HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Quality Control of Cryoprecipitate		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 The use of an internal quality control system is designated to monitor the procedure and the performance of the blood bank staff with the aim of providing the best patient care service.

2. DEFINITONS:

2.1 Fresh Frozen Plasma(FFP)-prepared from single donors by centrifugation shall be assayed for factor VIII and fibrinogen to ensure its proper preparation
2.2 Cryoprecipitation -is accomplished by slow thawing of Fresh Frozen Plasma (FFP) at 1 to 6℃
2.3 Cryoprecipitate is a cold-insoluble portion harvested from Fresh Frozen Plasma. It is concentration of fibrinogen, factor VIII, and von Willebrand factor (vWF)

3. POLICY:

3.1 If cryoprecipitate is not prepared, 1% of the quarterly production (FFP)- but not less than twelve units every three months- is subjected to quality control testing. 75% of the tested units must have a minimum factor VIII level of 700 IU/L.
3.2 If cryoprecipitate is prepared 1% of the quarterly production (CRYO) - but not less than twelve units every three months- is subjected to quality control testing. 75% of the tested units must have a minimum factor VIII level of 80 IU/unit and 150mg of fibrinogen/bag.
3.3 Registration in the specific sheet & and proper record keeping are mandatory.
3.4 In accordance with AABB standards, all units tested must contain more than 150 mg of fibrinogen and more than 80IU of factor VIII
3.5 Unacceptable Q.C. results must be corrected and documented immediately

4. PROCEDURE:

4.1 Select units of CRYO within 30 days of preparation -1% of quarterly production –not less than 12 units every three months
4.2 Units represent all ABO group ads from different dates of preparation
4.3 Weigh the units; calculate the volume by dividing by the plasma specific gravity 1.03
4.4 Place each unit in a disposable plastic bag and thaw in 37 Centigrade water bath
4.5 Enter unit numbers on the QC sheet, as well as the weight, and volume calculated
4.6 Mixes well, draw 3 ml into the properly labeled tube and send for assay of F VIII and fibrinogen in the hematology section
4.7 Calculations:
  4.7.1 F VIII: F VIII IU multiplied by volume (ml) = IU / BAG
  4.7.2 Fibrinogen: Fibrinogen gm /L multiplied by volume (ml) = mg / BAG
  4.7.3 Enter all results in the form of acceptable values:
    4.7.3.1 CRYO: 75% of the tested units must have a minimum factor VIII level of 80 IU/unit and 150 mg of fibrinogen/bag.
4.8 If the results do not correspond to those of the table, immediate repeating of the QC on

4.9 Another 4 bags from the same month should be verified
4.10 The tested samples must be processed closely tighter and quickly due to the labile nature of FVIII

5. MATERIALS AND EQUIPMENT:

5.1 N/A

6. RESPONSIBILITIES:

6.1 All Blood Bank Staff
6.2 Blood Bank Supervisor
6.3 Blood Bank Physician

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 Effectiveness of confidential unit exclusion for screening blood donors. Rev Bras Hematol Hemoter, 2012, 1:33(5):328-36.
8.5 Effectiveness of confidential self-exclusion (CSE) and failed options on blood donation safety in Sari organization of blood transfusion, 2005. Casp.J Intern Med 2010; 1(1): 20-22.
8.6 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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