HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Traceability of Blood Bags		
Applies To:	All Blood Bank Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-220
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-250(N)
Review Date:	February 20, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 To ensure the ability to follow the history of a product by means of recorded identification.

2. DEFINITONS:

2.1 **Traceability:** the ability to trace each individual unit of blood or blood component from the donor to its final destination (whether this is a recipient, other hospital, or disposal) and from its final destination back to the donor.

3. POLICY:

3.1 The blood bank ensures that all blood and blood components, as well as laboratory samples and donor and patient records, are identified and traceable.

3.2 The blood bank Keeps records to ensure easy tracing of a unit of blood from drawing until final disposition.

4. PROCEDURE:

4.1 **Benefits:**

- 4.1.1 Knowing the journey of the blood bags.
- 4.1.2 It will significantly increase the safety of the bag.
- 4.1.3 Better use of the blood components.
- 4.1.4 Ensure that red blood cells, plasma or platelets reach the right patient.

4.2 The blood bags are subjected to many steps during their journey in blood bank. All these steps are documented.

4.3 **Labeling:**

- 4.3.1 Information that is required or selected to accompany a unit of blood, component, tissue, derivative, or sample, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.
- 4.3.2 Labeling Requirements: The following requirements are applied:
  - 4.3.2.1 Labelling of blood and component containers:
    - 4.3.2.1.1 Prior to phlebotomy, unit barcode number and date of donation are written on the main collection bag and all transfer bags as well as on the donor form and containers for laboratory tests, and shall be reidentified immediately after filling.
    - 4.3.2.1.2 This identification must not be obscured, or removed.
    - 4.3.2.1.3 Blood containers used for whole blood collection must be identified by a lot and tube numbers. Both numbers are recorded on the donor form.
  - 4.3.2.2 The original label and added portions of the label are attached to the container and are in clear, eye-readable type.
  - 4.3.2.3 Handwritten additions or changes are legible and applied with permanent, moisture proof ink.

4.3.2.4 All modifications to component labels are specified and controlled.

4.3.2.5 The labelling process include a second check to ensure the accuracy of affixed label(s) including the correct donation identification number, ABO/Rh, collection and expiration date, and component's name, Instructions to the transfusionist, TTD results, Biohazard label, if applicable.

4.3.2.6 Labelling of test samples and requests.

4.4 **Documentation:**

4.4.1 The blood bank has a labeling process. The labeling system makes it possible to trace any unit of blood or blood component from source to final disposition.

4.4.2 All processes which are applied to blood bags are documented by hematos system of blood bank .

4.4.3 Records applying to the blood and blood components unit: The donor register is considered a master register and recently hematos system became the alternative of manual registration. The following are recorded:

4.4.3.1 Phlebotomist nurse or technician records the followings:

4.4.3.1.1 The date of collection on the donor form by using hematos system of blood bank.

4.4.3.1.2 The donor number and the bag tube number.

4.4.3.1.3 The donor name.

4.4.3.1.4 The preliminary blood group.

4.4.3.2 BB technician/specialist assigned for blood group confirmation and Ab screening of the bag record the followings:

4.4.3.2.1 The confirmed blood group.

4.4.3.2.2 Ab. Screening of the bag.

4.4.3.3 Supervisor of BB technicians or his deputy records:

4.4.3.3.1 TTD results.

4.4.3.4 BB technician/ specialist of the processing room record:

4.4.3.4.1 Components prepared from the bag.

4.4.3.5 BB technician/ specialist and supervisor of BB technician:

4.4.3.5.1 Check the bag TTD results.

4.4.3.5.2 Review all information on the label.

4.4.3.6 BB technician/ specialist who do cross match:

4.4.3.6.1 Records lab number of the patient to whom the component is prepared.

4.4.3.7 BB technician/ specialist and supervisor of BB technician record:

4.4.3.7.1 The fate of the bag if discarded, expired or sent to other hospitals.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Blood Donor register & Hematos system of blood bank

6. RESPONSIBILITIES:

6.1 All blood bank staffs have to follow the policy and procedure.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.

8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.
8.6 Mollison's Blood Transfusion in Clinical Medicine; 12th edition, 2014.
8.7 https://www.transfusionguidelines.org/regulations/clarification/documentation/traceability-update-2010.
8.8 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Mohammed Amer	Blood Bank Physician		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 12, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025