HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

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

1.1 To ensure that Fresh frozen plasma bags are complying with national and international standards.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 Monitoring of fresh frozen plasma component to be sure it complying with national and international standards is one of the quality control program in blood bank.

3.2 If cryoprecipitate is not prepared, 1% of the quarterly production, but not less than twelve units every three months- are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 700 IU/L.

3.3 Unacceptable Q.C. results must be corrected and documented immediately.

4. PROCEDURE:

4.1 Every month, Select 4 FFP Units within 30 days of preparation (Total units are twelve every three months).

4.2 Units represent all ABO groups and from different dates of preparation. (Note: Group A plasma has higher F .VIII than group O).

4.3 Remove units from deep freezer 30 minutes earlier.

4.4 Place each unit in a disposable plastic bag and thaw in 37 °C water bath.

4.5 Enter unit number on QC worksheet.

4.6 Weight each unit; calculate its volume by dividing wt. by plasma sp. gr. (1.03).

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

4.7 Mix well, draw 3 ml into properly labeled tube, and send for assay of FVIII. Enter the volume in QC worksheet.

4.8 Testing samples must be processed close together and quickly due to labile nature of factor VIII.

4.9 Calculation:

4.9.1 **FVIII:** FVIII IU / ml x volume (ml) = IU / bag.

4.10 Accepted values:

4.10.1 **FVIII**: 0.75 IU/ml:

4.10.1.1 75% of the tested units must have minimum factor VIII level of 700 IU/L

4.11 If more than one unit is not accepted, a corrective action should be implemented by supervisor after elucidating the cause . Repeat Q.C. on other units.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Fresh Frozen Plasma Quality Control Form.

5.2 **Materials:**

5.2.1 5 ml Syringes
5.2.2 Water bath 37°C
5.2.3 Plastic tubes with caps
5.2.4 Electronic Scale

6. RESPONSIBILITIES:

6.1 It is the responsibility of the senior technologist and blood bank director to ensure that the separated component is with good quality .
6.2 Blood Bank technician/ specialist to follow the detailed procedure.

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

9. APPROVALS:

	Name	Title	Signature	Date
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