HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

1.1 Separation of blood components for judicious use of blood as per the need rather than using whole blood.
1.2 Ensure the use of blood components only during the permissible period of storage.

2. DEFINITONS:

2.1 **Fresh frozen plasma (FFP):**
- 2.1.1 Plasma that is separated (from a single donor whole blood) and freshly frozen within the specified timing.
- 2.1.2 It contains normal amounts of all coagulation factors, especially the labile factors V and VIII.

2.2 **Thawed plasma:**
- 2.2.1 FFP that has been thawed and held at 1 to 6 °C for more than 24 hours.

3. POLICY:

3.1 To ensure maximum patient benefit, the plasma should be prepared and stored according international standards .

3.2 FFP components are prepared by separating and freezing the plasma from the whole blood within eight hours of collection (to preserve the activity of labile coagulation factors).
3.3 FFP components are stored under properly controlled conditions below -18°C.
3.4 FFP components are assigned an expiration date of one year from the day of whole blood collection.
3.5 During transportation, FFP units are maintained at frozen state in properly insulated container.
3.6 For plasma thawing:
- 3.6.1 Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.
- 3.6.2 Thawed FFP units are stored in blood bank refrigerator between 1 and 6°C.
- 3.6.3 Thawed FFP units are transported in properly insulated container between 1 and 10°C.
- 3.6.4 Thawed FFP units are assigned an expiration time of twenty four hours from the thawing time.

3.7 All components are stored in "Unscreened" storage equipments until getting TTD screening results, then released for transfusion (for free bags).
3.8 Access to component storage area and authorization for removal of contents is restricted to assigned blood bank personnel.
3.9 No cryoprecipitate preparations are made in MCH blood bank.

4. PROCEDURE:

4.1 **FFP preparation from platelet-rich plasma "PRP":**
- 4.1.1 Balance PRP units in pairs using electronic scale.

4.1.2 Centrifuge Platelet rich plasma "PRP" (within 8 hours) at speed, temperature and time of each centrifuge specified for separation of platelet concentrate.

4.1.2.1 To separate platelets from FFP, centrifuge using heavy spin (4000 RPM for 10 minutes) with a temperature setting 20-24 °C. Prior to this step, PRP was prepared using a soft spin (2650 RPM for 5 minutes) with a temperature setting of 20-24 °C

4.1.3 Place the primary bag containing centrifuged plasma on plasma expresser and release the spring allowing the plate of expresser to contact the bag.

4.1.4 Penetrate the closure of the primary bag (or remove the tubing clip) allowing flow of supernatant plasma into the satellite bag .

4.1.5 Express the plasma into the empty bag leaving 50-60 ml plasma along with the platelets . Seal the tube between the primary bag and the plasma satellite one in two places 5 cm in between. Sealing is done closer to the plasma bag leaving the remaining tube attached to platelet bag (for bacterial detection).

4.1.6 Check that the satellite bag has the same donation number as that on the primary pack and cut the tube between the two seals .

4.1.7 .Recieve & separate the whole blood bag in hematos system by selecting production access then enter operation then select REC then write tempreture of centrifuge then write the balance number then select the product whole blood then enter donation number of the bag then go to separation select the operation SEP from enter operation then select balance used then select product as whole blood then enter donation number then write the weight of FFP bag

4.1.8 Keep FFP bag at ≤ -18 °C in plasma freezer to ensure that it is frozen solid within 8 hours of phlebotomy and stored for 1 year.

4.1.7.1 Plasma may be frozen by placing the product bag in a mechanical freezer maintained at -65 °C or colder.

4.2 **FFP preparation from the whole blood:**

4.2.1 Whole blood processing by second spin (i.e. heavy spin) bypassing the first spin (soft spin) occurs in unsuitable unit for platelet production due to slow bleed, aspirin ingestion by the donor, and low volume blood unit.

4.2.2 Use a refrigerated centrifuge, centrifuge the blood soon after collection, using a "heavy spin" at 1-6 °C.

. 4.2.2.1 The heavy spin is at 3500 RPM speed for 7 minutes for the current centrifuge.

4.2.3 Place primary bag containing centrifuged blood on plasma extractor and place the attached satellite bag on a scale adjusted to zero. Express the plasma to the satellite bag and weight the plasma.

4.2.4 Seal the transfer tubing with a sealer. Place another seal nearer the transfer bag.

4.2.5 Label the transfer bag with the unit number before it is separated from the original container.

4.2.6 Keep FFP bag at ≤ -18 °C in plasma freezer to ensure that it is frozen solid within 8 hours of phlebotomy and stored for 1 year

4.3 **The details of component separation are stored in hematos system .**

Record the component separated in Donor blood group register.

4.4 **Specifications of Fresh Frozen Plasma:**

4.4.1 Crossmatch: Not required, a blood sample may be required to determine patient ABO and Rh type.

4.4.2 Approximate Volume: 150-250 ml. The volume of FFP prepared after platelet preparation will be substantially less than that prepared directly from Whole Blood.

4.4.3 Expiration: One year.

4.4.4 Storage Conditions: One year at below -18 °C.

4.4.5 Transport conditions: Maintain frozen state.

4.4.6 Maximum administration Time: To ensure maximum patient benefit, the plasma should be infused within 6 hours of thawing.

4.4.7 Minimum Preparation Time: 15 minutes unless processing of a blood specimen is required .

4.4.8 Description: Each unit of Fresh Frozen Plasma contains the plasma obtained by centrifugation and separation from one unit of whole blood. The Fresh Frozen Plasma has been frozen within eight hours of collection to minimize loss of the coagulation Factors V and VIII. Published data

indicate that after 5 days of refrigerator storage, thawed plasma retains at least 80% Factor VIII activity and 90% of Factor V activity. This is within the expected inter-donor variability. Other plasma proteins are not altered by liquid storage. Plasma has the same risk of disease transmission as Red Blood Cells. These components lack platelets .

4.4.9 Indications:

4.4.9.1 FFP specifically indicated for patients with a documented deficiency of coagulation Factor V .

4.4.9.1.1 Patients requiring coagulation factor VIII are best treated with coagulation factor VIII concentrate (available from the pharmacy) or cryoprecipitated antihemophilic globulin.

4.4.9.2 FFP may be used for correction of isolated coagulation factor deficiencies, Warfarin® reversal and micro-angiopathic haemolytic anaemia such as thrombotic thrombocytopathic anaemia or haemolytic uremic syndrome .

4.4.9.3 FFP is also indicated for coagulopathy due to massive transfusion, and deficiency of anti-thrombin III.

4.4.10 Contraindications:

4.4.10.1 Plasma is not indicated for prophylactic use when the prothrombin time is <18 seconds (1.5 times the control).

4.5 **Thawing of FFP:**

4.5.1 Principle:

4.5.1.1 Thawed Plasma is prepared from Fresh Frozen Plasma. FFP should be rapidly thawed at 30 to 37 °C but should not remain at this temperature once thawing is complete.

4.5.2 Procedure:

4.5.2.1 Cover the container with a plastic overwrap to prevent contamination of the ports with unsterile water, (or if available, use a device to keep the containers upright with the ports above water). Place container in 37 °C water bath.

4.5.2.2 Record the new expired date on the unit's label: 24 hours from the thawing time.

4.5.2.3 Keep the thawed plasma in blood bank refrigerator (for WB and RBCs units) at 1-6 °C until release.

4.5.2.4 Once thawed, FFP should be used as soon as possible (better within 6 hours). It must be transfused within 24 hours of thawing to preserve acceptable amounts of factor VIII. Discard the thawed FFP maintained at 1-6 °C for more than 24 hours.

4.6 **Procedure notes:**

4.6.1 Whole blood processing by second spin (i.e. heavy spin) bypassing the first spin (soft spin) occurs in unsuitable unit for platelet production due to slow bleed, aspirin ingestion by the donor, and low volume blood unit.

4.6.2 Exception units are identified by donor room staff, and handled by component preparation staff as follows:

4.6.2.1 Low volume (300 – 404 ml) labeled. (Low volume AS - Red Cells)

4.6.2.2 "QNS" units weighing less than 316 gm.

4.6.2.3 Heavy units weighing more than 521 gm.

4.6.2.4 QNS and heavy units are disposed after the serology result becomes available.

4.6.3 Platelets and FFP should not be prepared from low-volume units.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Hematos system of blood bank & Components preparation register

5.1.2 Hematos system of blood bank & Donor blood group register.

5.2 **Equipment:**

5.2.1 Refrigerated blood bag centrifuge.

5.2.2 Plasma expresser.

5.2.3 Dielectric Tube Sealer.

5.2.4 Electronic Weight Scale.
5.2.5 Plastic tubing clips/clamps and FFP boxes.
5.2.6 Blood Bank Refrigerator.
5.2.7 Blood Bank plasma Freezer.
5.2.8 Blood Bank Platelet incubator.

6. RESPONSIBILITIES:

6.1 It is the responsibility of the component separation area's technician/specialist to separate components from whole blood collected in multiple bags.
6.2 It is the responsibility of the component separation area's technician/specialist to label for component name, expiration date, blood group, and Rh typing.

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

9. APPROVALS:

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