HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Labelling and Release of Component to Inventory		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 Ensure correct identification, documentation and labelling with required information.

1.2 Ensure controlled release process of donated blood/ blood components which is essential for patient safety.

2. DEFINITONS:

2.1 **Quarantine:** To isolate nonconforming blood or blood components to prevent their distribution or use.

2.2 **Release:** Removal of product from quarantine status for distribution.

3. POLICY:

3.1 Correct identification, documentation and labelling of donated blood/ blood components are essential for patient safety.

3.2 Identification, documentation, labelling and release to inventory of donated blood/blood components is aprocess can be done from hematos blood bank system through the production access on hematos then select the operation LAB for labelling of any blood product then select the product type then scan the donation number on the bag then the label will come out of the label printer then follow steps written on the hematos to apply the label on the product of blood

3.3 Blood and components must be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

3.4 The blood bank establishes a process for the identification and discard of unacceptable blood/blood product.

3.4.1 A process can be done from hematos blood bank system through the production access on hematos then select the operation DISC for discarding any of any blood product then select the product type then scan the donation number on the bag then select the cause of discard

3.4.2 Discard the unacceptable components from hematos system before the initial labelling of blood and blood components.

3.5 The blood bank develops a process for initial labelling of blood and blood components.

3.5.1 Blood and blood components are not labelled before completion of the donor testing.

3.5.2 Discard of unacceptable units before the initial labelling of blood and blood components.

3.6 Initial labelling requirements include:

3.6.1 Identification of the collecting facility.

3.6.2 Product name.

3.6.3 Unit number.

3.6.4 ABO/Rh.

3.6.5 Expiration date and time all these items now available on hematos system and data come automatically on the label

3.7 The blood bank has a process to confirm the ABO/Rh-D of donated blood.

3.7.1 segment from RBC components of donated blood must be subjected to the following testing:

3.7.1.1 Determination of the donor's forward ABO group (RBC grouping).

3.7.1.2 Determination of the donor's Rh-D type.

3.7.1.3 ABO/Rh-D conformation is performed after initial labelling.

3.8 Any discrepancies must be solved before releasing any blood/blood components.

3.9 All blood and blood components that are found unsuitable for transfusion or for further manufacturing must be stored in a separate quarantine area until all TTD test results released and final disposition.

3.10 All blood component units with positive screen TTD test results must be discarded from the first screen test results.

3.11 The blood bank establishes a process to prevent the release of units that are not suitable for transfusion to the available inventory through the hematos system hence any positive serology ,NAT,malaria or discrepancy in ABO& Rh grouping it will give label of biohazard bag to be discarded .

3.11.1 Ensure the accuracy and legibility of identification information.

3.11.2 Ensure the agreement of the identification information (records and donor units).

3.11.3 Ensure the performance of visual inspection for discoloration, clots, hemolysis, and adequacy of seal.

3.11.4 Two qualified staff members must perform and document this activity.

3.12 The blood bank transfusion services establish a process for the release of incompletely tested blood/blood components.

3.12.1 Ensure that incompletely tested blood/blood components can be released under the following circumstances:

3.12.1.1 For urgent need only.

3.12.1.2 Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.

3.12.1.2.1 In dire emergencies, patient/family signs consent for "transfusion without ELISA &/or NAT testing".

3.12.1.3 Approved only for a particular patient and one transfusion event.

3.12.1.4 The released blood products are conspicuously labelled to this effect.

3.12.2 Testing of the blood/blood components must be completed and reported promptly to the attending physician.

3.12.3 Deviations and exceptions standard in this chapter applies.

4. PROCEDURE:

4.1 Access to component storage area and authorization for removal of contents is restricted to assigned blood bank personnel

4.2 Unit quarantine:

4.2.1 All Blood /blood components are quarantined under the following circumstances:

4.2.1.1 Until serology and NAT results become available.

4.2.1.2 Confidential unit exclusion request by Donor (CUE).

4.2.1.3 A discrepancy exists between a units ABO/Rh type and the corresponding donors historical or tube results.

4.2.1.4 Permanently deferred donors units will be quarantined upon donation.

4.2.1.5 Unsuitable units for transfusion:

4.2.1.5.1 Quantity not sufficient (QNS): weight < 316 gm

4.2.1.5.2 Heavy units: >522 grams

4.2.1.5.3 Closed system compromised.

4.2.2 All unscreened units are placed units in a separate secured storage place, labelled "Unscreened", until serology and NAT results become available.

4.2.3 Positive serological test result for anyone of the transfusion-transmitted disease, on the first screening test, will be discarded even if become negative by repeat screening or confirmation tests.

4.3 Discard of unacceptable units:

4.3.1 Unacceptable units:

4.3.1.1 Blood/blood components with positive serological and/or NAT results. Units with positive antibody screening are also included.

4.3.1.2 Confidential unit exclusion request by Donor (CUE).

4.3.1.3 Permanently deferred donors units.

4.3.1.4 QNS and heavy units are disposed after the serology result becomes available.

4.3.1.5 Closed system compromised.

4.3.1.6 Presence of discoloration (e.g. deep yellow plasma), large clots, or hemolysis.

4.3.1.7 If an obvious abnormality is detected during labelling.

4.3.1.8 Returning units after the permissible time or in unsuitable condition.

4.3.1.9 If the unit passed the expiration date.

4.3.1.10 Variances in procedure, resulting in units unsuitable for transfusion.

4.3.1.11 Polycythaemia patients units for therapeutic donation.

4.3.2 Identify units and components need to be quarantined or discarded, from a given donation number of the bags.

4.3.3 If whole blood was separated to its components, Blood bank technician will search for the all components to be discarded (tracking all blood units).

4.3.4 All unacceptable units will be discarded. Record "TTD Positive", by pen marker on the bag's label, on units with positive serological test result for anyone of the transfusion-transmitted disease.

4.3.5 Discard unacceptable components from hematos system as discussed before .

4.3.8 Discard all unusable products into biohazardous waste yellow bag.

4.4 Initial labelling of blood and blood components:

4.4.1 Blood and blood components are not labelled before completion of the donor testing .

4.4.2 Initial labelling requirements include:

4.4.2.1 Identification of the collecting facility.

4.4.2.2 Product name.

4.4.2.3 Unit number.

4.4.2.4 ABO/Rh.

4.4.2.5 Expiration date and time

4.4.3 Products tested by culture-based devices with continuous monitoring are distributed as "negative-to-date "based on the status of the culture at the time the unit is released to the transfusion service .

4.4.4 The labelling process includes a second check to ensure the accuracy of affixed label(s).

4.4.5 ABO/Rh-D conformation is performed before labelling cos hematos system not allow printing label of any bag without completion of all laboratory tests .

4.5 Release of units suitable for transfusion to the stock refrigerator:

4.5.1 Checking and release are performed and documented by two qualified staff members.

4.5.2 Ensure that all required tests are performed for all whole blood and component units.

4.5.2.1 Checking of TTD results:

4.5.2.1.1 Using the TTD results received.

4.5.2.1.2 Using donor number.

4.5.2.1.3 Release only units with negative TTD results.

4.5.2.2 Confirmation of ABO/Rh typing. Discrepancies must be resolved before release.

4.5.2.3 Antibody screen of the donor for the detection of unexpected antibodies to Red Cell antigens for allogeneic donors:

4.5.2.3.1 The Ab screen must be negative.

4.5.3 The component must be visually inspected for discoloration, clots, hemolysis, and adequacy of seal.

4.5.4 Put the blood product in the suitable storage place of inventory specified for screened units

4.6 Emergency release of incompletely tested blood and blood components:

4.6.1 This situation is detailed in a separate chapter (the emergency release of incompletely tested blood and blood components).

5. MATERIALS AND EQUIPMENT:

5.1 Forms and Records:

5.1.1 NAT and Serology result Record
5.1.2 Malaria results Record
5.1.3 Platelet culture Record
5.1.4 Whole blood donation Record
5.1.5 Donor blood group register
5.1.6 Deferred Donors Record
5.1.7 Hematos software for blood banks

5.2 **Materials:**

5.2.1 Labelling printer
5.2.2 Label for blood bags
5.2.3 Negative screen label (stamp)
5.2.4 Negative to-date label (stamp)

6. RESPONSIBILITIES:

6.1 BB staff members like technician/ specialist and supervisor of blood bank or his deputy have to follow the detailed procedures.

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 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.

9. APPROVALS:

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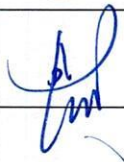
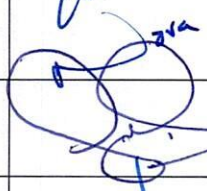
Prepared by:	Dr. Mohamed Amer	Blood Bank Physician		August 06, 2024
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		August 08, 2024
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		August 11, 2024
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		August 12, 2024
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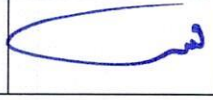
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		August 20, 2024