LABELLING OF CELLULAR APHERESIS AND BONE MARROW PRODUCTS

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STANDARD OPERATING PROCEDURE (SOP)

TITLE: LABELLING OF CELLULAR APHERESIS AND BONE MARROW PRODUCTS

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1.0 INDICATIONS OF PRACTICE

1.1 This labeling procedure is designed to ensure that products are correctly and consistently labeled and facilitate tracking through all stages of the process

1.2 The objectives of this SOP are to ensure that mislabeling 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 REQUIRED

2.0 *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

2.1 *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

2.2 Each harvest is assigned a unique numeric identifier ('BB number') comprising of BB and 7 digits. 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

2.3 *Collection Facility Medical Director* – will be responsible for implementation of the SOP and corrective actions if required.

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3.0 LABELING PROCEDURE

3.1 Labels required for internal products will be printed on a named patient basis in the processing laboratory in accordance with the labeling 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

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

3.3 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

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

3.5 A set of labels will be generated per procedure

Product Labels	Includes patient and procedure specific information together with an affixed BB label. For HPC and T cell collections 2 labels will be issued, one of which will be marked 'plasma'. For HPC- M 3 product labels will be issued
Warning Labels	One complete set per procedure
Transport Label	Includes printed patient and procedure specific information. This is attached to the outside of the transport box
BB labels	To be placed on accompanying documentation

3.6 Product specific details can be accessed via the Haematology Q-Pulse system, please see section 9 References for useful external documents to access.

3.7 Labels are supplied in a clear plastic wallet, as a complete set for each patient.

3.8 Labels will be checked by clinical apheresis unit staff on receipt to ensure

- the patient and donor information is correct
- A two person verification process by 2 nurses is required and to be documented on the Adverse reaction/Complications form for all product labels

3.9 During the procedure prior to patient disconnection from the machine the blank fields of the product label will be completed as far as possible.

3.10 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.

3.11 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 labeling and bagging will be performed in a designated area in the clinical apheresis unit.

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3.12 The placement of warning labels should not obscure information on the product label or the contents of the bag.

Label type	Label 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)

3.13 Where products are labeled with warning labels, this will be noted on the post procedure complications form.
3.14 The outstanding fields on the label are filled in as per label requirements
3.15 The product is packed for transportation (see SOP: SCT/SCL/POL "Transport Policy (Lab and Collection Facility)").

4.0 LABELLING OF HPC-BM

4.1 For HPC-M the labels are transferred to theaters by the apheresis nurse taking collection of them prior to anesthetic
4.2 At the completion of the procedure the blank fields of the product label will be completed accordingly.
4.3 All HPC BM bags are to be labeled in theatre whilst the patient is still present. donor/ patient identity has been confirmed prior to anesthetic.
4.4 The label is placed over the manufacturers label
4.5 The application of warning and bio hazard labels and packing for transportation is done as per HPC collection. Bags are labeled 1 of 2, 2 of 2 etc.

5.0 LABELING THE TRANSPORT BOX

5.1 The fields on the patient label for the transport box are completed and placed on the transport box by the responsible apheresis nurse.
5.2 Apheresis products from different patients must be packed in separate boxes; each with a completed transport label.
5.3 All boxes are to be labeled in such a way that patient details are not visible during transportation
5.4 For product being transferred externally refer to individual guidelines (Anthony Nolan donors, trials. Commercial ATPM, Transplants sent to external centres)
5.5 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.

5.6 Patient labels will be printed electronically and hand written labels will not be used except in the case of emergency

5.7 If additional labels are required (e.g. due to damage), the processing laboratory will be contacted and additional copies will be printed.

6.0 ASSOCIATED DOCUMENTATION AND LABELLING

6.1 BB number labels should be affixed to the following documents. The BB label should not obscure any of the information on the document:

Post procedure complications sheet	FRM/APHERESIS/CO (7.2.12)
Processing request form	FRM/SCL/PROC
Daily Medical assessment form	APH-65
Procedural worksheet	CRC/ALU/PROC

6.2 Completed documentation will be scanned on to CWP

6.3 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.

7.0 CONTINGENCY IN THE EVENT OF COMPUTER FAILURE

7.1 In the event of computer failure such that labels cannot be printed, handwritten information may be entered onto pre-printed labels.

7.2 The laboratory director and collection facility director (or deputies) must be informed in the event of failure of the labeling process at the earliest opportunity.

8.0 CONTACTS

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

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9.0 REFERENCES

Policy
SCT/SCL/POL/LABE "Labelling Policy"
SCT\SCL/POL/NCP "Policy for dealing with non-conforming product"
SCT/SCL/POL/TSCH "Transport Policy (Lab and Collection Facility)"

SOP
SCT/SCL/SOP/PL "Printing and Using Labels"
TC/SOP/DC/01 "Consenting for stem cell transplant – donors"
SCT/PH/SSDR "Selection and Assessment of Sibling or Haplo-Identical Donors for Recipients of alloSCT"
QM-2 "Management of Corrective actions and process change"
APH-40 "Optia MNC Procedure for HPC and DLI Collection"

Label
SCT/SCL/LAB/APH "SCL collection label"
SCT/SCL/LAB/DS2 "Label for transport container"
SCT/LAB/APH "Warning Labels"
Lab-4 "Box Label – Fresh"

Form
FRM/SCL/PROC "Stem Cell (HPC) and T Cell (T-CT) Processing Request Form"
CRC/ALU/PROC "WBC procedural worksheet"
FRM/APHERESIS/CO (7.2.12) "Adverse Reactions/Complications form: to be completed after each apheresis procedure"
MEDASSPTS "Medical Assessment form for patients"
MEDASSDONOR "Medical Assessment form for donors attending the CAU"
APH-11 "Consent to testing, storage and discard (HTA) – donors"
SCT/APHERESIS/ST "Consent to testing, storage and discard (HTA) – autologous"

External reference
HTA Standards and Regulations
JACIE International Standards 7th Edition
DOC914 Yescarta CAR-T SOP verification, collection and packaging (Kite)
DOC915 Yescarta CAR-T SOP Final product handling (Kite)