Labelling of Cellular Apheresis and Bone Marrow Products

Lead Organisation: iMATCH

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Author	
Revision	7.0
Changes from previous Version	Format Change + clarification statement to meet JACIE 8 in relation to labelling products with an expiry date, this is already in place with current labels so no impact on actual practice.

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1.0 Introduction & Scope

This labelling procedure is designed to ensure that products are correctly and consistently labelled and facilitate tracking through all stages of the process.

The objectives of this SOP are to ensure that mislabelling or misidentification of products is prevented and to ensure the positive identification of each harvest and facilitate cell chain to tracked from donation to reinfusion. For products transferred to areas outside the Clinical Apheresis Unit, and those reinfused within the transplant programme.

2.0 Authorised Personnel/Training

The Programme Director, Quality Manager and Ward Nursing Leads are responsible for ensuring staff who are required to carry out activities described in this document receive a copy via the Q Pulse document distribution system.

All staff who are required to undertake activities described in this document must read and acknowledge receipt of this document, and where training is required shall not undertake described activities unsupervised until relevant training has been delivered.

Clinical Apheresis Unit Staff – Specialist nursing staff who have undertaken mandatory training and competency assessments in therapeutic apheresis and all nursing and clinical staff involved in conducting HPC-M procedures.

Laboratory Staff – Label templates are generated by the head of the processing laboratory (or designee). All pre-printed labels regardless of product will be available pre procedure for the apheresis nurse to apply to the product bag once the procedure has commenced.

3.0 Objectives

The objectives of this SOP are to ensure that mislabelling or misidentification of products is prevented and to ensure the positive identification of each harvest and facilitate cell chain to tracked from donation to reinfusion. For products transferred to areas outside the Clinical Apheresis Unit, and those reinfused within the transplant programme.

4.0 Training and Competence

Prior to implementation of any new or revised procedure there shall be a review and if considered appropriate training and competency shall be delivered prior to implementation of the procedure.

5.0 Procedural Statements

Each harvest is assigned a unique numeric identifier DIN comprising of the centre code (5 alpha numeric digits) 2 digits for the year followed by a 6 digit unique identification number plus a check digit. The last 4 digits of the DIN are used as the BB number.

The BB number is assigned sequentially from the processing laboratory and is used to identify the product at each stage of the processing, storage and release of the product.

The ISBT DIN labelling conventions apply to external collection centres as well as those within the Christie programme.

5.1 Labelling Procedure

1. Labels required for internal products will be printed on a named patient basis in the processing laboratory in accordance with the labelling policy. Labels for products which require external transfer and /or processing (ATMPs, ANDP donors, trials) may be provided by the external organization and made available to the apheresis nurse pre procedure. They will be delivered either to the apheresis/ANDP coordinators or to the stem cell manager

2. On the day of collection, nursing staff will contact the processing laboratory to inform them of the collection providing patient/donor details

3. Planned procedures will have been logged on the stem cell scheduling sheet by the apheresis co-ordinators so as to ensure labels are available in a timely manner

4. The following labels are used internally to identify and track products between the Clinical Apheresis Unit and the Processing Laboratory.

5. A set of labels will be generated per procedure

Product Labels	Includes patient and procedure specific information together with **the unique ISBT128 DIN number (donation identification number).** For HPC and T cell collections 2 labels will be issued, one of which will be marked 'plasma'. For HPC-M 4 product labels will be issued. All labels shall include date of expiry of the product where applicable and appropriate.
Warning information will be included on the collection label, provided the Stem cell lab is informed in advance.	
Transport Label	Includes printed patient and procedure specific information. All labels shall include date of expiry of the product where applicable and appropriate. This is attached to the outside of the transport box
BB labels	To be placed on accompanying documentation (the BB number comprises of the last 4 digits of the DIN). All labels shall include date of expiry of the product where applicable and appropriate.

1. Product specific details can be accessed via the Haematology Q-Pulse system, please see section 9 References for useful external documents to access.
2. Labels are supplied in a clear plastic wallet, as a complete set for each patient.
3. Labels will be checked by clinical apheresis unit staff on receipt to ensure
4. The patient and donor information is correct
5. A two-person verification process by 2 nurses is required and to be documented on the Adverse reaction/Complications form for all product labels
6. During the procedure prior to patient disconnection from the machine the blank fields of the product label will be completed as far as possible.
7. Once donor/patient identity is confirmed, product labels are placed on the cellular collection bags and plasma bag. These are placed over the manufacturer's label. Check that the label and donor details match.
8. Where there is more than one apheresis procedure being performed within the collection facility, labels must be attached, one patient at a time. Any additional labelling and bagging will be performed in a designated area in the clinical apheresis unit.
9. Details of any warnings are included in the top right-hand quadrant of the ISBT128 label.

10. Where products require warning labels, this will be noted on the post procedure complications form and will be reported as a non-conforming product. and recorded in Datix as a deviation.
11. The outstanding fields on the label are filled in as per label requirements
12. The product is packed for transportation (see SOP: SCL/POL/TSCH "Transport Policy (Lab and Collection Facility)").

WARNING	USE
Biohazard	Reactive test for communicable infectious disease or risk factors for transmission.
Not evaluated for Infectious substances	Results of testing incomplete, missing or awaited
Warning. Reactive test results (specify result):	Use in addition to Biohazard label where reactive test result for infectious agent.
Warning. Advise patient of communicable disease risks:	Use in addition to Biohazard label where high risk identified
Warning. Possible microbial contamination	Use in addition to Biohazard label where bacterial contamination suspected (for example signs of line exit infection)
Warning: Eligibility determination not completed	Use in cases of urgent medical need

5.2 Labelling of HPC-BM

1. For HPC-M the labels are transferred to theatres by the apheresis nurse taking collection of them prior to anaesthetic
2. At the completion of the procedure the blank fields of the product label will be completed accordingly.
3. All HPC BM bags are to be labelled in theatre whilst the patient is still present. donor/ patient identity has been confirmed prior to anaesthetic.
4. The label is placed over the manufacturers label
5. The application of warning and bio hazard labels and packing for transportation is done as per HPC collection. Bags are labelled 00 for the main collection bag then filtered into the 3 transfer bags each labelled with the DIN showing the split e.g. A0, B0, C0, which refer to bags 1, 2 & 3.
6. Other collection labels may be provided by the donor registries.

5.3 Labelling the Transport Box

1. The fields on the patient label for the transport box are completed and placed on the transport box by the responsible apheresis nurse.
2. Apheresis products from different patients must be packed in separate boxes; each with a completed transport label.
3. All boxes are to be labelled in such a way that patient details are not visible during transportation

4. For product being transferred externally refer to individual guidelines (Anthony Nolan donors, trials. Commercial ATPM, Transplants sent to external centres)
5. All unused labels at the end of a procedure will be destroyed. Unused labels are not to be stored other than in the processing laboratory.
6. Patient labels will be printed electronically and hand written labels will not be used except in the case of emergency
7. If additional labels are required (e.g. due to damage), the processing laboratory will be contacted and additional copies will be printed.

5.4 Associated Documentation and Labelling

1. BB number labels should be affixed to the following documents. The BB label should not obscure any of the information on the document:
2. Completed documentation will be scanned on to CWP
3. Copies of each of the documents listed above (with the exception of the procedural worksheet) should be sent with the cellular apheresis product to the processing laboratory.

Post procedure complications sheet	APH-116
Processing request form	LAB-47
Daily Medical assessment form	APH-65
Procedural worksheet	APH-113

5.5 Contingency in the Event of Computer Failure

1. In the event of computer failure such that labels cannot be printed, handwritten information may be entered onto pre-printed labels.
2. The laboratory director and collection facility director (or deputies) must be informed in the event of failure of the labelling process at the earliest opportunity.

5.6 Contact Details

Processing Laboratory – Ext 8096, bleep 12571
Apheresis Nurses – Ext 8011, bleep 12735

6.0 Monitoring Compliance

Compliance to this document will be monitored by a combination of audit where appliable, non-conformance monitoring and Datix incident reporting.

7.0 Dissemination/Distribution

This document will be distributed to staff members who need visibility of the document via Q Pulse.

8.0 References and Related Forms, Labels, Policies and Procedures

Policy

SCT/SCL/POL/LABE - Labelling Policy
CLN-100 – Management of Non-Conforming Cellular Products
SCL/POL/TSCH "Transport Policy (Lab and Collection Facility)"

SOP

SCT/SCL/SOP/PL - Printing and Using Labels
CLN-97 - Consenting for Stem Cell Transplant
APH-158 - Selection and Assessment of Sibling or Haplo-Identical Donors for Recipients of Allogeniec Stem Cell Transplant
QM-2 - CAPA and Change Control Management
APH-40 - Optia MNC Apheresis Procedure for HPC and T-Cell Collection

Label

SCT/SCL/LAB/APH - Manual Collection Label
MANtx - Internal Transport Label for Product
FRM/SCL/TC - External Transport Form
SCT/LAB/APH "Warning Labels"
LAB-4 – Box Label Fresh

Form

LAB-47 - "Processing Request Form for Cryopreservation"
APH-113 - WBC Procedural Worksheet
APH-116 - Adverse reactions/Complications Form - to be Completed After Each Apheresis Procedure
APH-118 - Medical Assessment Form for Patients
APH-117 - Medical Assessment form for Sibling Donors
APH-11 - Consent for Testing, Storage and Discard of Stem Cells or Lymphocytes for Donors
APH-119 - Consent to Testing, Storage and Discard (HTA) – Autologous

External Reference

HTA Standards and Regulations
JACIE International Standards 7th Edition
EXT-81 - Apheresis Verification, Collection and Packaging (Kite) Yescarta/Tecartus CAR-T SOP-00512
EXT-82 - Yescarta/Tecartus CAR-T SOP Final Product Handling (Kite)

9.0 Approval Process & Review Process

All new procedures are approved by the Clinical Program Director or approved designate before implementation of the procedure.

Revisions to existing procedures will be approved by the Clinical Director or approved designate prior to implementation.

Procedures will be reviewed every 2 years as a minimum.