN cutout from the printed label, and place over the current product label (that was applied by nurse in OR).
   11.1 The original DIN must be clearlyvisible when the printed label is applied.

12. Continue with OR Harvest,SCT-SOP-0161.

EXPECTED OUTCOME RESULTS: Marrow ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

**H. FROZEN ALLOGENEIC PRODUCTS**

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 3.75 x 1.5 inches (CT-375x15-FOLD-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 3.75 x 1.5 inches
Specimen Requirements: n/a

1. Print 4x4 inch Full Face Labels for freezing bags:

1.1 Click Print Log
1.2 Highlight the line that corresponds to the DIN# you are working with on the Print Log.
1.3 Click Get Data.
1.4 Label design screen appears.
1.5 Select S1475 HPC,Apheresis|Citrate|xx|≤-120C|10% DMSO|Other Additives:Yes|Cryopreserved|Mobilized|Plasma Reduced (or appropriate code) in the Product Code drop down box.
a. Refer to Code Descriptions, Attachment 1.
1.6 Press Tab to update the label preview.
1.7 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
1.8 Check the box for Expiration Date/Time.
a. Enter the Expiration Date and Time.
1.9 Click Select Label.
1.10 Ensure that 4x4 Full Face label is selected.
1.11 Change label quantity to the number of labels needed depending on the cell concentration per bag.
1.12 Ensure 4x4 label is selected in the Printer drop down box.
1.13 Click print.
1.14 Print Volumes box will appear.
a. Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box.
b. Product volume is total volume (product + ACDA)
1.15 Select A from the Division 1 drop down box.
1.16 Leave 0 in the Division 2 drop down box.

**H. FROZEN ALLOGENEIC PRODUCTS, CONTINUED**

1.17 Click Print.
1.18 The Print Volumes Box will reappear based on the quantity of labels printed.
a. Select the next alphabetic division in the Division 1 drop down box for each label printed.
Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0
1.19 Attach each label to a freezing bag.

2. Print Partial Labels:
2.1 Click Print Log.
2.2 Highlight the line that corresponds to the Auto DIN on which you are working on the Print Log.
2.3 Click Get Data and the label design screen appears.
2.4 Select S1475- HPC,Apheresis|Citrate|xx|≤-120C|10% DMSO|Other Additives:Yes|Cryopreserved|Mobilized|Plasma Reduced in the Product Code

drop down box.
a. Press Tab to update the label preview.
2.5 Select Label Quantity: 2 (or greater is more freezing bags)
2.6 Click Select Label, highlight 3.75 x 1.5 label.
2.7 Select 3.75 x 1.5 label from the Printer drop down box.
2.8 The Print Volumes Box will reappear based on the quantity of labels printed.
a. Select the next alphabetic division in the Division 1 drop down box for each label printed.
Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0
2.9 Enter Product, Anticoagulant, and if applicable Heparin Volumes in their respective blanks in the Print Volumes Box
2.10 Click Print once for each label printed.

3. Have a second technologist check the 4x4 and the cryo labels.

3.1 The source document for the check must be the EPIC electronic order.
3.2 The labeling technologist must read the name, medical record number, and ISBT number aloud while the checking technologist views the labels.
3.3 The checking technologist must initial on the Processing Worksheet to document the check.

4. Fold the label in half and insert in the pocket of the freezing bag.
5. Place a label on the freezing bag indicating volume of Plasmalyte-A in frozen bag.
5.1 Label Master can be accessed at G:/Lab Shared/BMT Common/BMT Processing Lab/For Review/mL Plasmalyte Added Label

EXPECTED OUTCOME RESULTS: ISBT labels for freezing bags will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## I. REPRINTING LABELS

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: None

Supplies: Digitrax labels: 4x4 inches with DIN cutout (RR-CT-G4) and 3.75 x 1.5 inches (CT-375x15-FOLD-1A)
Reagents: n/a
Equipment: ISBT computer in SCTCT Lab (713-1M5K8Y1), 3 Digitrax Zebra printers, 4x4 inches and 3.75 x 1.5 inches
Specimen Requirements: n/a

1. Open HemaTraxCT software, current validated version from the ISBT computer desktop.
1.1 Login box will appear.
2. Log in to the HematraxCT software.
2.1 Main screen will appear at login.
3. Click on Label Design Tab.
4. Reprint 4x4 Full Face Labels:
4.1 Click on Select Label.
4.2 Select 4x4 Full Face from the drop down box.
4.3 Use bar code scanner to scan the DIN from the original product label.

4.4 Select appropriate code from the Product Code drop-down box.
4.5 Refer to code descriptions, linked in Title21.
4.6 Select the Standard button.
4.7Select Donation Type from the Donation Type drop down box.
4.8 Select Donor from the Donor Type drop down box.
4.9 Complete Donor ID and Recipient Name and ID from the source document.
a. Physician Order Form from the Nurse Coordinators is the source document.
4.10 Select Wake Forest Baptist Health from the Collection Facility and Processing Facility drop down boxes.
4.11 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
b. Enter the Expiration Date and Time.
4.12 Select Label quantity.
4.13 Select label type from the Printer drop down box.
4.14 Click Print.
a. Print Volumes box will appear.
4.15 Enter Product Volumes from original bag label.
4.16 Select the next alphabetic division in the Division 1 drop down box for each label printed.

Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0

4.17 Click print.
a. Print Volumes box will appear.
b. Click Print again to print label.

## I. REPRINTING LABELS, CONTINUED

5. Reprint 3.75” x 1.5” Partial Labels:

5.1 Click on Select Label.
5.2 Select 3.75” x 1.5” label from the drop down box.
5.3 Use bar code scanner to scan the DIN from the original product label.
5.4 Select appropriate code from the Product Code drop-down box.
5.5 Refer to code descriptions, Attachment 1.
5.6 Select the Standard button.

5.7Select Donation Type from the Donation Type drop down box.
5.8 Select Donor from the Donor Type drop down box.
5.9 Complete Donor ID and Recipient Name and ID from the source document.
a. Physician Order Form from the Nurse Coordinators is the source document.

5.10 Select Wake Forest Baptist Health from the Collection Facility and Processing Facility drop down boxes.

5.11 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
b. Enter the Expiration Date and Time.

5.12 Select Label quantity.
5.13 Select label type from the Printer drop down box.

5.14 Click Print.
a. Print Volumes box will appear.
5.15 Enter Product Volumes from original bag label.
5.16 Select the next alphabetic division in the Division 1 drop down box for each label printed.

Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0
Bag 4 = D0

5.17 Click print.
a. Print Volumes box will appear.
b. Click Print again to print label.

6. Reprint 1.5" x .75" cryolabels:

6.1 Click on Select Label.
6.2 Select 4x4 Full Face from the drop down box.
6.3 Use bar code scanner to scan the DIN from the original product label.
6.4 Select appropriate code from the Product Code drop-down box.

6.5 Refer to code descriptions, linked in Title21.
6.6 Select the Standard button.
6.7Select Donation Type from the Donation Type drop down box.
6.8 Select Donor from the Donor Type drop down box.

## I. REPRINTING LABELS, CONTINUED

6.9 Complete Donor ID and Recipient Name and ID from the source document.
a. Physician Order Form from the Nurse Coordinators is the source document.

6.10 Check the box for Collection Date/Time.
a. Enter the Collection Date and Time.
b. Enter the Expiration Date and Time.

6.11 Select Label quantity.
6.12 Select label type from the Printer drop down box.

6.13 Click Print.
a. Print Volumes box will appear.
6.14 Select the next alphabetic division in the Division 1 drop down box for each label printed.

Example: Bag 1 = A0
Bag 2 = B0
Bag 3 = C0

Bag 4 = D0

6.15 Click print.

a. Print Volumes box will appear.

b. Click Print again to print label.

EXPECTED OUTCOME RESULTS: Reprinted ISBT labels will be generated and assigned to a patient collection.

ACCEPTABLE RANGES: n/a

## SECTION X. QUICK REFERENCE TABLES

### AUTO PRODUCTS – FROZEN

| Product Attributes | ISBT Label | Partial Label | Additives Label | Biohazard legend | Tie Tag 1 | Tie Tag 2 | Warning Tag |
|---|---|---|---|---|---|---|---|
| Frozen Auto - All IDMs negative | X | X | X | | X | | |
| Frozen Auto - Known + IDM (Including CMV) | X | X | X | X | X | X | |
| Known Positive Microbial Culture | X | X | X | | X | | X |

### ALLOGENEIC PRODUCTS – FRESH (INCLUDES CONCURRENT PLASMA)

| Related Allo: Product Attributes | ISBT Label | Additives Label | Tie Tag 1 | Tie Tag 2 | Tie Tag 3 | Warning Tag | Final Declaration of Eligiblilty | Urgent Medical | Reason for Ineligibility |
|---|---|---|---|---|---|---|---|---|---|

| | | | | | | | | Need Form | |
|---|---|---|---|---|---|---|---|---|---|
| IDMs not tested in CLIA certified, FDA registered lab within 30 days (HPC) or 7 days(DLI) of collection | X | | X | | | | X | | |
| Known + IDM | X | | | X | | | X | | |
| Known Risk Factors on PE | X | | | | X | | X | | |
| Eligible Donor | X | | | | | | X | | |
| Ineligible Donor | X | | | | | | X | X | X |
| Known Positive Microbial Culture | X | | X | X | | X | X | | |
| Plasma depleted | X | X | | | | | | | |

## ALLOGENEIC PRODUCTS – FROZEN

| Related Allo: Product Attributes | ISBT Label | Partial Label | Additives Label | Tie Tag 1 | Tie Tag 2 | Tie Tag 3 | Warning Tag | Final Declaration of Eligibility | Urgent Medical Need Form | Reason for Ineligible |
|---|---|---|---|---|---|---|---|---|---|---|
| IDMs not tested in CLIA certified, FDA registered lab within 30 days (HPC) or 7 days(DLI) of collection | X | X | X | X | | | | X | | |
| Known + IDM | X | X | X | | X | | | X | | |
| Known Risk Factors on PE | X | X | X | | | X | | X | | |
| Eligible Donor | X | X | X | | | | | X | | |
| Ineligible Donor | X | X | X | | | | | X | X | X |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Known Positive Microbial Culture | X | X | X | | | | X | X | | |

**1.**
**2.**
3. Donor Eligibility is determined by the nurse coordinators or the NMDP. Refer to *Explanation of Eligibility Determination and Associated Product Labeling, SCT-SOP-0407*
4.
5. Note: The Final Declaration of Donor Eligibility, Urgent Medical Need Form, and the reason for the donor's ineligibility do not need to be attached or affixed to the product bag, they only need to accompany the product at the time of distribution.
**6.**

**Citrate Calculation (Amount of Citrate in Frozen Bag):**

Total volume Citrate in frozen bags = $\frac{\text{mL Citrate in Original product bag} \times \text{Concentrated cell volume}}{\text{Original product volume}}$

mL Citrate to put on frozen bag label = $\frac{\text{Total volume Citrate in frozen bags}}{\text{\# of frozen bags}}$

**Example:** 300mL product bag with 28mL Citrate. 50mL concentrated cells.

Total volume Citrate in frozen bags = $\frac{28 \times 50}{300}$ = 4.7mL

50mL concentrated cells would be split into 2 bags for freezing, so:

4.7 ÷ 2 = 2.35mL (can round up to one decimal place, 2.4mL)

Plasmalyte Calculation (Amount of Plasmalyte in Frozen Bag):

mL Plasmalyte Recorded on Additives Sticker = mL concentrated cells x mL Plasmalyte in freezing medium Total volume of freezing medium

**Example**: 35mL concentrated cells, single batch of freezing medium (30mL Plasmalyte, 15mL DMSO, 30mL donor plasma)

mL Plasmalyte Recorded on Additives Sticker = $\frac{35 \times 30}{75}$ = 14mL

**SECTION X. DOWNTIME PROCEDURES**

- In case of computer downtime, blank ISBT labels will be completed as much as possible by SCTCT staff and supplied to apheresis or marrow collection staff.
- A stock of blank labels for each S code is stored in SCTCT lab.

## VI. CROSS REFERENCES

Declaration of Urgent Medical Need
Final Declaration of Donor Eligibility
Positive Culture Tag
Allogeneic Tie Tag #3
Auto Tie Tags #1 and 2
Allo Tie Tag #1
Allo Tie Tag #2
FDA Requirements
Code Descriptions HPC, A
Code Descriptions HPC, M
Code Descriptions T Cells
Code Descriptions Concurrent Plasma
Related Allogeneic Stem Cell Products
Calibr sCAR19 CAR-T Products

## VII. RESOURCES AND REFERENCES

1.0 Circular of Information for the Use of Cellular Therapy Products, NMDP Document Control #L00016 rev 7, July 2021
2.0 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, revised periodically

## VIII. ATTACHMENTS

Not Applicable