HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Packed Red Cells Quality Control		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 To ensure that packed red cells bags are complying with national and international standards.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 Monitoring the quality of the packed red cells component is important for the benefit of the patient and a step of quality control program of blood bank.
3.2 1% of the monthly production- but not less than 4 RBCs units every month- are subjected to quality control testing.
3.3 All tested RBC units have a hematocrit of less than 80% to ensure the presence of sufficient plasma and anticoagulant for RBCs survival.
3.4 RBC in additive solution are exempted from quality control requirement.
3.5 For Leukocyte-reduced RBCs units (LR-RBC): Refer to "Counting Residual White Cells In Leukocyte Reduced Blood And Components" policy (LB-IPP-211)
  3.5.1 1% of the quarterly production, but not less than 12 units every three months, are subjected to quality control testing.
  3.5.2 All tested LR-RBC units have a RBC recovery rate of more than 85% and a residual WBC count of less than $5X10^6$ WBC/unit in all subjected units.
3.6 It is an approach of early identification and resolution of a manufacturing problem.

4. PROCEDURE:

4.1 Almost all blood collection bags contain additive solution. Therefore, RBCs quality control regarding Hematocrit values does not usually apply. The following procedure only applies when CPD/CPDA1 are used.
4.2 Choose 4 CPD/ CPDA1 recently expired RBC's units.
4.3 Record unit's numbers in RBC's Q.C. form.
4.4 Mix units by horizontal platelet rotator for 30 - 60 minutes.
4.5 Label a 5 ml Red Top tube with unit number, date and time.
4.6 Draw 5 ml of RBCs by syringe and empty content in the corresponding Red Top labeled tube.
4.7 Send the sample for HCT ratio check.
4.8 Enter HCT result in RBCs Q.C. form.
4.9 Discard units in biohazard bags.
4.10 **Acceptable values:**
  4.10.1 All units tested are within acceptable levels. PRBC's must be prepared with final Hct 60- 80% without additives.

elucidating the cause .

4.10.3 Note: If units with additive solution were tested, the acceptable values are (HCT 46-65%).

4.11 **In cases of non-accepted RBC QC:**

4.11.1 Review the preparation process, adjust the amount of plasma left in RBCs and do QC again.

4.12 For testing RBC recovery rate and residual WBC count, see "Counting residual white cells in leukocyte-reduced blood and components and Cell Recovery after leucoreduction" policies.

4.12.1 Residual WBC count/ bag: less than $5X10^6$ WBC/unit.

4.12.2 Recovery rate: 85% of the RBC in the original product is retained.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Packed red cells quality control form

5.2 **Materials:**

5.2.1 Platelet agitator

5.2.2 10 ml syringes with needles

5.2.3 5 ml red top collection tube

6. RESPONSIBILITIES:

6.1 It is the responsibility of the blood bank supervisor to ensure that the separated component is with good quality .

6.2 Blood Bank technician/ specialist to follow detailed procedure and to follow corrective actions taken.

6.3 Hematology unit staff to test for HCT ratio.

7. APPENDICES:

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 Modern Blood Banking & Transfusion Practices, 6th edition, 2012.

8.7 U.S. Department of Health and Human Services; Food and Drug Administration (FDA), September 2012: Guidance for Industry; Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion.

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

9. APPROVALS:

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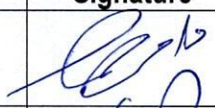
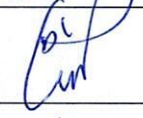
Prepared by:	Dr. Mohammed Amer	Blood Bank Physician		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
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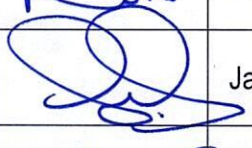
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
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