Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Labeling Cellular Therapy Products

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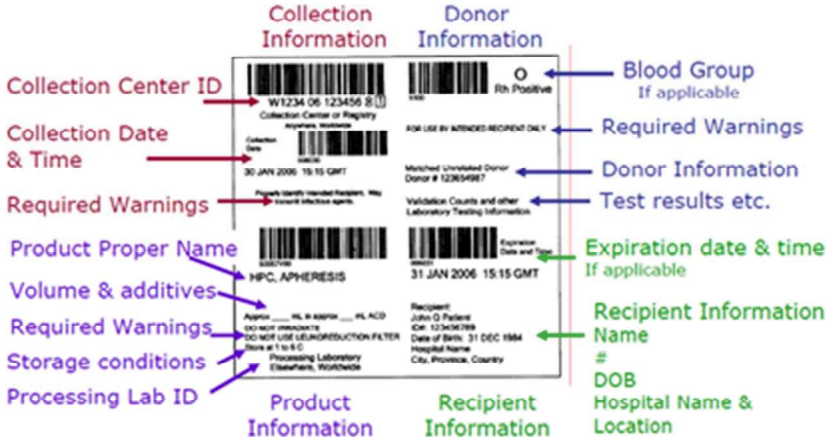
COMM-PAS-003
LABELING CELLULAR THERAPY PRODUCTS

1 PURPOSE

1.1 To establish a uniform labeling procedure for cellular therapy products at the time of collection, processing, distribution, or transfer to another facility for processing, cryopreservation, and infusion.

2 INTRODUCTION

2.1 The Department of Health and Human Service recently proposed an initiative to bar code drugs and biological products in an effort to reduce errors. Proper identification of designated blood, HPC (Hematopoietic Progenitor Cells) for intended recipients challenges the adequacy of the current electronic data and labeling structure and systems for such products. Increasingly, these products may be collected in one country and used in another. To enhance safety and efficiency, more sophisticated computer systems are now used to track collection, transfusion and transplantation processes. Transfer of information amongst facilities is done via electronic devices for speed and accuracy. However, this transfer can only be effective if it follows an internationally agreed standard for data identifiers, data format information and the data pertaining to the product. This standard is known as ISBT 128. ISBT label is a standard labeling format that ensures a consistent layout of critical information for product labels. The label is divided into four quadrants with bar codes, blood groups and other specific information appearing in fixed positions.



2.2 The first quadrant contains the unique donation/ product identifier, date of collection, collection facility and specific use criteria of the product. The second quadrant contains the ABO and Rh and other information, e.g. type of donation etc. The third quadrant identifies the product type and anticoagulant used. The fourth quadrant identifies the processing site, expiration date and time. This format is used for labeling the HPC products.

2.3 Refer to *COMM-PAS-003 JA2 Cellular Therapy Product Labeling (Appendix II)* reflecting the current FACT-JACIE International Standards outlining the labeling requirements for cellular products at:

2.3.1 the completion of collection

2.3.2 the completion of processing

2.3.3 the time of partial labeling at distribution for administration (*if applicable*)

2.3.4 the time of labeling at distribution for administration

3 SCOPE AND RESPONSIBILITIES

3.1 This document applies to all HPC products labeled within the Stem Cell Laboratory and the Adult and Pediatric Blood and Marrow Transplant Program collection facilities.

3.2 Cellular therapy staff that performs all processes associated with the selection of product identifying labels for attachment to cellular components are responsible for ensuring that the requirements in this procedure are met.

3.3 Product Labeler is person responsible for completing and affixing the final label, ensuring that applicable tags are completed and attached, and ensuring that all are accurate, legible and complete.

3.4 Labeling Verifier is a second trained independent person who verifies that the product labeling is accurate, legible and complete.

4 DEFINITIONS/ACRONYMS

4.1 **ISBT label** is a standard labeling format that ensures a consistent layout of critical information for product labels.

4.2 **FIN –** Facility Identification Number is an identifier which includes a 5-character country and site code.

4.3 **ISBT Unique Donation Identifier –** The identifier includes a 5-character country and site code (Facility Identification Number), a 2-digit year code, a 6-digit sequence number, a 2-digit process control code printed vertically (flag characters), and a boxed checksum character for use in verifying keyboard entry (see W1234 96 123456 44 S in sample label). Only the first thirteen digits are considered. All cellular therapy products collected from the same donor concurrently, including product samples, will be labeled with the same identifier.

NOTE: Since annual clinical volumes are hard to predict, there may be some overlap of barcodes from one year to another in an effort to minimize waste (*ie 2023 barcodes can be used through 01/31/2024; one month after previous year*).

4.4 **HPC, Apheresis** is collected from the peripheral blood by an apheresis procedure, usually after recombinant hematopoietic growth factor administration. Autologous donors may also have undergone chemotherapy mobilization. Allogeneic peripheral blood HPC, Apheresis is frequently infused in an unmodified state, but may be processed for common modifications, such as decreasing the volume of ABO-incompatible red cells, removing ABO-

incompatible plasma, purifying CD34+ progenitor cells, and removing donor T lymphocytes. The most common modifications of autologous HPC, Apheresis are reducing the volume by removing plasma prior to cryopreservation, purifying CD34+ progenitor cells, and washing to remove DMSO after thawing.

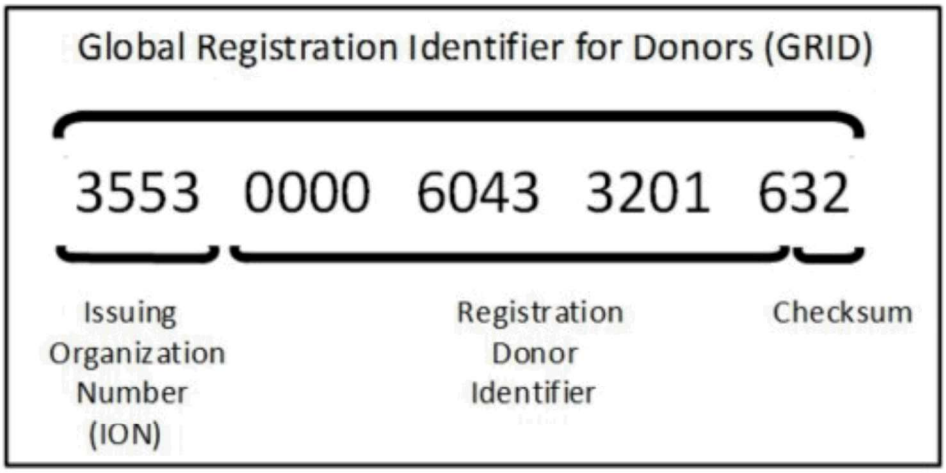
4.5 **HPC, Cord Blood** is obtained from the umbilical cord and, occasionally, placental vessels at the time of delivery and immediately placed in an anticoagulant solution. Initial processing may include removal of red blood cells and plasma. After collection and initial processing, HPC, Cord Blood are usually cryopreserved. A portion of cord blood cells may be reserved prior to or after thawing for culture using a cytokine-enriched culture medium in an effort to increase (expand) the number of committed progenitor cells in the product.

4.6 **HPC, Marrow** is obtained through multiple needle aspirations from the posterior iliac crests and occasionally from the anterior iliac crests or sternum of an autologous or allogeneic donor. The marrow is placed in a sterile container with an electrolyte solution and an appropriate anticoagulant. The cell suspension is run through sterile filters to remove fat, bone particles, and cellular debris before being transplanted. HPC, Marrow may also be cryopreserved for later transplant.

4.7 **On-Demand Printing** is the mechanism to use computer-based software to print labels singly or in multiples at the time of use.

4.8 **Tie tag** is a backing for the label that will be tied securely to the HPC container. The tie tag provides information or instructions that are specific for the HPC component.

4.9 **GRID –** Global Registration Identifier for Donors, implemented on 04/29/2019, was established to improve national and international communication by using a system to identify potential donors on a global scale. **GRID is only for donors** (*not for donations or Cord Blood Units (CBU*). GRID standard is a **19-character identifier** composed of three elements: (1) 4-digit Issuing Organization Number (ION), (2) 13-character Registration Donor Identifier (RDI), and (3) 2-digit checksum (a calculated number that ensures the preceding 17 digits are accurate and not mistyped.



NOTES:

- The WMDA has recognized that physical space on some labels may not accommodate both DID and GRID. In these cases, it will be acceptable for one of the IDs (ie. GRID) to display on the label provided **the accompanying documentation contains both DID and GRID**. If either ID is missing, the registry receiving communication is justified to ask for another ID.
- The NMDP / Be the Match will be displaying both the GRID and DID to allow seamless transition to the new GRID format.

4.10 **WMDA –** World Marrow Donor Association required an updated global standard for donor identification; WMDA collaborated with ICCBBA to develop and implement a Global Registration Identifier for Donors (GRID).

4.11 **ION –** Issuing Organization Number (*ie. NMDP # 3553, C.W. Bill Young Department of Defense Marrow Donor Program # 5315, DKMS US # 5081*). The ION identifies organizations that issue GRIDs and is assigned by ICCBBA in its role as an issuing agency under ISO 15459. A unique random ION is assigned to each issuing organization

4.12 **Primary Donor Identifier(s) –** More generic reference to Donor ID (DID) in NMDP-related documents, SOPs, etc. and can be used to reference DID or GRID.

4.13 **ICCBBA –** International Council for Commonality in Blood Banking Automation

4.14 **CIBMTR –** Center for International Blood and Marrow Transplant Research (Federally regulated approval process of the forms: 2400 (*Pre-Transplant Essential Data*), 2004 (*Infectious Disease Markers*), 2005 (*Confirmation of HLA Typing*), and 2006 (*Hematopoietic Stem Cell Transplant (HCT) Infusion)* will include a GRID field on these forms).

4.15 **AC –** Accompany (*labeling requirements in Appendix II must accompany, be attached, or be affixed to the product*); this could include paperwork that accompanies the product to the infusion location at the time of distribution (*such as Cellular Product Infusion Request Form, Infusion Form, etc.*)

4.16 **AF –** Affixed (*labeling requirements must be affixed to the product*); these labeling requirements must be physically on the product bag (*ie. on Demand 128 label on the bag*)

4.17 **AT –** Attached (*labeling requirements must be attached or affixed to the product*); this would be information attached typically using a tie tag that contains recipient-related information on the product.

5 MATERIALS

5.1 HemaTrax-CT software

5.2 Computype label stock – 4 x 4

5.3 DigiTrax label stock – 4 x 4 label with DIN cutout (*for use with NMDP products*)

5.4 Tie-tag 4.25 x 6 or 3 x 3.625

5.5 Avery label stock # 5162 (1 1/3" x 4")

5.6 Unique ISBT-128 barcodes (*registered to the Stem Cell Laboratory*)

6 EQUIPMENT

6.1 Computer with Windows 2000 (*or equivalent compatible version*)

6.2 Zebra label printer

6.3 Printer

6.4 Scanner

7 SAFETY

7.1 NA

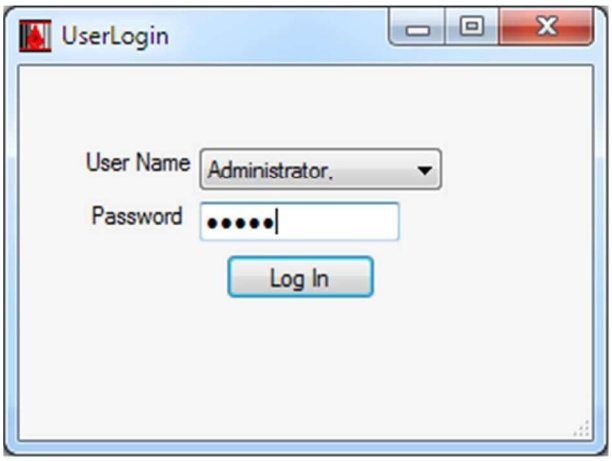
8 PROCEDURE

NOTE: *For all sections of this procedure where labels are affixed to containers, ensure there is a sufficient area of the product container that remains uncovered to permit inspection of the contents.*

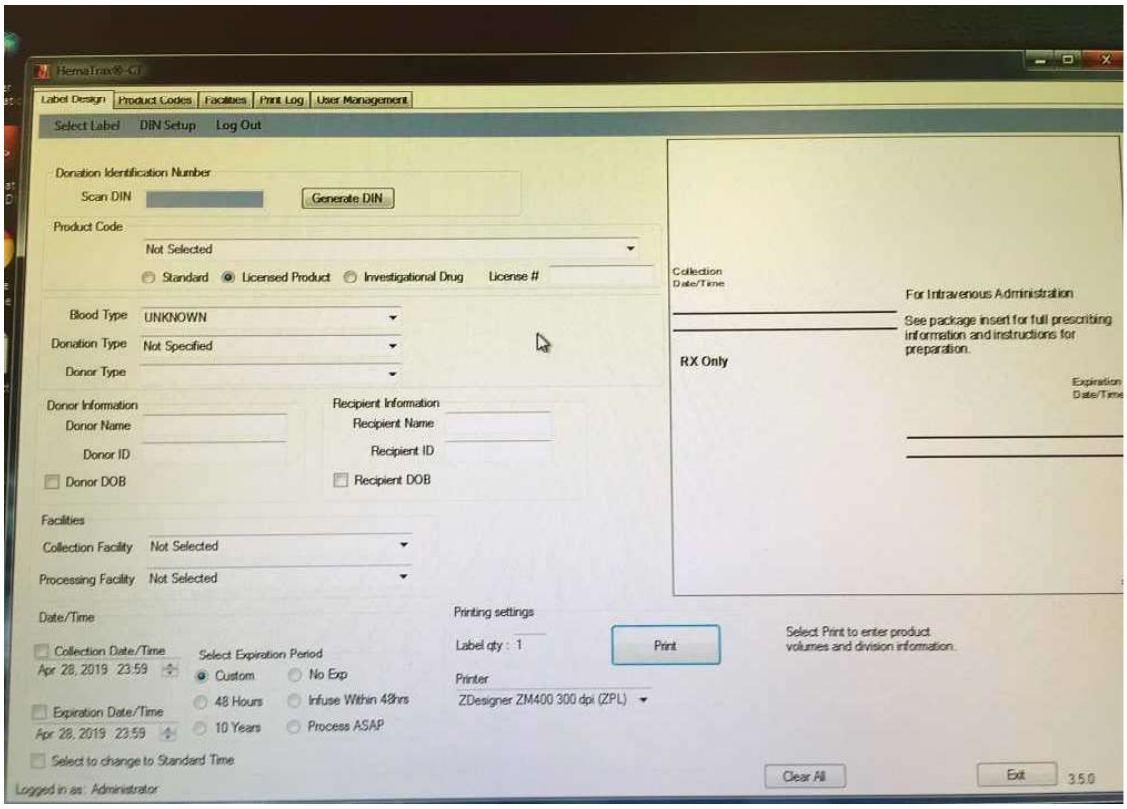
8.1 Log In

8.1.1 Double-click the HemaTrax-CT shortcut icon (*If you do not have a shortcut on your computer, click the Windows icon (Start) on the tool bar of your computer; look for HemaTrax-CT under Program*).

8.1.2 Click on your user name from the list and type in your password to log in.



8.1.3 The following screen will appear.



8.2 Printing Blank Base Labels for collection

NOTE: *DigiTrax label stock must be used when printing blank labels for NMDP products.*

8.2.1 Leave DIN blank

8.2.2 Click on dropdown arrow at product code

8.2.2.1 Select desired product code for label

8.2.2.2 When selecting product code the following must be considered:

8.2.2.2.1 Name of product

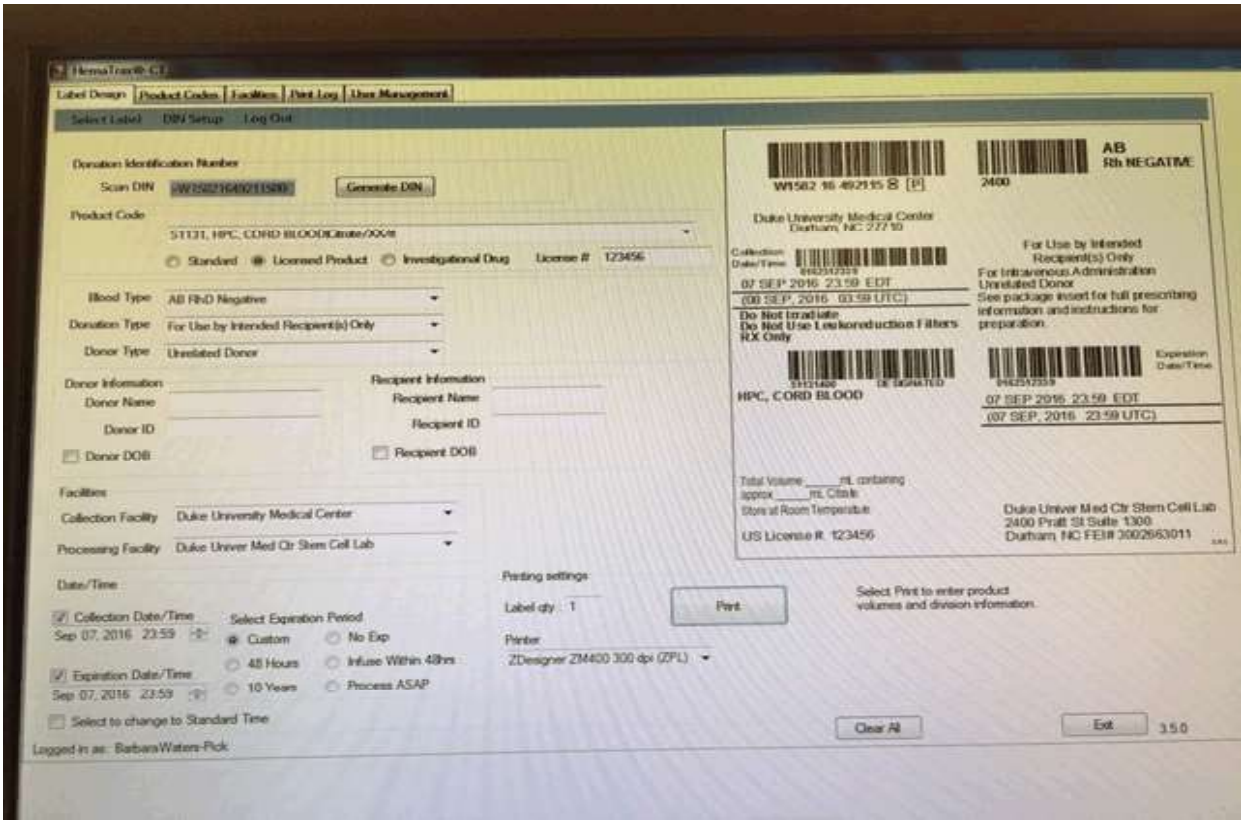
8.2.2.2.2 Anticoagulant being used

8.2.2.2.3 Storage temperature

8.2.2.2.4 If donor was mobilized

8.2.2.3 Select if the product is a standard, licensed or an investigational drug.

8.2.2.3.1 If the product is license, the license number may be entered on the label.



8.2.2.4 Click on dropdown arrow for Blood type. Select “Special Message”.

8.2.2.5 Click on “Special Message” dropdown and select “Quarantine Hold for Further Testing or Processing”.

8.2.2.6 Click on “Donor Type”. Select the appropriate donor type i.e. Unrelated, Auto, etc.

8.2.2.7 Leave donor and recipient blank.

8.2.2.8 Click on “Collection Center” dropdown and select collection center. “Collection Center” must be left blank for NMDP products.

8.2.2.9 Click on “Processing Center” and select processing center. “Processing Center” must be left blank for a NMDP product.

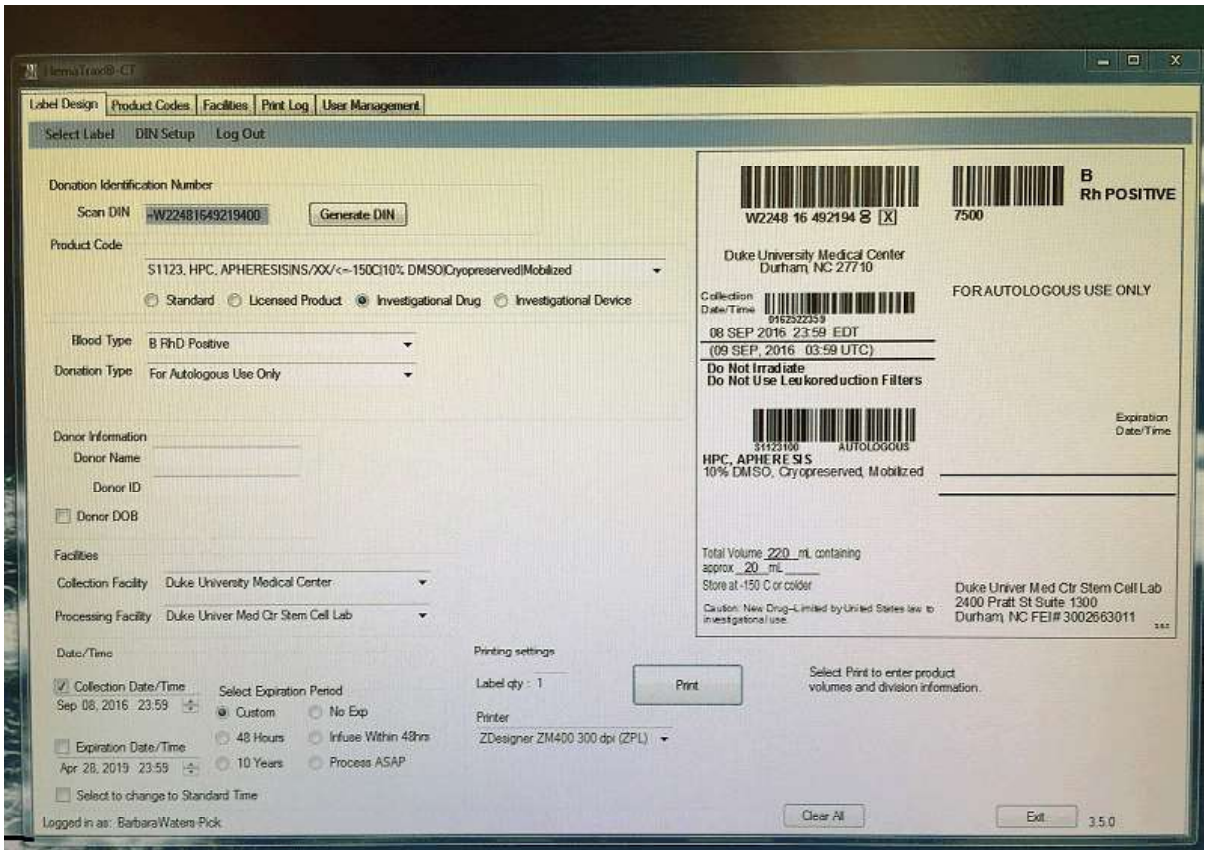
8.2.2.10 Leave collection and expiration date and time blank.

8.2.2.11 Enter the desired number of blank label to print. Click print. A pop up window will come up to enter product volumes. Leave blank and click print. A new pop-up window will come up until the desired quantity has been printed.

8.3 Data Entry

8.3.1 Scan in ISBT DIN (*if applicable*)

8.3.2 Click on dropdown arrow at product code



8.3.3 Select the appropriate product that is being collected or processed.

NOTE: *If Albumin or other blood component is being used during processing by the laboratory, a product code with 3rd party comp must be used (S1196 HPC, APHERESIS|NS/XX/<=-120C|10% DMSO|3rd Party Comp:Yes|Cryopreserved|Mobilized). If during processing the donor concurrent plasma is added to product a product code such as (S2005 HPC, APHERESIS|Citrate/XX/refg|Concurrent plasma|Mobilized) should be used.*

8.3.4 Select if the product is a standard, licensed or an investigational drug.

8.3.5 Click on dropdown arrow for Blood type.

8.3.6 Blood Type: Select Blood Type.

NOTE: ICCBBA allows for special messages instead of Blood Type. If a special message is required instead of blood type, select "Special Message" from the Blood Type dropdown menu. Once selected, a Special Message selection box will appear. Select desired special message to the right of the Blood Type dropdown.

8.3.7 Select donor's appropriate ABO Rh type (*if applicable*).

8.3.8 Click on drop down arrow for Donation Type.

8.3.9 Select appropriate donation type for donation.

8.3.10 Click on drop down arrow for Donor Type.

8.3.11 Select appropriate donor type if applicable.

8.3.12 Click on drop down arrow for Collection Facility.

8.3.12.1 Select appropriate collection facility for the cellular therapy product.

8.3.13 Click on drop down arrow for Processing Facility.

8.3.13.1 Select the appropriate processing facility.

8.3.14 Check the collection date/time if you want this information on the label. Enter collection date and time for the product.

8.3.15 Check expiration date/time if you want this information on the label. Enter expiration date and time if applicable.

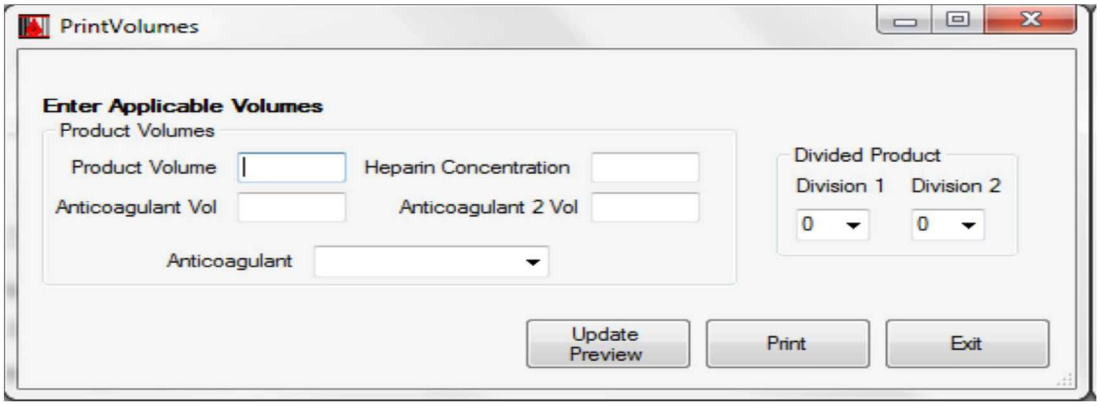
8.3.16 Enter a label quantity.

8.3.17 Make sure the printer selected is the one you are intending to print to.

8.3.18 Select Print and the following pop-up window will appear.

8.3.19 Enter any applicable product volume, anticoagulant volume, heparin concentration, cryoprotectant volume, or anticoagulant for that label. If left blank there will be a blank space available to manually record the volumes on the label.

NOTE: *Product codes will only use the volumes applicable for that product.*

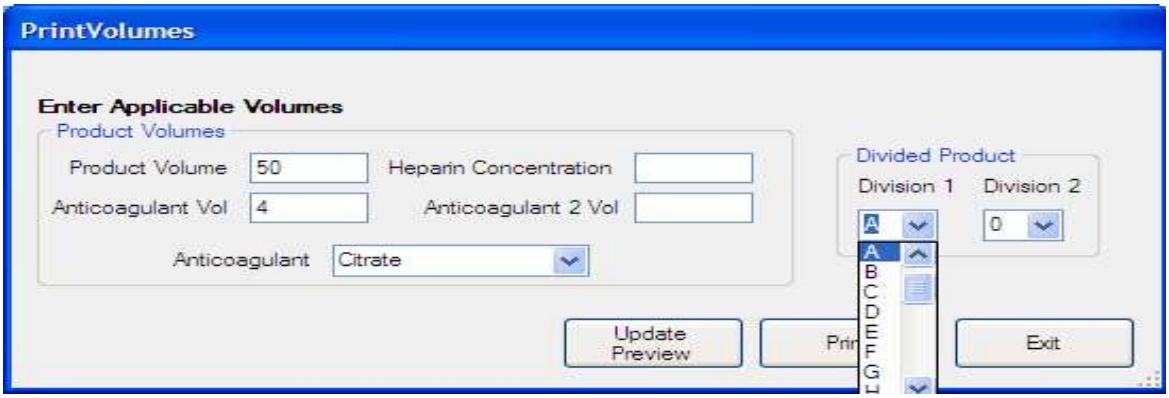


8.3.20 Select Print to print the completed label. If printing more than one label, a second pop-up window will appear. Repeat steps 8.3.1.9 and print again.

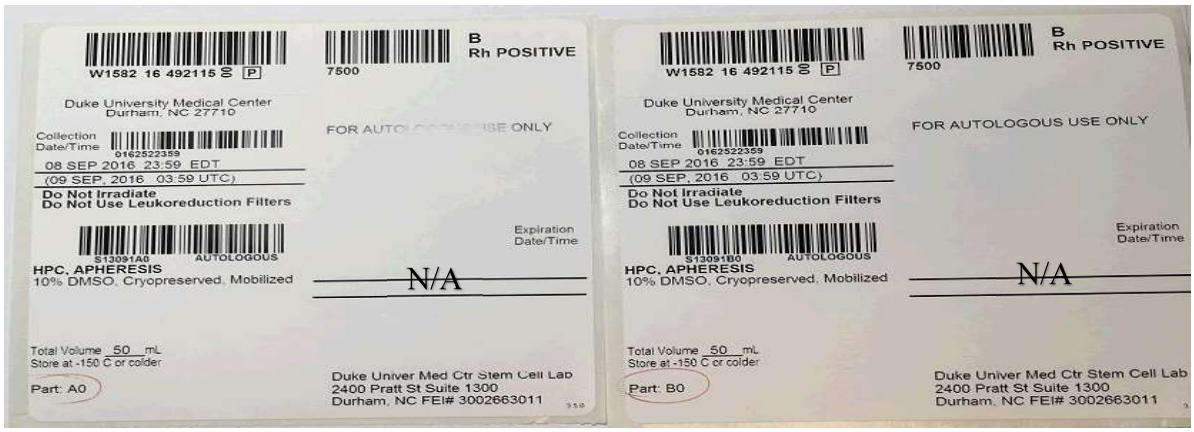
8.3.21 Printing labels for divided products

8.3.21.1 When a HPC product is frozen in multiple bags, a letter designation is required for each bag.

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



8.3.21.3 Select the corresponding letter designation for each bag (i.e., A, B, C, D, etc.). The final product label will be labeled with letter designation on lower left quadrant.



8.4 Ancillary Tie Tag

8.4.1 For Autologous Products, the ancillary tie tag attached should contain the following information:

8.4.1.1 Recipient's full name

8.4.1.2 Recipient's Duke history number

8.4.1.3 Recipient's date of birth

8.4.1.4 Recipient's blood type

8.4.1.5 Recipient's sex

8.4.1.6 "Do NOT Irradiate" disclaimer

8.4.1.7 "FOR AUTOLOGOUS USE ONLY" disclaimer

8.4.1.8 Cellular product type (*i.e. HPC, Apheresis, HPC, Cord Blood, HPC, Marrow, etc*.)

8.4.1.9 Affix ISBT 128 barcode label

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC

RECIPIENT:
Doe, Jane
History # XX1234, DOB: 12/25/1962
Patient ABO/RH = A Positive
Patient Sex = Female

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC

DONOR:
Doe, John
History # XX1235, DOB: 04/01/1990
Donor ABO/RH = A Negative, Donor Sex = Male
HPC, Apheresis (HPC-A)
"For Intended Recipient ONLY"
"Do NOT Irradiate"

8.4.2 For related Allogeneic Products, the ancillary tie tag should contain the following information:

8.4.2.1 Recipient's full name

8.4.2.2 Recipient's Duke history number

8.4.2.3 Recipient's date of birth

8.4.2.4 Recipient's blood type

8.4.2.5 Recipient's sex

8.4.2.6 Recipient's ID #

8.4.2.7 "For Intended Recipient Only" disclaimer

8.4.2.8 "Do NOT Irradiate" disclaimer

8.4.2.9 Donor's full name or # /GRID #

8.4.2.10 Donor's Duke history number or location ID #

8.4.2.11 Donor's date of birth

8.4.2.12 Donor's blood type

8.4.2.13 Donor's sex

8.4.2.14 Cellular product type (*i.e. HPC, Apheresis, HPC, Cord Blood, HPC, Marrow, etc*.)

8.4.2.15 Affix ISBT 128 barcode label.

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC

RECIPIENT:
Doe, Jane
History # XX1234, DOB: 12/25/1962
Patient ABO/RH = A Positive
Patient Sex = Female

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC

DONOR:
Doe, John
History # XX1235, DOB: 04/01/1990
Donor ABO/RH = A Negative, Donor Sex = Male
HPC, Apheresis (HPC-A)
"For Intended Recipient ONLY"
"Do NOT Irradiate"

8.4.3 For NMDP Products, the ancillary tie tag at time of collection should contain the following information:

8.4.3.1 Recipient's NMDP number

8.4.3.2 Donor ID or GRID #

8.4.4 The technologist must confirm the recipient/donor information demographics including, but not limited to name, medical record #, and

DOB, before attaching the tie tag to any cellular product. Label the cellular product by comparing and confirming all pertinent information in the EPIC or equivalent and/or the Laboratory Information System (*LIS – EPIC Beaker or equivalent*). Blood types can be confirmed in EPIC and/or SafeTrace (*system used by Transfusion Services*). This information is printed and filed with every recipient laboratory record for reference/verification.

8.4.5 A label containing the pertinent recipient/donor (*if applicable*) demographic information must be prepared using the designated label templates shown above (AUTO vs ALLO) on Avery labels. The recipient/donor (*if applicable*) Avery label will be affixed to a tie tag and then attached to each bag containing that cellular product.

8.4.6 A unique identification number (*ISBT-128 barcode registered to the Stem Cell Laboratory at Duke University Medical Center*) must be assigned to each cellular product. This unique ISBT-128 label may have already been issued for a cellular product before it arrives in the lab to be processed.

NOTE: *Barcodes are issued by the Stem Cell Laboratory to the apheresis collection sites, marrow collection sites, etc*. If the cellular product arrives in the laboratory with an ISBT-128 label already affixed to the cellular product, log the information onto the "Barcode Assignments for Products" log sheet located in the lab.

8.4.7 This unique identifier will follow the unit from collection or receipt of product to distribution of the product to the recipient.

8.4.8 If a product from NMDP or from other facilities does NOT have an ISBT 128 unique identifier already assigned to it, an ISBT-128 barcode label should be assigned to the product as follows:

8.4.8.1 Remove the next sheet of barcodes from the top of the stack located in the processing area of the Stem Cell Laboratory.

8.4.8.2 Place one ISBT-128 label onto the cellular product.

8.4.8.3 Place one ISBT-128 label onto the "Barcode Assignments for Products" log form and complete the log as indicated.

8.4.8.4 Place ISBT-128 labels on all pertinent processing records.

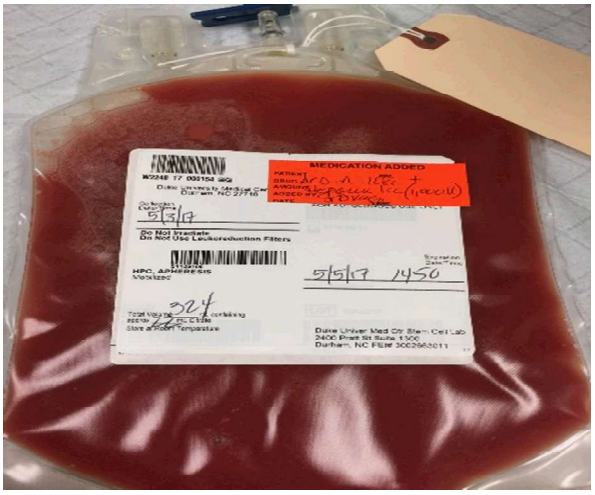
8.4.8.5 If multiple bags from the same collection must be frozen, each individual bag has a split product code.

8.5 COLLECTION LABELS – Apheresis

NOTE: *Do <u>NOT</u> leave blanks on the labels; populate information or enter N/A*

8.5.1 Prior to end of apheresis collection

8.5.1.1 Use a DigiTrax full label printed without Collection Date and Time and Expiration Date and Time. Place on-demand label over the existing base label on the collection bag.



8.5.1.2 Place ISBT Unique Donation Identifier in Quad 1(*top left corner*) of the on-demand label.

8.5.1.3 Place "For Use by Intended Recipient Only" label on tie tag and attach to bag if applicable.

8.5.2 After collection, using an indelible pen:

8.5.2.1 Record the Collection Date and End Time on the label.

8.5.2.2 Enter 48 hours from time of collection for Expiration Date and Time. *(**Exception** is a Granulocyte collection which is 24 hours from time of collection for Expiration Date and Time).*

8.5.2.3 On the label, record the following information:

8.5.2.3.1 Product volume

8.5.2.3.2 Amount of anticoagulant in the product

8.5.2.3.3 Name and amount of any additional additives

8.5.2.4 Verify all information and labels

8.6 COLLECTION LABELS – Marrow

NOTE: *Do NOT leave blanks on the labels; populate information or enter N/A*

8.6.1 Prior to marrow collection

8.6.1.1 Place the on-demand label above or to side of the lot number on collection bag.

8.6.1.2 Place ISBT Unique Donation Identifier in Quad 1(*top left corner*) of Demand label.

8.6.2 After collection, record the following information on the product label:

8.6.2.1 Product volume

8.6.2.2 Amount of anticoagulant in the product

8.6.2.3 Collection date and time

8.6.2.4 Expiration date and time is 48 hours post collection

8.6.2.5 Name and amount of any additional additives

8.6.3 Verify all information on labels

8.7 PROCESSING LABELS – Apheresis

NOTE: *Do NOT leave blanks on the labels; populate information or enter N/A*

8.7.1 Apheresis during Processing (Partial Label), *if applicable*

8.7.1.1 At a minimum, the following labels must be affixed:

8.7.1.1.1 Unique ISBT 128 barcode

8.7.1.1.2 Proper name of product

8.7.1.1.3 Recipient name and Duke History #

8.7.1.1.4 Product manipulations, if applicable *(i.e. red cell reduced, CD34-selected, etc.*).

8.7.2 Apheresis at Completion of Processing

8.7.2.1 At a minimum, the following labels must be **AFFIXED (AF)** to the product:

8.7.2.1.1 Unique ISBT 128 barcode for each freezing bag

8.7.2.1.2 Proper name of product

8.7.2.1.3 Product Code

8.7.2.1.4 Approximate volume

8.7.2.1.5 Name and volume or concentration of anticoagulant and other additives (*i.e. freezing solution*)

8.7.2.1.6 Recommended storage temperature

8.7.2.2 At a minimum, the following labels must **ACCOMPANY (AC)** the product:

8.7.2.2.1 Product attributes

8.7.2.2.2 Identity and address of collection facility or donor registry

8.7.2.2.3 Date, time collection ends, and (*if applicable*) time zone

8.7.2.2.4 Identity and address of processing and distribution facility(ies)

8.7.2.2.5 Expiration Date (*if applicable*)

8.7.2.2.6 Expiration Time (*if applicable*)

8.7.2.2.7 ABO and Rh donor (*if applicable*)

8.7.3 At a minimum, the following labels must be **ATTACHED (AT)** to the product:

8.7.3.1 Recipient name and/or identifier (ie. *Duke MRN #*)

8.7.3.2 Donor identifier and (*if applicable*) name

8.7.3.3 Biohazard and/or Warning labels (*as applicable, see CM7.4, C7.4, D7.4*)

8.7.4 As applicable, statements must be **ATTACHED (AT)** to the product:

8.7.4.1 "Warning: NOT Evaluated for Infectious Substances"

8.7.4.2 "Warning: Advise Patient of Communicable Disease Risks"

8.7.4.3 "Warning: Reactive Test Results for [name of disease agent or disease]".

8.7.4.4 Statement "Do NOT Irradiate"

8.7.4.5 Statement "FOR AUTOLOGOUS USE ONLY" (*if applicable*)

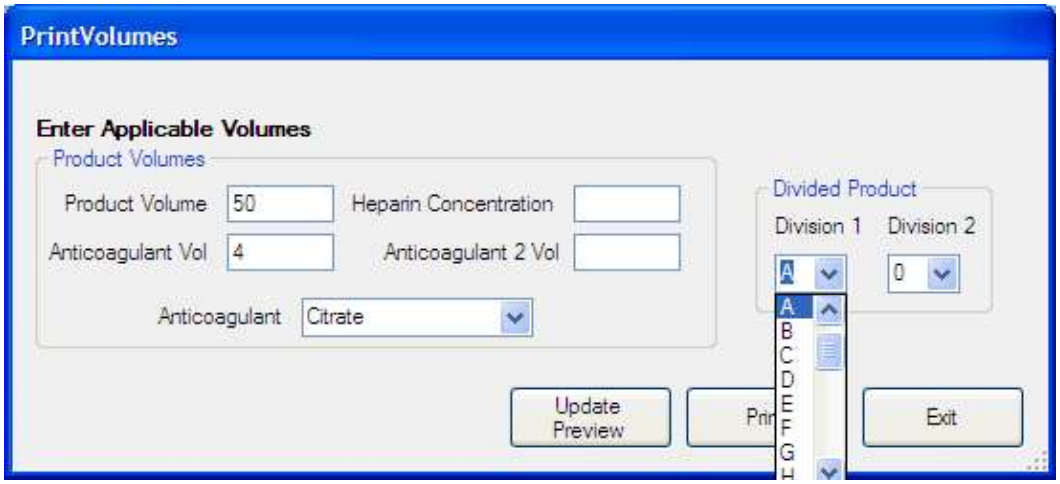
8.8 Apheresis prior to Cryopreservation

8.8.1 The following information must be on the label. The information may be printed on the on-demand label to be placed on bag or a tie tag to be attached securely on the freezing bag(s) or must be hand written on the label.

8.8.1.1 Collection date and time

8.8.1.2 Since Expiration date and time has not been determined select "No Expiration"

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

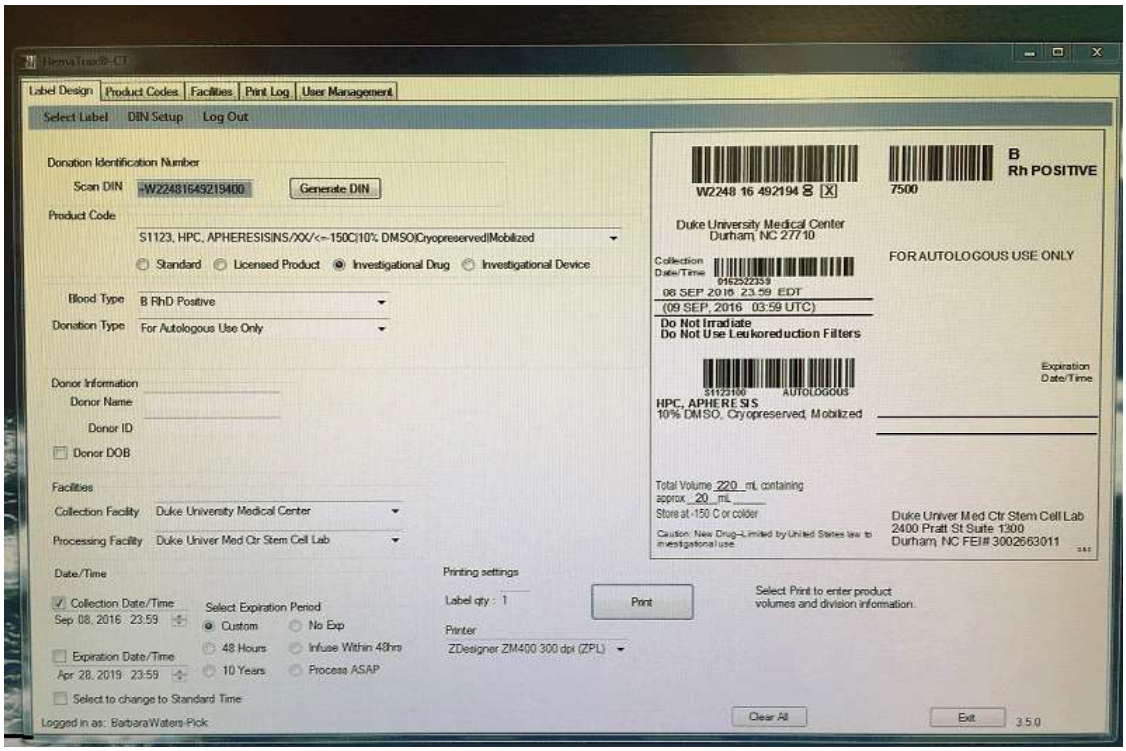


8.8.1.4 Select the corresponding letter designation for each bag (i.e., A, B, C, D, etc.). The final product label will be labeled with letter designation on lower left quadrant.

8.8.2 Place the on-demand label on the cellular product.

8.8.3 Verify the Unique Donation Identifiers on the bag(s) and attached tie tag(s).

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC
RECIPIENT:
Doe, Jane
History # XX1234, DOB: 12/25/1962
1.1 Patient ABO/RH = A Positive
1.2 Patient Sex = Female



8.9 PROCESSING LABELS – Marrow

NOTE: *Do NOT leave blanks on the labels; populate information or enter N/A*

8.9.1 Marrow during Processing (Partial Label), *if partial labels are used*

8.9.1.1 At a minimum, the following labels must be affixed:

8.9.1.1.1 Unique ISBT 128 barcode

8.9.1.1.2 Proper name of product

8.9.1.1.3 Recipient name and Duke History #

8.9.1.1.4 Product manipulations, if applicable (i.e. red cell reduced, CD34-selected, etc.).

8.9.2 Marrow at Completion of Processing

8.9.2.1 At a minimum, the following labels must be **AFFIXED (AF)** to the product:

8.9.2.1.1 Unique ISBT 128 barcode for each freezing bag

8.9.2.1.2 Proper name of product

8.9.2.1.3 Product code

8.9.2.1.4 Approximate volume

8.9.2.1.5 Name and volume or concentration of anticoagulant and other additives (*ie. freezing solution*)

8.9.2.1.6 Recommended storage temperature

8.9.2.2 At a minimum, the following labels must **ACCOMPANY (AC)** the product:

8.9.2.2.1 Product attributes

8.9.2.2.2 Identity and address of collection facility or donor registry

8.9.2.2.3 Date, time collection ends, and (*if applicable*) time zone

8.9.2.2.4 Identity and address of processing and distribution facility(ies)

8.9.2.2.5 Expiration Date (*if applicable*)

8.9.2.2.6 Expiration Time (*if applicable*)

8.9.2.2.7 ABO and Rh donor (*if applicable*)

8.9.2.2.8 Date of distribution

8.9.2.3 At a minimum, the following labels must be **ATTACHED (AT)** to the product:

8.9.2.3.1 Recipient name and/or identifier (ie. *Duke MRN #*)

8.9.2.3.2 Donor identifier and (*if applicable*) name

8.9.2.3.3 Biohazard and/or Warning labels (*as applicable, see CM7.4, C7.4, D7.4*)

8.9.3 If applicable, statements must be **ATTACHED (AT)** to the product:

8.9.3.1 "Warning: NOT Evaluated for Infectious Substances"

8.9.3.2 "Warning: Advise Patient of Communicable Disease Risks"

8.9.3.3 "Warning: Reactive Test Results for name of disease agent or disease".

8.9.3.4 Statement "Do NOT Irradiate"

8.9.3.5 Statement "FOR AUTOLOGOUS USE ONLY" (*if applicable*)

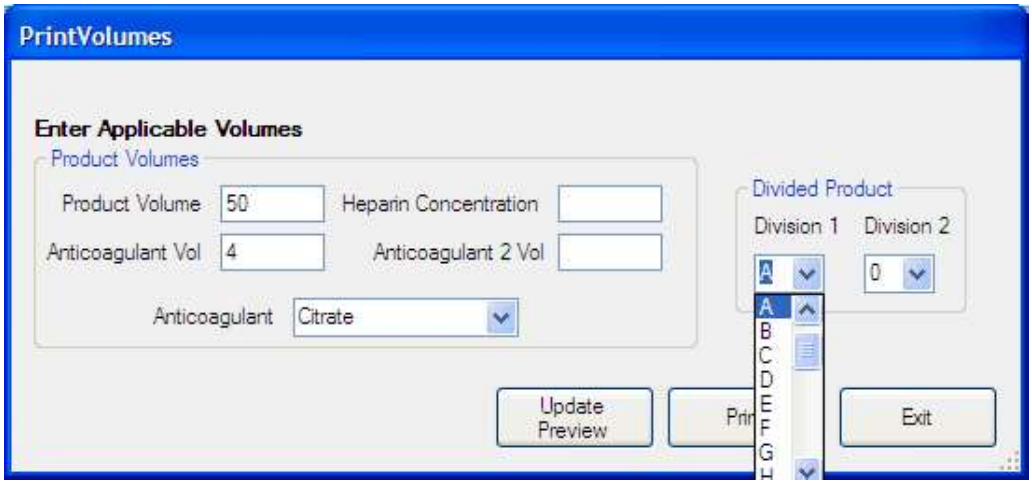
8.10 Marrow prior to Cryopreservation

8.10.1 The following information must be on the label. The information may be printed on the on-demand label to be placed on bag or a tie tag to be attached securely on the freezing bag(s) or must be hand written on the label.

8.10.2 Collection date and time

8.10.3 Since Expiration date and time has not been determined select No Expiration"

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



8.10.3.2 Select the corresponding letter designation for each bag (i.e., A, B, C, D, etc.). The final product label will be labeled with letter designation on lower left quadrant.

8.10.4 Place the on-demand label on the cellular product.

8.10.5 Verify the Unique Donation Identifiers on the bag(s) and attached tie tag(s).

Stem Cell Lab, Duke University Medical Center, Pratt Street, Durham, NC

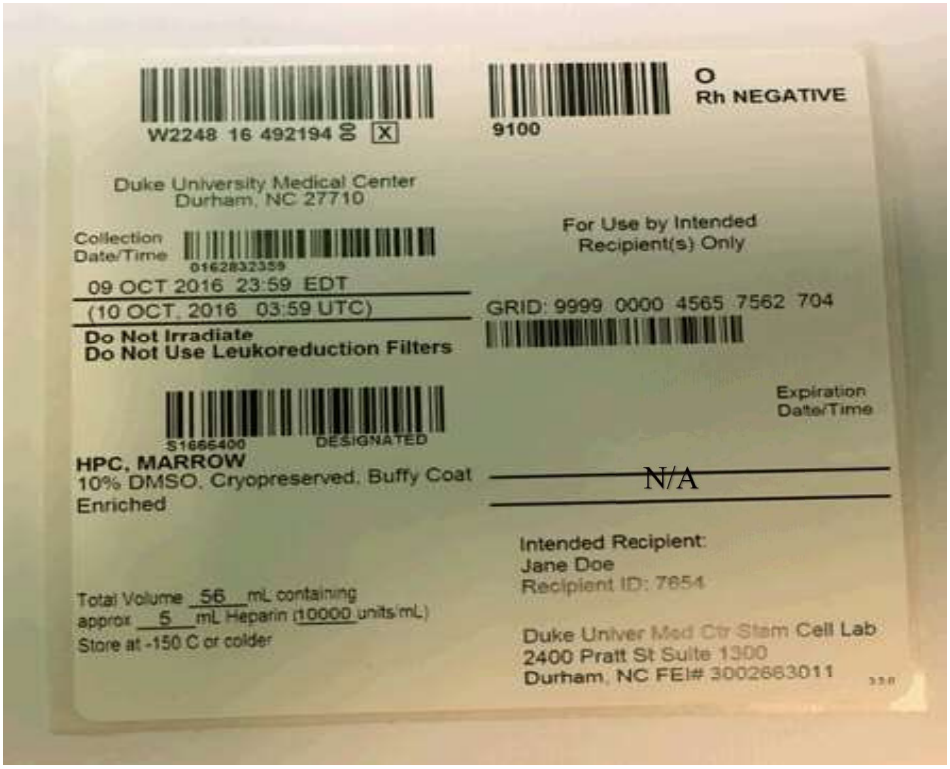
RECIPIENT:

Doe, Jane

History # XX1234, DOB: 12/25/1962

Patient ABO/RH = A Positive

Patient Sex = Female



8.11 PROCESSING LABELS – Cord Blood

NOTE: *Do NOT leave blanks on the labels; populate information or enter N/A*

8.11.1 While the unit is being processed the following labels must be on the unit:

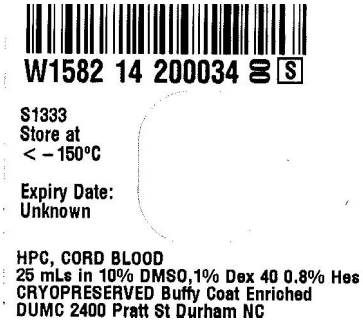
8.11.1.1 Name of product

8.11.1.2 ISBT Unique Donation Identifier

8.11.1.3 Thermogenesis Label for cord freezing bag

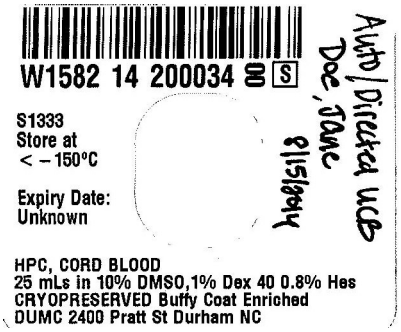
8.11.1.4 Scan ISBT Unique Donation Identifier into the designated printer.

8.11.1.5 The following label will be printed with the unique identification number, name of unit and the storage temperature.

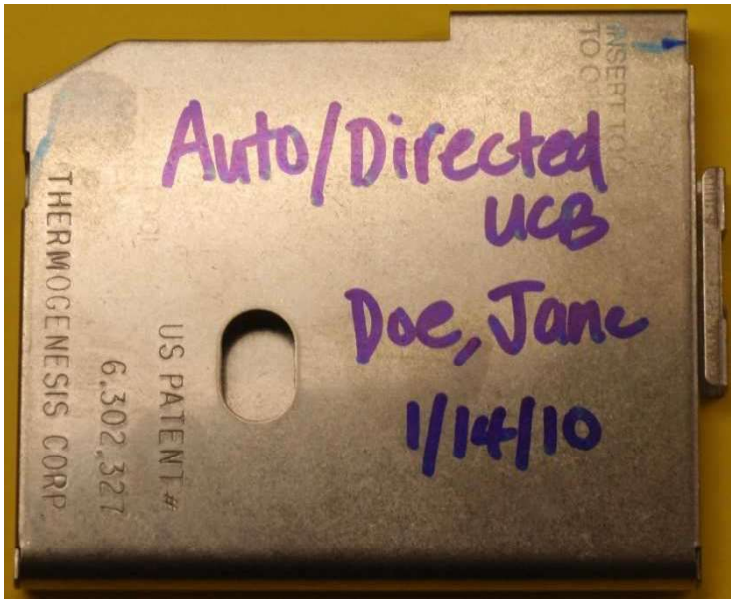


8.11.2 Thermogenesis Label for autologous or directed donor product freezing bag

8.11.2.1 Write mother's name and statement "Auto/Directed UCB" and date frozen using a permanent marker on the freezer bag label before the freezer bag is placed in the overwrap bag.



8.11.2.2 Write mother's name and the statement "Auto/Directed UCB" and date frozen using a permanent marker on the freezer canister.



8.12 DISTRIBUTION LABELS

NOTE: *Do NOT leave blanks on the labels; populate information or enter N/A*

8.12.1 The following information must be on the label at the time of distribution. The information may be printed on the on-demand label to be placed on a tie tag which is attached securely on the freezer bag(s) or must be hand written on the label.

8.12.2 At a minimum, the following labels must be **AFFIXED (AF)** to the product:

- 8.12.2.1 Unique ISBT 128 barcode for each freezing bag
- 8.12.2.2 Proper name of product
- 8.12.2.3 Product Code
- 8.12.2.4 Product Attributes
- 8.12.2.5 Approximate volume
- 8.12.2.6 Name and volume or concentration of anticoagulant and other additives (*ie freezing solution*)
- 8.12.2.7 Recommended storage temperature
- 8.12.2.8 Donor identifier and (*if applicable*) name
- 8.12.2.9 Statement "Do Not Irradiate"
- 8.12.2.10 Expiration Date (*if applicable*)
- 8.12.2.11 Statement indicating that "Leukoreduction filters shall not be used"
- 8.12.2.12 Statement "FOR AUTOLOGOUS USE ONLY" (*if applicable*)

8.12.3 At a minimum, the following labels must **ACCOMPANY (AC)** the product:

- 8.12.3.1 Identity and address of collection facility or donor registry
- 8.12.3.2 Date, time collection ends, and, (*if applicable*) time zone
- 8.12.3.3 Identity and address of processing and distribution facility(ies)
- 8.12.3.4 Expiration Time (*if applicable*)
- 8.12.3.5 ABO and Rh donor (*if applicable*)
- 8.12.3.6 RBC compatibility determination (*if applicable*)
- 8.12.3.7 Date of distribution

8.12.4 At a minimum, the following labels must be **ATTACHED (AT)** to the product:

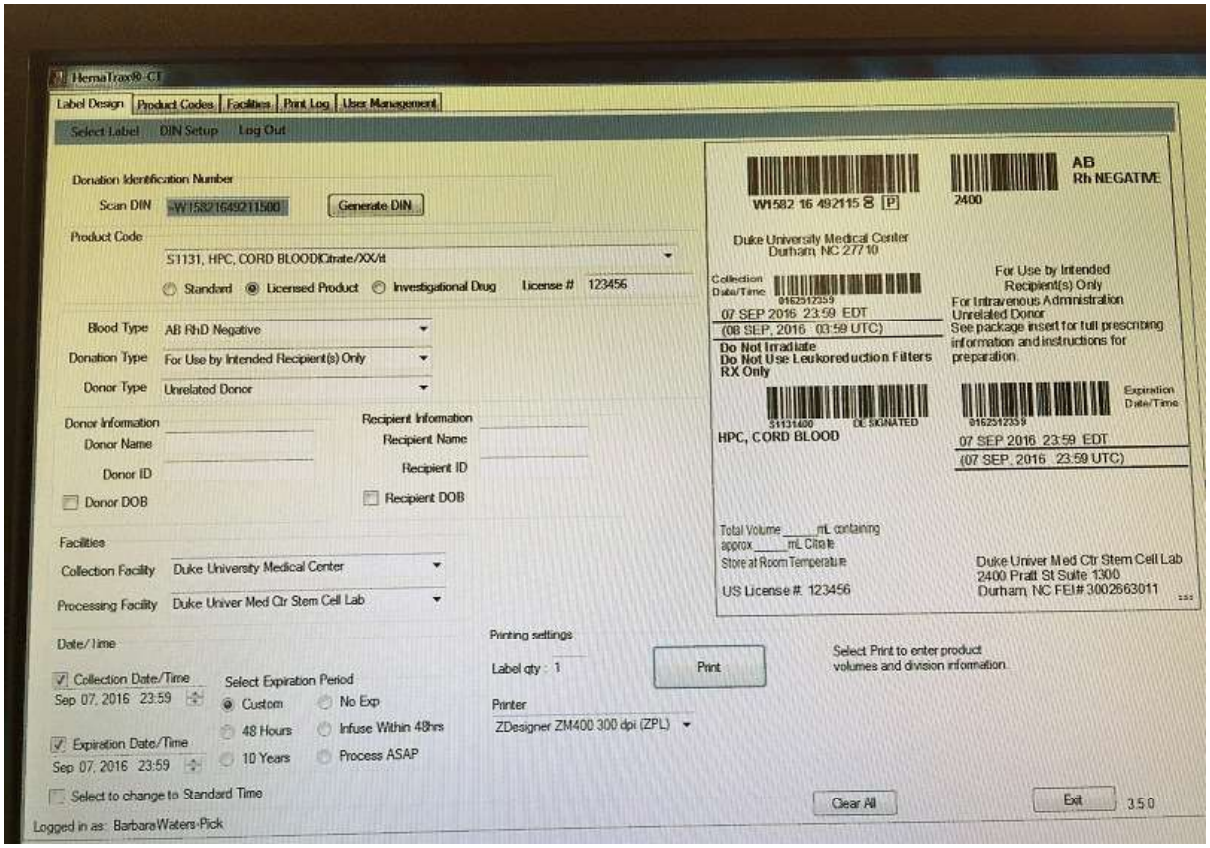
- 8.12.4.1 Recipient name and/or identifier (ie. *Duke MRN #*)
- 8.12.4.2 Biohazard and/or Warning labels (*as applicable, see CM7.4, C7.4, D7.4*)

8.12.5 If applicable, statements must be **ATTACHED (AT)** to the product:

8.12.5.1 "Warning: NOT Evaluated for Infectious Substances"

8.12.5.2 "Warning: Advise Patient of Communicable Disease Risks"

8.12.5.3 "Warning: Reactive Test Results for name of disease agent or disease".



NOTE: *Verify that Unique ISBT 128 barcode labels are the same on the bag(s) and the tie-tag(s).*

8.12.6 WARNING LABELS – Non-Conforming Products for Urgent Medical Need

8.12.6.1 When using a "Not for Transfusion" label on product write the reason why the unit is not suitable on the label.

8.12.6.2 Warning labels for an allogeneic ineligible donor prior to release

8.12.6.3 When an allogeneic donor does not meet the eligibility requirements for donation they may be approved for donation if declared an urgent medical need by the medical director. The following are examples of possible labeling for ineligibility:

8.12.6.4 The donor samples and drawn and the results for disease testing are not back.

Donor Tested- Results Pending

WARNING: Advise patient of communicable disease risk

8.12.6.5 Donor's disease testing is reactive and the medical director has accepted the donor.

WARNING: Advise patient of communicable disease risk

WARNING: Reactive test results for _____

8.12.6.6 Donor's infectious disease testing was not performed and the product has been declared an urgent medical need. The following must be applied.

WARNING: Advise patient of communicable disease risk	**NOT EVALUATED FOR INFECTIOUS SUBSTANCES**

8.12.6.7 Products collected for autologous use must be labeled with "Autologous Use Only".

8.12.6.8 If the autologous donor infectious testing was not performed the following label should be applied also.

NOT EVALUATED FOR INFECTIOUS SUBSTANCES

8.13 LABEL VERIFICATION

8.13.1 Verification of Unique Donation Identifiers

8.13.1.1 Assure that all the Unique Donation Identifiers are the same. If an error is detected, notify supervisor and initiate an investigation to resolve discrepancies.

8.13.1.2 Initial the appropriate collection or processing record at the time of verification to indicate that all the Identifiers have been verified against information in EPIC and/or SafeTrace.

8.13.1.3 Verification of additional information

NOTE: ***All labels must be verified by <u>two trained staff members</u>.***

8.13.1.4 Each person must ensure that the following information is on the label at the time of collection, processing, and/or distribution, and that all the fields in the label are completed in their entirety. *Do <u>NOT</u> leave blanks on the labels; populate information or enter N/A*

- 8.13.1.4.1 Unique ISBT 128 barcode for each freezing bag
- 8.13.1.4.2 Proper name of product
- 8.13.1.4.3 Product code
- 8.13.1.4.4 Product attributes
- 8.13.1.4.5 Identity and address of collection facility or donor registry
- 8.13.1.4.6 Date, time collection ends, (*if applicable*) time zone
- 8.13.1.4.7 Approximate volume
- 8.13.1.4.8 Name and volume or concentration of anticoagulant and other additives (*i.e. freezing solution*)
- 8.13.1.4.9 Recommended storage temperature
- 8.13.1.4.10 Donor identifier and (*if applicable*) name
- 8.13.1.4.11 Biohazard and/or Warning labels (*as applicable, see CM7.4, C7.4, D7.4*)
- 8.13.1.4.12 Identity and address of processing and distribution facility(ies)
- 8.13.1.4.13 Statement “Do Not Irradiate”
- 8.13.1.4.14 Statement “Leukoreduction filters should NOT be used

8.13.2 If applicable, statements:

- 8.13.2.1 Warning: NOT Evaluated for Infectious Substances”
- 8.13.2.2 “Warning: Advise Patient of Communicable Disease Risks”
- 8.13.2.3 “Warning: Reactive Test Results for name of disease agent or disease”.
- 8.13.2.4 Expiration Date (*if applicable*)
- 8.13.2.5 Expiration Time (*if applicable*)
- 8.13.2.6 ABO/Rh of donor (*if applicable*)
- 8.13.2.7 RBC compatibility testing results (*if applicable*)

8.13.2.8 Statement "FOR AUTOLOGOUS USE ONLY" (*if applicable*)

8.14 Labeling NMDP products for distribution

8.14.1 Label products collected for NMDP using the DigiTrax 4 x 4 label stock.

8.14.2 Gather source documents necessary for completion of the final product labeling, such as:

8.14.2.1 STAR Link Tracking Sheet

8.14.2.2 F00315, Declaration of Eligibility-Adult Donor

8.14.2.3 F00071, NMDP Verification of HPC, Apheresis Request

8.14.2.4 Procedure record

8.14.2.5 Laboratory worksheet

8.14.3 Ensure that the following information is available, if applicable, for product labeling

8.14.3.1 Donation Identification Number (DIN)

8.14.3.2 NMDP Donor Identification Number (DID) and GRID Number

8.14.3.3 NMDP Recipient Identification Number (RID)

8.14.3.4 Intended Recipient: At minimum, last and first name is required

8.14.3.5 Collection Date and End Time

8.14.4 Anticoagulant

NOTE: *Because of variability in concentration, heparin is recorded separately from other anticoagulants.*

8.14.4.1 Name of anticoagulant

8.14.4.2 Total volume (mL) of anticoagulant included in the product.

8.14.4.3 Total volume includes, as applicable:

8.14.4.3.1 Volume of anticoagulant calculated by apheresis instrument

8.14.4.3.2 Volume of additional anticoagulant added directly to collection bag at collection

8.14.4.3.3 Volume of additional anticoagulant added in the laboratory or other location, directly to the collection bag after collection

8.14.4.3.4 Volume of anticoagulant in concurrent plasma added to the collection bag at the time of collection or after collection

8.14.5 Heparin

8.14.5.1 Concentration: units/mL of the original vial of heparin used; e.g. 1000 units/mL, 5000 units/mL

8.14.5.2 Total volume (mL) of the heparin included in the product.

8.14.5.3 Total volume includes, as applicable:

8.14.5.3.1 Volume of heparin (not combined with other anticoagulant) added directly to collection bag at collection

8.14.5.3.2 Volume of heparin (not combined with other anticoagulant) added in the laboratory or other location, directly to collection bag after collection

8.14.5.3.3 Volume of heparin mixed with other anticoagulant and added directly to collection bag before or after collection

8.14.6 Concurrently Collected Plasma

8.14.6.1 When Added: During or after collection

8.14.6.2 Total volume plasma added to the product

8.14.7 Other Additives

8.14.7.1 Name of additive

8.14.7.2 Total volume (mL) of additive included in the product

8.14.7.3 3rd Party Blood Component

8.14.7.3.1 Name of 3rd Party Blood Component, such as human albumin

8.14.7.3.2 Total volume (mL) of 3rd Party Blood Component included in the product

8.14.8 Total Volume of product

8.14.8.1 Total Volume = Net weight (g) ÷ 1.06 (specific gravity: g/mL)

NOTES:

- Net weight of the product includes the weight of product, anticoagulant, additives and/or 3rd party components in the bag.
- Net weight must be determined using a scale after:
  - Removing all product samples
  - Taring the scale, for the weight of the bag

8.14.9 Creation of an ISBT 128 Product Label

8.14.9.1 Select the appropriate Product Code from dropdown list.

8.14.9.2 Refer to product information provided on NMDP's procedure A00680 NMDP Product Code List to find appropriate code depending on anticoagulant, storage temperature and product attributes (*mobilization, additive(s), concurrent plasma added, 3rd party component, etc*.).

NMDP ISBT 128 Product Description Code List

Product Code	HPC, Apheresis Product Descriptions
S1128	HPC, APHERESIS|Citrate/XX/refg|Mobilized
S2005	HPC, APHERESIS|Citrate/XX/refg|Concurrent plasma|Mobilized
S2463	HPC, APHERESIS|Citrate/XX/refg|Concurrent plasma + other|Mobilized
S1134	HPC, APHERESIS|Citrate/XX/refg|Other Additives:Yes|Mobilized
S1177	HPC, APHERESIS|Citrate/XX/refg|3rd Party Comp:Yes|Mobilized
S1307	HPC, APHERESIS|Citrate+Heparin/XX/refg|Mobilized
S1990	HPC, APHERESIS|Citrate+Heparin/XX/refg|Concurrent plasma|Mobilized
S2465	HPC, APHERESIS|Citrate+Heparin/XX/refg|Concurrent plasma + other|Mobilized
S1487	HPC, APHERESIS|Citrate+Heparin/XX/refg|Other Additives:Yes|Mobilized
S2647	HPC, APHERESIS|Citrate+Heparin/XX/refg|3rd Party Comp:Yes|Mobilized
S2376	HPC, APHERESIS|Citrate/XX/refg|For further processing|Mobilized

Product Code	Concurrent Plasma, Apheresis Product Descriptions
S1185	CONCURRENT PLASMA, APHERESIS|Citrate/XX/refg|For further processing: donor cell prod

Product Code	MNC, Apheresis Product Descriptions
S1226	MNC, APHERESIS|Citrate/XX/refg
S1992	MNC, APHERESIS|Citrate/XX/refg|Concurrent plasma
S1599	MNC, APHERESIS|Citrate/XX/refg|Other Additives:Yes
S2649	MNC, APHERESIS|Citrate/XX/refg|3rd Party Comp:Yes
S1303	MNC, APHERESIS|Citrate/XX/refg|For further processing
S1166	MNC, APHERESIS|Citrate/XX/rt
S2650	MNC, APHERESIS|Citrate/XX/rt|Concurrent plasma
S2651	MNC, APHERESIS|Citrate/XX/rt|Other Additives:Yes
S2652	MNC, APHERESIS|Citrate/XX/rt|3rd Party Comp:Yes
S2967	MNC, APHERESIS|Citrate/XX/rt|For further processing
S1459	MNC, APHERESIS|Citrate+Heparin/XX/refg
S1993	MNC, APHERESIS|Citrate+Heparin/XX/refg|Concurrent plasma
S1600	MNC, APHERESIS|Citrate+Heparin/XX/refg|Other Additives:Yes
S2653	MNC, APHERESIS|Citrate+Heparin/XX/refg|3rd Party Comp:Yes
S2470	MNC, APHERESIS|Citrate+Heparin/XX/refg|For further processing
S1486	MNC, APHERESIS|Citrate+Heparin/XX/rt
S2654	MNC, APHERESIS|Citrate+Heparin/XX/rt|Concurrent plasma
S2655	MNC, APHERESIS|Citrate+Heparin/XX/rt|Other Additives:Yes
S2656	MNC, APHERESIS|Citrate+Heparin/XX/rt|3rd Party Comp:Yes
S2471	MNC, APHERESIS|Citrate+Heparin/XX/rt|For further processing

NOTES:

- 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.

8.14.9.3 Select IND if product being labeled is an apheresis product.

8.14.9.4 Select standard if product being labeled is a bone marrow product.

8.14.9.5 Select blood type as unknown

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

8.14.9.7 Select donor type as Unrelated Donor

8.14.9.8 Leave Donor Name field blank

8.14.9.9 Enter NMDP Donor Identification Number and GRID Number in Donor ID field.

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

8.14.9.11 Enter Recipient Identification Number in Recipient Field.

8.14.9.12 Leave Collection and Processing Facility blank.

8.14.9.13 Enter Collection Date and Time

8.14.9.14 Select Infuse Within 48 hrs as the Expiration date/time.

8.14.9.15 Enter the quantity of labels needed and click print.

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

8.14.9.17 If a single collection is divided into multiple bags for distribution, select appropriate division codes for each bag e.g., AO, BO etc.

8.14.9.18 Click Update Preview.

8.14.9.19 Review the label for accuracy.

8.14.9.20 Correct any data entry errors if necessary.

8.14.9.21 Click Exit button to return to Label Design tab to make corrections there.

8.14.9.22 Click the Print button in the Print Volumes window. When printing multiple labels, a new Print Volumes pop-up window appears.

8.14.9.23 Complete data fields for subsequent labels, as applicable. When all labels are printed the application will return to Label Design tab.

8.14.10 Examine the printed label for:

8.14.10.1 Proper alignment: no content is cut off along any edges.

8.14.10.2 Print quality: all data is legible.

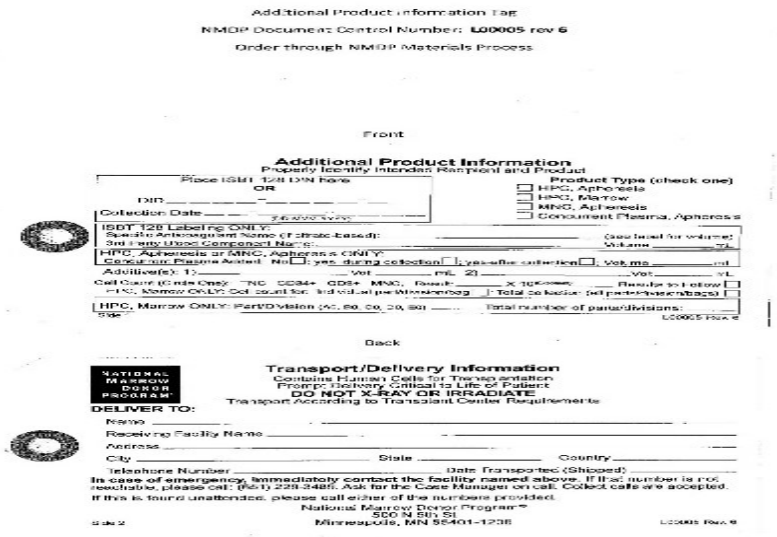
8.14.11 Remove the DIN from the printed final product label.

8.14.12 Affix the DIN to the Additional Product Information Tag (L00005) for the corresponding product bag.

8.14.13 Remove collection label and affix to form MO226 and place in donor file. Affix the completed product label to the product bag.

8.14.13.1 Ensure the label does not cover the Donation Identification Number (DIN) applied at the time of collection. The label stock has a cutout for placement around the DIN.

8.14.14 Attach the NMDP's Additional Product Information Tag to product bag.



Additional Product Information Tag
NMDP Document Control Number: L00005 rev 6
Order through NMDP Materials Process

Front

Additional Product Information
Properly Identify Intended Recipient and Product

Place ISBT 128 DIN here
OR
DIN
Collection Date

Product Type (check one)
HPC, Apheresis
HPC, Marrow
MNC, Apheresis
Concurrent Plasma, Apheresis

ISBT 128 Labeling ONLY:
Specific Anticoagulant Name (if applicable):
3rd Party Blood Component Name:

HPC, Apheresis or MNC, Apheresis ONLY:
Concurrent Plasma Added: No yes, during collection yes, after collection Volume

Additive(s) 1 Vol mL 2) Vol mL

Cell Count (Circle One) TNC CD34+ CD3+ MNC Result: X Results to Follow

HPC, Marrow ONLY: Cell count for individual pre-filtered bag Total collected (all parts/all bags)

HPC, Marrow ONLY: Part/Division (A, B, C, D, etc) Total number of parts/divisions:

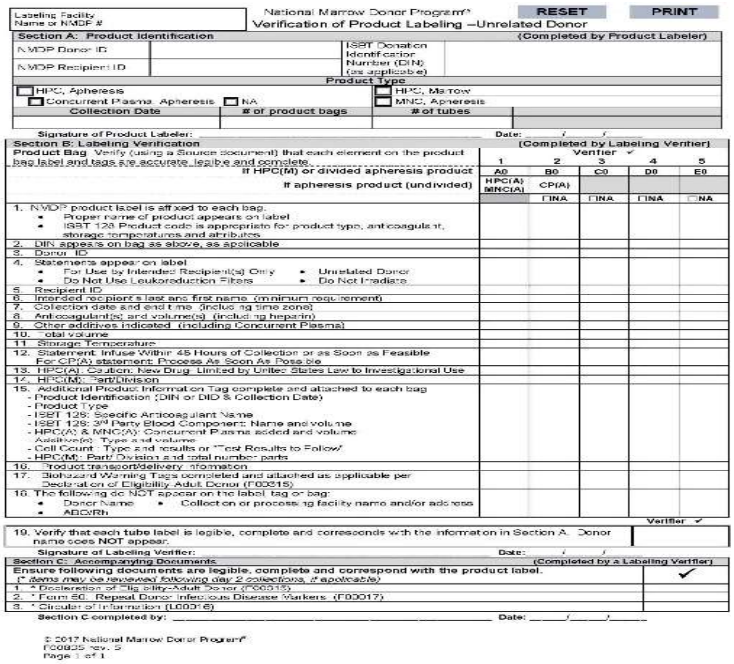
Back

Transport/Delivery Information
Containing Human Cells for Transplantation
Prompt Delivery Critical to Life of Patient
DO NOT X-RAY OR IRRADIATE
Transport According to Transplant Center Requirements

NATIONAL MARROW DONOR PROGRAM

DELIVER TO:
Name
Receiving Facility Name
Address
City State Country
Telephone Number Date Transported (Shipped)
In case of emergency, immediately contact the facility named above. If that number is not reachable, please call: (651) 228-3481. Ask for the Case Manager on call. Collect calls are accepted.
If this is found unattended, please call either of the numbers provided.
National Marrow Donor Program®
500 N 5th St
Minneapolis, MN 55401-1238

8.14.15 Verify product labeling using NMDP form Verification of Product Labeling (F00835).



Labeling Facility Name or NMDP #

National Marrow Donor Program® RESET PRINT
Verification of Product Labeling –Unrelated Donor

Section A: Product Identification (Completed by Product Labeler)

NMDP Donor ID
NMDP Recipient ID
ISBT Donation Identification Number (DIN) (as applicable)

Product Type
HPC, Apheresis
Concurrent Plasma, Apheresis NA
HPC, Marrow
MNC, Apheresis

Collection Date	# of product bags	# of tubes

Signature of Product Labeler: Date: / /

Section B: Labeling Verification (Completed by Labeling Verifier)

Product Bag Verify (using a Source document) that each element on the product bag label and tags are accurate, legible and complete.

Verifier ✓

	1	2	3	4	5
If HPC(M) or divided apheresis product	A0	B0	C0	D0	E0
If apheresis product (undivided)	HPC(A) MNC(A)	CP(A)			
		NA	NA	NA	NA
1. NMDP product label is affixed to each bag. • Proper name of product appears on label • ISBT 128 Product code is appropriate for product type, anticoagulant, storage temperatures and attributes					
2. DIN appears on bag as above, as applicable					
3. Donor ID					
4. Statements appear on label • For Use by Intended Recipient(s) Only • Unrelated Donor • Do Not Use Leukoreduction Filters • Do Not Irradiate					
5. Recipient ID					
6. Intended recipient's last and first name (minimum requirement)					
7. Collection date and time (including time zone)					
8. Anticoagulant(s) and volume(s) (including heparin)					
9. Other additives indicated (including Concurrent Plasma)					
10. Total volume					
11. Storage Temperature					
12. Statement: Infuse Within 48 Hours of Collection or as Soon as Feasible For CP(A) statement: Process As Soon As Possible					
13. HPC(A): Collection, New Drug Limited by United States Law to Investigational Use					
14. HPC(M): Part/Division					
15. Additional Product Information Tag complete and attached to each bag - Product Identification (DIN or DID & Collection Date) - Product Type - ISBT 128: Specific Anticoagulant Name - ISBT 128: 3rd Party Blood Component: Name and volume - HPC(A) & MNC(A): Concurrent Plasma added and volume Additive(s): Type and volume - Cell Count: Type and results or "Test Results to Follow" - HPC(M): Part/ Division and total number: parts					
16. Product transport/delivery information					
17. Biohazard Warning Tags completed and attached as applicable per Declaration of Eligibility: Adult Donor (F00315)					
18. The following do NOT appear on the label, tag or bag: • Donor Name • Collection or processing facility name and/or address • ABO/Rh					

Verifier ✓

19. Verify that each tube label is legible, complete and corresponds with the information in Section A. Donor name does NOT appear.

Signature of Labeling Verifier: Date: / /

Section C: Accompanying Documents (Completed by a Labeling Verifier)

Ensure following documents are legible, complete and correspond with the product label. (* items may be reviewed following day 2 collections, if applicable)	✓
1. * Declaration of Eligibility-Adult Donor (F00315)	
2. * Form 50, Repeat Donor: Infectious Disease Markers (F00017)	
3. * Circular of Information (L00016)	

Section C completed by: Date: / /

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8.15 Back-up plan for labeling of NMDP products.

8.15.1 One computer in the STCL has HemaTrax-CT software installed on it; the Apheresis area also has a computer with HemaTrax-CT software installed on it. These computers can serve as backups for one another, if needed.

8.15.2 Both computers will be validated to print labels using both the DigiTrax and Computype label stock

9 RELATED DOCUMENTS/FORMS

9.1 NMDP's procedure S00505 Final Product labeling for Distribution of an NMDP HPC, Apheresis

9.2 NMDP's procedure S00506 Final Product Labeling for Distribution of an NMDP HPC, Marrow Product

9.3 NMDP's procedure S00507 Final Product Labeling for Distribution of an NMDP MNC, Apheresis Product

9.4 NMDP form F00315, Declaration of Eligibility-Adult Donor

9.5 NMDP's form F00835 Verification of Product Labeling

9.6 A00680 NMDP Product Code List

9.7 NMDP Additional Product Information Tag (L00005)

9.8 COMM-PAS-003 JA1 Storage Temperature and Expiration of Cellular Products

9.9 COMM-PAS-003 JA2 Cellular Therapy Product Labeling (Appendix II)

10 REFERENCES

10.1 United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128. International Council for Commonality in Blood Banking Automation: Current edition.

10.2 Code of Federal Regulations 21 part 610.60.

10.3 Standards for Hematopoietic Progenitor Cell and Cellular Product Services, AABB Current edition.

10.4 Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation, FACT Current edition.

10.5 Circular of Information – For the Use of Cellular Therapy Products, Current edition.

10.6 Current User's Guide for HemaTrax®-CT

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
15	Barbara Waters-Pick	• The vast majority of the changes made to this document are the result of a new version of *Cellular Therapy Product Labeling (Appendix II)* (FACT-JACIE International Standards (Eight Edition – Version 8.1) • Requirements outlined of Appendix II reflect the elements that must be on label at the completion of collection, completion of processing, partial labeling (*if used*) at distribution, and at distribution for administration. • Review of *COMM-PAS-003 JA2 Cellular Therapy Product Labeling (Appendix II)* will summarize the majority of the changes made to the document based on the current standards. • Added Section 2.3 to introduce new job aid created • Added last sentence to NOTE in Section 4.3 • Added 4.15 – 4.17 to include abbreviations for AC, AF, AT • Added NOTE under Section 8.5

		• Added NOTE under Section 8.6 • Added NOTE under Section 8.7 • Added "if applicable" after Section 8.7.1 • Put AFFIXED in bold and added "to the product" to Section 8.7.2.1 • Modified Section 8.7.2.1.3 to "Product Code" from product manipulations, if applicable (ie. red cell reduced, CD34 selected, etc.) • Added Section 8.7.2.1.4 (*moved from Section 8.7.3.2*) • Added Section 8.7.2.1.5 (*moved from Section 8.7.3.3*) • Added Section 8.7.2.1.6 (*moved from Section 8.7.3.5*) • Put ACCOMPANY in bold and added "the product" to Section 8.7.2.2 • Added "Product attributes" to Section 8.7.2.2.1 • Moved "Date, time collection end, and (if applicable) time zone to Section 8.7.2.2.3 • Added "Identity and address of processing facility and distribution facility(ies)" to Section 8.7.2.2.4 • Put ATTACHED in bold and added "to the product" to Section 8.7.3 • Changed "Recipient name and Duke History#" to "Recipient name and/or identifier (ie. Duke MRN#)" to Section 8.7.3.1 • Moved "Product Volume" from Section 8.7.3.2 • Moved "Name and volume or concentration of anticoagulant and other additives (ie. freezing solution) from Section 8.7.3.3. to 8.7.2.1.5. • Moved "Recommended storage temperature" from Section 8.7.3.5 to Section 8.7.2.1.6 • Added "if applicable, see CM7.4, C7.4, D7.4)" to Section 8.7.3.3. • Added "must be ATTACHED (AT) to the product" to Section 8.7.4 • Removed "Identity and address of processing and distribution facility(ies)" from Section 8.7.4.4 to Section 8.7.2.2.4 • Added NOTE under Section 8.9 • Added "*if partial labels are used*" to Section 8.9.1 • Put AFFIXED in bold and added "to the product" to Section 8.9.2.1 • Modified Section 8.9.2.1.3 to "Product Code" from product manipulations, if applicable (ie. red cell reduced, CD34 selected, etc.) • Added Section 8.9.2.1.4 (*moved from Section 8.9.2.3.2*) • Added Section 8.9.2.1.5 (*moved from Section 8.9.2.3.3*) • Added Section 8.9.2.1.6 (*moved from Section 8.9.2.3.5*) • Put ACCOMPANY (AC) in bold and added "to product" to Section 8.9.2.2

		• Added “Product attributes” to Section 8.9.2.2.1 • Modified “Date collection ends and time zone” to “Date, time collection ends, and (if applicable)” time zone to Section 8.9.2.2.3 • Added “Identity and address of processing and distribution facility(ies)” to Section 8.9.2.2.4 (*moved from Section 8.9.4*) • Added “Date of distribution” to Section 8.9.2.2.8 • Put ATTACHED (AT) in bold and added “to the product” to Section 8.9.2.3 • Changed “Recipient name and Duke History#” to “Recipient name and/or identifier (*ie. Duke MRN#*)” to Section 8.9.2.3.1 • Removed “product volume” from Section 8.9.2.3.2 and moved to Section 8.9.2.1.4) • Removed “Name and volume or concentration of anticoagulant and other additives (*ie. freezing solution*)” from Section 8.9.2.3.3 and moved to Section 8.9.2.1.5 • Removed “Recommended storage temperature” from Section 8.9.2.3.5 and moved to Section 8.9.2.1.6 • Added “if applicable, see CM7.4, C7.4, D7.4)” to Section 8.9.2.3.3 • Added “must be ATTACHED (AT) to the product” to Section 8.9.3 • Deleted “Identity and address of processing and distribution facility(ies)” from Section 8.9.4 and moved to Section 8.9.2.2.4 • Added NOTE under Section 8.11 • Added NOTE under Section 8.12 • Put AFFIXED (AF) in bold and added “to the product” to Section 8.12.2 • Modified Section 8.12.2.3 to “Product Code” from “product manipulations, if applicable (ie. red cell reduced, CD34 selected, etc.)” • Added “Product Attributes” to Section 8.12.2.4 • Added “Approximate volume” to Section 8.12.2.5 • Added “Name and volume or concentration of anticoagulant and other additives (*ie. freezing solution*)” to Section 8.12.2.6 • Added “Recommended storage temperature” to Section 8.12.2.7 • Added “Donor identifier and (*if applicable*) name” to Section 8.12.2.8 • Added “Statement “Do Not Irradiate” to Section 8.12.2.9 • Added “Expiration Date (*if applicable*)” to Section 8.12.2.10 • Added “Statement indicating that “Leukoreduction filters shall not be used” to Section 8.12.2.11 • Added “Statement “FOR AUTOLOGOUS USE ONLY” (*if applicable*) to Section 8.12.2.12 • Put ACCOMPANY (AC) in bold in Section 8.12.3

		• Added “Identity and address of collection facility or donor registry” Section 8.12.3.1 • Added “Identity and address of processing and distribution facility(ies)” to Section 8.12.3.3 • Added “Expiration Time (*if applicable*) to Section 8.12.3.4 • Moved “ABO and Rh donor (*if applicable*)” from Section 8.12.5.8 and moved to Section 8.12.3.5 • Moved “RBC compatibility determination (*if applicable*)” from Section 8.12.5.9 to Section 8.12.3.6 • Added “Date of distribution” to Section 8.12.3.7 • Put ATTACHED (AC) in bold and added “to the product” to Section 8.12.4 • Changed “Recipient name and Duke History#” to “Recipient name and/or identifier (ie. Duke MRN#)” in Section 8.12.4.1 • Removed “Product volume” from Section 8.12.4.2 to Section 8.12.2.5 • Removed “Name and volume or concentration of anticoagulant and other additives (*ie. freezing solution*)” from Section 8.12.4.3 to Section 8.12.2.6 • Removed “Donor identifier and name (if applicable)” from Section 8.12.4.4 to Section 8.12.2.8 • Removed “Recommended storage temperature” from Section 8.12.4.5 to Section 8.12.2.7 • Modified “if applicable, see CM7.4, C7.4, D7.4)” to Section 8.12.4.2 • Put ATTACHED (AT) in bold and added “to the product” to Section 8.12.5 • Deleted 8.12.5.4 – 8.12.5.13 • Added “*Do NOT leave blanks on the labels; populate information or enter “N/A*” to Section 8.13.1.4 • Added “Product code” to Section 8.13.1.4.3 • Added “Product attributes” to Section 8.13.1.4.4 • Removed “Product manipulations, if applicable (ie. red cell reduced, CD34 selected, etc.*)*” from Section 8.13.1. • Modified “Date collection ends and time zone” to “Date, time collection ends, and (if applicable) time zone*”* to Section 8.13.1.4.6 • Replaced “Product volume” (*originally in Section 8.13.1.4.8*) with “Approximate volume” in Section 8.13.1.4.7 • Removed “Recipient name and Duke History #” originally in Section 8.13.1.4.7 • Added “Recommended storage temperature” (originally in Section 8.13.1.4.11) to Section 8.13.1.4.9 • Added “(if applicable)” to Section 8.13.1.4.10 • Added “Biohazard and/or Warning labels (as applicable), see CM7.4, C7.4, D7.4” to Section 8.13.1.4.11

		• Added "Identity and address of processing and distribution facility(ies)" to Section 8.13.1.4.12 (*moved from Section 8.13.2.4*) • Added "Statement "Do Not Irradiate" to Section 8.13.1.4.13 (*moved from Section 8.13.2.5*) • Added "Statement "Leukoreduction filters should NOT be used" to Section 8.13.1.4.14 (*moved from Section 8.13.2.11*) • Removed "Identity and address of processing and distribution facility(ies)" from Section 8.13.2.4 (*moved to Section 8.13.1.4.12*) • Removed "Statement "Do Not Irradiate" from Section 8.13.2.5 (*moved to Section 8.13.1.4.13*) • Removed "Statement "Properly identify intended recipient and product" from Section 8.13.2.10 • Removed "Statement "Leukoreduction filters should NOT be used" from Section 8.13.2.11 (moved to 8.13.1.4.14) • Removed "For Intended Recipient ONLY" (*if allogeneic recipient*) from Section 8.13.2.13 • Removed "Statement "For Non-clinical use ONLY" (*if applicable*) from Section 8.13.2.14 • Changed wording in Section 8.15.1 to "One computer in the STCL has HemaTrax-CT software installed on it; the Apheresis area also has a computer with HemaTrax-CT software installed on it. These computers can serve as backups for one another, if needed" • Added "COMM-PAS-003 JA1 Storage Temperature and Expiration of Cellular Products" to Section 9.8 • Added "COMM-PAS-003 JA2 Cellular Therapy Product Labeling (Appendix II) to Section 9.9

Signature Manifest

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COMM-PAS-003 Labeling Cellular Therapy Products

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