

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Fresh Frozen Plasma Quality Control		
Applies To:	All Blood Bank Staff		
Preparation Date:	January 06, 2025	Index No:	LB-IPP-213
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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.

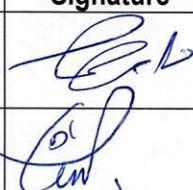
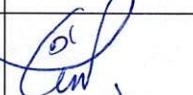
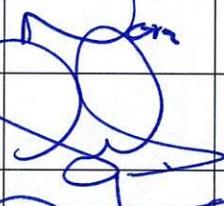
7. APPENDICES:

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
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