

Procedure Title: Labeling Instructions For Canisters, Bags and Vials

Procedure #: HSC.E301.01

Procedure

A. Cryocyte freezing bags

1. Bags should have the following labels :
 - a. One computer-generated label (printed on Avery index cards using the LaserJet and laminated) attached with a string through the loop of a port cover.
 - b. One computer-generated label (printed on Shamrock Kimdura labels on the Epson dot-matrix printer) placed on the front face at the bottom of the bag itself.
 - c. One written with an indelible marker on the top right-hand pocket of the bag itself.
2. The labels printed on Avery index cards:
 1. Must be laminated
 2. A hole must be punched through the top of the laminated label, and the label must then be tied to one of the port-cover loops of the bag with a string.
 3. Certain sections will vary depending on the processing and the type of cells processed.
 4. The labels should contain the following information (see Appendix A for sample printouts):

On one side of the index card:

- e. The CHLA logo.
- f. Childrens Hospital Los Angeles
Division of Hematology and Oncology
Developmental Therapeutics Section
Hematopoietic Stem Cell Processing Laboratory
- g. The phone and fax numbers of the processing laboratory.
- h. The type of procedure carried out on the cells.
- i. "For Autologous Use Only"
- j. "Store at or below -150°C"
- k. A short description of the processing carried out on the cells, if any.
- l. A list of the cryoprotectants used, if any.
- m. Instructions to the Transfusionist:
 - 1) Consult the CHLA document "Thawing and Infusion of Autologous Marrow in Frozen Bags" and local institutional guidelines.
 - 2) Properly identify intended recipient and unit
 - 3) **WARNING** : This product may transmit infectious agents!"

On the reverse side of the index card:

- n. Donor name
- o. (CHLA) Unique component ID number
- p. Donor's date of birth and sex
- q. Donor hospital
- r. Collection date(s)

- s. Initials of the technicians doing the processing
 - t. Processing date
 - u. ABO/Rh type (if available: from a sample taken at component collection). If ABO/Rh type is not available, write N/A into the space for the blood type.
 - v. The total preserved volume
 - w. Bag number and total number of bags
 - x. Volume contained in bag
 - y. “Final sterility, tumor content and hematopoietic stem cell assay were not completed at time of cryopreservation.”
 - z. Expiration date: NONE DETERMINED
 - zz. “Consult product summary sheet for these data before infusing this product.”
3. Labels printed on Shamrock Kimdura tractor-roll must be placed on the front face at the bottom of the bag itself and must contain the following information (see Appendix B for sample printouts):
- a. Donor name
 - b. A unique patient identification number (examples of acceptable numbers are hospital medical record number, social security number, or unique patient identifier assigned via national study protocol).
- Note: A unique patient identification number is generated at CHLA by the Autologous Bone Marrow Transplant Coordinator (referred to as “NP” number). This number can be used if no other patient identification number is available at the time of labeling.
- c. Date of Birth
 - d. Unique Component Identification (UCI) Number

- e. Processing type (ie. BM6, BM9, PB6, PB9 or PB1)
 - f. Sample collection date(s).
4. The label written on the top right-hand pocket of the bag with indelible marker should contain the following information (see Appendix C for an example).
- a. Donor name
 - b. Date of Birth
 - c. Unique Component Identification Number
 - d. Processing type (ie. BM6, BM9, PB6, PB9 or PB1)
 - e. Volume preserved in bag.
 - f. Sample collection date(s).

B. Canisters

1. The computer-generated label is identical to that described in section A. 3. of this procedure and should contain the same information detailed in that section. It should be placed at the bottom of the front face of the canister.
2. Information identifying the patient and component should be written on the front face of the canister, at the top, with indelible marker. It should contain the following information:
 - a. Donor name
 - b. Sample type (ie. BM6, BM9, PB6 or PB1)
 - c. Unique Component Identification (UCI) Number
 - d. Volume preserved in bag
 - e. Donor's date of birth
 - f. Sample collection date(s)

3. There should be another label written with indelible marker on the bottom edge of the canister. It should contain the following information:
 - a. Donor name
 - b. Sample type (ie. BM6, BM9, PB6 or PB1)
 - c. Sample collection date(s)
4. The top edge of the canister should be marked "TOP" in indelible marker. See Appendix D for examples of the written labels and diagrams of their positions on the canisters.

C. Vials

Test vial labels are printed on Shamrock Kimdura tractor-roll labels using the Epson dot-matrix printer. The test vials are labelled as follows:

1. Donor name
2. Sample type (ie. BM6, BM9, PB6 or PB1)
3. Sample collection date(s)

D. Labeling verification

All prepared labels described above will be reviewed by a second technician prior to cryopreservation. The technician responsible for verifying information placed on the labels will initial as such on the processing worksheet.