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.
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.

4.4 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.

4.5 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, purifyingCD34+ progenitor cells, and washing to remove DMSO after thawing.

4.6 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.
4.7 **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.

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

4.9 **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.

4.10 **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).

![Global Registration Identifier for Donors (GRID)](image)

**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.

- Through December 2019, you will continue to see both the DID and the GRID. This is to comply with WMDA requirements to ensure that every partner can adopt the changes for GRID according to the WMDA timeline as well as help the NMDP ensure traceability.
4.11 **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).

4.12 **ION** – Issuing Organization Number (*i.e.* 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.

4.13 **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.

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

4.15 **CIBMTR** – Center for International Blood and Marrow Transplant Research (Due to unforeseen issues with the 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*) there will not be a GRID field available on these forms until the FormsNet3 fall release (*around October 25, 2019*).

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 toolbar 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.

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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

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

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.

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

**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

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

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
8.7.1 Apheresis during Processing (Partial Label)
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:
   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 manipulations, if applicable (i.e. red cell reduced, CD34-selected, etc.).

8.7.2.2 At a minimum, the following labels must accompany the product:
   8.7.2.2.1 Identity and address of collection facility or donor registry
   8.7.2.2.2 Date and Time collection ends and time zone (if applicable)
   8.7.2.2.3 Expiration Date (if applicable)
   8.7.2.2.4 Expiration Time (if applicable)
   8.7.2.2.5 ABO and Rh donor (if applicable)
8.7.3 At a minimum, the following labels must be attached:

8.7.3.1 Recipient name and Duke History #
8.7.3.2 Product volume
8.7.3.3 Name and volume or concentration of anticoagulant and other additives (i.e. freezing solution)
8.7.3.4 Donor identifier and (if applicable) name
8.7.3.5 Recommended storage temperature
8.7.3.6 Biohazard and/or Warning labels (if applicable)

8.7.4 If applicable, statements:

8.7.4.1 “Warning: NOT Evaluated for Infectious Substances”
8.7.4.2 “Warning: Advise Patient of Communicable Disease Risk”
8.7.4.3 “Warning: Reactive Test Results for name of disease agent or disease”.
8.7.4.4 Identity and address of processing and distribution facility (ies)
8.7.4.5 Statement “Do NOT Irradiate”
8.7.4.6 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).

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

8.9.1 Marrow during Processing (Partial Label)

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:

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

8.9.2.2 At a minimum, the following labels must accompany the product:

8.9.2.2.1 Identity and address of collection facility or donor registry
8.9.2.2.2 Date and Time collection ends and time zone (if applicable)
8.9.2.2.3 Expiration Date (if applicable)
8.9.2.2.4 Expiration Time (if applicable)
8.9.2.2.5 ABO and Rh donor (if applicable)

8.9.2.3 At a minimum, the following labels must be attached:

8.9.2.3.1 Recipient name and Duke History #
8.9.2.3.2 Product volume
8.9.2.3.3 Name and volume or concentration of anticoagulant and other additives (i.e. freezing solution)
8.9.2.3.4 Donor identifier and (if applicable) name
8.9.2.3.5 Recommended storage temperature
8.9.2.3.6 Biohazard and/or Warning labels (as applicable)

8.9.3 If applicable, statements:

8.9.3.1 “Warning: NOT Evaluated for Infectious Substances”
8.9.3.2 “Warning: Advise Patient of Communicable Disease Risk”
8.9.3.3 “Warning: Reactive Test Results for name of disease agent or disease”.

8.9.4 Identity and address of processing and distribution facility (ies)
8.9.4.1 Statement “Do NOT Irradiate”
8.9.4.2 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 tag(s).

RECIPIENT:

Doe, Jane
History # XX1234, DOB: 12/25/1962
Patient ABO/RH = A Positive
Patient Sex = Female
8.11 PROCESSING LABELS – Cord Blood

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

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:
   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 manipulations, if applicable (i.e. red cell reduced,
           CD34 selected, etc).

8.12.3 At a minimum, the following labels must accompany the product:
   8.12.3.1 Identity and address of collection facility or donor registry
   8.12.3.2 Date and Time collection ends and time zone *(if applicable)*
   8.12.3.3 Date of distribution

8.12.4 At a minimum, the following labels must be attached:
   8.12.4.1 Recipient name and Duke History #
   8.12.4.2 Product volume
   8.12.4.3 Name and volume or concentration of anticoagulant and
           other additives (i.e. freezing solution)
   8.12.4.4 Donor identifier and name *(if applicable)*
   8.12.4.5 Recommended storage temperature
   8.12.4.6 Biohazard and/or Warning labels *(as applicable)*
8.12.5 If applicable, statements:

8.12.5.1 "Warning: NOT Evaluated for Infectious Substances"

8.12.5.2 "Warning: Advise Patient of Communicable Disease Risk"

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

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

8.12.5.5 Statement “Do NOT Irradiate"

8.12.5.6 Expiration date (if applicable)

8.12.5.7 Expiration time (if applicable)

8.12.5.8 ABO/Rh of donor (if applicable)

8.12.5.9 RBC compatibility testing results (if applicable)

8.12.5.10 Statement “Properly identify intended recipient and product”

8.12.5.11 Statement “Leukoreduction filters should NOT be used”

8.12.5.12 Statement “For Autologous Use Only” (if applicable)

8.12.5.13 Statement “For Intended recipient ONLY” (if allogeneic recipient)

8.12.5.14 Statement “For Non-clinical use ONLY” (if applicable)
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.

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<tr>
<th>Donor Tested-Results Pending</th>
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<tr>
<td>WARNING:</td>
</tr>
<tr>
<td>Advise patient of</td>
</tr>
<tr>
<td>communicable disease risk</td>
</tr>
</tbody>
</table>

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 INFECTION 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 two trained staff members.

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.

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

8.13.1.4.4 Identity and address of collection facility or donor registry

8.13.1.4.5 Date and Time collection ends and time zone (if applicable)

8.13.1.4.6 Date of distribution

8.13.1.4.7 Recipient name and Duke History #

8.13.1.4.8 Product volume

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

8.13.1.4.10 Donor identifier and name (if applicable)

8.13.1.4.11 Recommended storage temperature

8.13.1.4.12 Biohazard and/or Warning labels (if applicable)
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 Risk”
8.13.2.3 “Warning: Reactive Test Results for name of disease agent or disease”.
8.13.2.4 Identity and address of processing and distribution facility (ies)
8.13.2.5 Statement “Do NOT Irradiate”
8.13.2.6 Expiration date (if applicable)
8.13.2.7 Expiration time (if applicable)
8.13.2.8 ABO/Rh of donor (if applicable)
8.13.2.9 RBC compatibility testing results (if applicable)
8.13.2.10 Statement “Properly identify intended recipient and product”
8.13.2.11 Statement “Leukoreduction filters should NOT be used”
8.13.2.12 Statement “For Autologous Use Only” (if applicable)
8.13.2.13 Statement “For Intended recipient ONLY” (if allogeneic recipient)
8.13.2.14 Statement “For Non-clinical 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/or GRID Number (after 04/29/2019)
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:
  o Removing all product samples
  o 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.).
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/or GRID Number (after 04/29/2019) 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.
8.14.9.13 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.
8.14.9.20 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 M0226 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.

8.14.15 Verify product labeling using NMDP form Verification of Product Labeling (F00835).
8.15 Back-up plan for labeling of NMDP products.

8.15.1 Two computers within the STCL will have the HemaTrax-CT software install.

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)

10 REFERENCES


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.


10.6 Current User’s Guide for HemaTrax®-CT

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<td>13</td>
<td>M. Christen</td>
<td>• Updated Section 8.5.2 to include use of indelible pen for documenting collection date and time, expiration date and time, product volume, and AC in the product.</td>
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Document Number: COMM-PAS-003  Revision: 13
Title: Labeling Cellular Therapy Products

All dates and times are in Eastern Time.

COMM-PAS-003 Labeling Cellular Therapy Products

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Document Release

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