HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

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

1.1 To ensure that platelet concentrate bags are complying with the national and international standards.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 Monitoring the quality of platelet concentrate is important For the benefit of the patient and step of quality.

3.2 1% of the monthly platelet production-but not less than 4 units every month (expired units or at the time of issue) are checked for platelet count and pH to ensure the therapeutic efficiency of the products.

3.3 On the expiration date or at issue, 90% of the subjected units have a platelet count of $5.5X10^{10}$ platelets/unit or more and a minimum pH of 6.2.

3.4 For Leukocyte-Reduced Platelet concentrates (LR-PC) units: 1% of the quarterly production -but not less than twelve units every three months- are subjected to quality control testing. All tested LR-PC units have a platelets recovery rate of more than 85% and a residual WBC count of less than $8.3X10^5$ WBC/unit.

3.5 Unacceptable Q.C results must be followed by immediate corrective action.

4. PROCEDURE:

4.1 Select 4 expired P.C. units (6^{th} day of life).

4.2 All units demonstrate "swirl" effects.

4.3 Enter unit numbers on Q.C. worksheet.

4.4 Weigh each platelet unit, calculate volume (weight (in grams) divided by S.G of plasma (1.03)), and enter in QC worksheet.

4.4.1 Deduct the weight of the empty bag from the total weight.

4.5 Place the chosen units on platelet shaker. Ensure that the contents of the platelet bags are well mixed.

4.6 Label Red Top tubes with the unit number.

4.7 For random platelet's bags, resuspend platelets; draw 7 ml from the bag's ports using plastic syringes, and dispense in 10 ml corresponding labelled Red Top tube.

4.8 Dispense 500 ul of the platelet in 5ml Red Top tube properly labelled and add 1000 ul normal saline to dilute 1:3, cap and mix and send to Hematology section for platelet count.

4.9 Check pH for each unit using PH meter or PH detection strip (use the undiluted platelets in the original tube).

4.10 Enter platelet count and pH for each unit in Q.C. worksheet.

4.11 Record component's identity, the date, and the identity of the person performing the testing. The result must be reviewed and signed by the supervisor of blood bank technicians.

4.12 Discard units in biohazard bags for disposal .

4.13 **Red cell contaminated platelet:**

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4.13 **Red cell contaminated platelet:**

4.13.1 Draw 5 ml and dispense in CBC red top tube.

4.13.2 Send to Hematology section for HCT.

4.14 **Calculation of total platelet bag:**

4.14.1 Platelet count / bag = platelet count x 10^9/L x 3 (dilution) x Volume / 1000

4.15 Calculation of Absolute Red Cells volume (ml):

4.15.1 Red cells volume in unit = HCT% X volume of unit

4.16 **Accepted value:**

4.16.1 Random platelet.count: 90 % of units must have:

4.16.1.1 ≥ 5.5x10^{10} platelet /bag

4.16.1.2 pH of ≥ 6.2

4.16.1.3 PRBC's must be less than 2ml/ bag

4.16.1.4 For Leukocyte-Reduced Platelet concentrates (LR-PC) units:

4.16.1.4.1 Platelet count/filtered bag: ≥ 4.7 x10^{10} platelet /bag. in at least 90% tested (recovery rate of more than 85%)

4.16.1.4.2 Residual WBC count / bag: < 8.3 x10^5 WBC

4.17 **Corrective action:**

4.17.1 In case of not accepted QC (i.e. more than one unit is not accepted), a corrective action should be implemented by supervisor after elucidating the cause. Recalibration of the centrifuge for platelet separation may be needed.

4.18 **Notes:**

4.18.1 For results reported as cells/µL, change values to cells/mL by multiplying by 1000 (or 10^3).

4.18.2 For results reported as cells/L, change values to cells/mL by dividing by 1000 (or 10^3).

4.18.3 Multiply cells/mL by the volume of the component, in mL, to obtain total cell count in the component.

4.18.4 Refer to manufacturer's directions for any additional requirements.

4.18.5 For testing platelet recovery rate and residual WBC count, see 'Counting residual white cells in leukocyte-reduced blood and components and Cell Recovery after leucoreduction' chapters.

4.19 **Limitations of procedure:**

4.19.1 Platelet product should be well mixed before sampling.

4.19.2 Non-swirling platelets will not meet the QC requirements.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Platelet quality control form.

5.2 **Materials:**

5.2.1 10 ml syringes with needles.

5.2.2 500 ul and 1000 ul pipettes with tips.

5.2.3 Normal saline.

5.2.4 Electronic scale. .

5.2.5 Metal clips and hand sealer or dielectric sealer.

5.2.6 Tubing stripper.

5.2.7 Clean instruments (scissors, hemostats).

5.2.8 5 and 10 ml red top collection tube.

5.2.9 Cell-counting equipment.

5.2.10 pH meter.

6. RESPONSIBILITIES:

6.1 Blood Bank technician/ specialist and supervisor of blood bank technicians to follow the detailed procedure and to follow corrective actions taken.

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 Mollison's Blood Transfusion in Clinical Medicine; 12th edition, 2014.
8.7 Modern Blood Banking & Transfusion Practices, 6th edition, 2012.
8.8 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.
8.9 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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