HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Platelet Concentrate 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 N/A

3. POLICY:

3.1 To ensure maximum patient benefit, the platelet component should be prepared and stored according international standards.
3.2 Platelet concentrate (PC) components are prepared by separating the platelets from whole blood within 8 hours of collection.
  3.2.1 Platelets-rich plasma is separated from whole blood by "soft-spin" centrifugation and the platelets are concentrated by "heavy-spin" centrifugation with subsequent removal of supernatant plasma.
3.3 PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.
3.4 PC components are assigned an expiration date of twenty four hours to five days from the day of whole blood collection according to the manufacturer's recommendations or four hours of opening PC unit.
3.5 PC components are transported in properly insulated container as close as possible to 20 and 24°C.
3.6 Leukocyte-Reduced Platelet concentrates (LR-PC) units are prepared by a method known to retain 85% of the platelets in the original product and a residual WBC count of less than 8.3×10^5 WBC/ unit (or 5×10^6 WBC/pool of six units).
3.7 For LR-PC units, requirements for PC preparation, storage, transport and expiration apply.
3.8 No apheresis are available in MCH blood bank.

4. PROCEDURE:

4.1 **Preparation of platelet rich plasma (PRP):**
  4.1.1 Whole blood is collected (450 ml) in, at least, triple bag configuration (primary + 2 satellite bags) connected with integral tubing.
  4.1.2 Do not chill (4 ± 2°C) the blood at any time, before or after centrifugation.
  4.1.3 Centrifuge the whole blood at 22 ± 2°C using a soft spin (2650 RPM, for 5 minutes duration).
  4.1.4 Express the supernatant platelets -rich plasma (PRP) into the transfer bag intended for the platelets storage. Temporarily seal this bag from the other two, and add the additive solution (100 ml) to the erythrocytes in the primary bag. Now heat-seal the tubing twice between the primary bag and Y-connector of the two satellite bags and cut between the two seals. This is important to maintain the sterility of the products. Promptly store the RBCs in the blood refrigerator at 4 ± 2°C.

4.1.5 In case of bags with filters: Seal the tube between 'the primary bag and AS satellite bag' and 'PRP and FFP satellite bags' in two places 5 cm in between. Add the additive solution. Start filtration as described in (Red cell preparation procedure).

4.1.6 Recheck that the satellite bags have the same donor number as that on the primary bag.

4.1.7 Cut the tubing between the two seals.

4.2 **Platelet separation from PRP:**

4.2.1 Balance PRP units in pairs using electronic scale.

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

4.2.2.1 To separate platelets from FFP, centrifuge using heavy spin (4000 RPM for 10 minutes) with a temperature setting 20-24 ºC.

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

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

4.2.5 Express the platelet-poor plasma into the empty bag leaving 50-60 ml plasma along with the platelet. 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).

4.2.6 Determine exactly the weight of concentrated platelets .

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

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

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

4.2.9 In order to resuspend the pelted platelets in the plasma without undue irreversible aggregation, the plastic bag containing concentrated platelets are left stationary with label side down at room temperature (22±2°C) for approximately one hour, and then placed in horizontal shaker with gentle agitation.

4.2.10 Resuspended platelets are stored at 22±2°C in the horizontal shaker until their expiry. Shelf life is 5 days, and the volume is 40-70 ml .

4.3 **For Preparation of Pre-storage Leukocyte- Reduced Platelets**:

4.3.1 Pre-storage leukocyte-reduced platelets (LR-PC) units may be prepared from whole blood using in-line filtration of the platelet-rich plasma (PRP).

4.3.2 The resulting intermediate product is a filtered PRP, from which LR platelet concentrate and LR plasma may be prepared.

4.4 The details of component separation are available at Hematos system of blood bank & are registered in Components preparation register. Record the component separated in Donor blood group register.

4.5 **Specifications of PC unit:**

4.5.1 Crossmatch: Not required, a blood sample may be required.

4.5.2 Approximate Volume: 40- 70 ml/unit.

4.5.3 Expiration for single units:

4.5.3.1 5 days from the day of whole blood collection;

4.5.3.2 24 hours if without agitation;

4.5.3.3 4 hours (open system);

4.5.3.4 Return component to Blood Bank immediately if component is no longer required.

4.5.4 Storage Conditions: 22±2°C (room temperature), with constant, gentle agitation. DO NOT REFRIGERATE. Do not store on patient units or in the operating room.

4.5.5 Transport conditions: 22±2°C (room temperature).
4.5.6 Minimum Preparation Time: 10 minutes.
4.5.7 Description: A minimum of 5.5 x 10^{10} platelets harvested from one unit of fresh whole blood in about 50 ml of donor plasma. The product may be leukocyte-reduced by the use of special leukocyte reduction filters.
4.5.8 Platelet Counts: A 24-hour post-transfusion, platelet count is recommended to assess patient response.
4.5.9 Indications:
4.5.9.1 Treatment of thrombocytopenia or defects of platelet function. Requests must be substantiated by appropriate laboratory tests and clinical data.
4.5.9.1.1 Prophylactic use of this component for a thrombocytopenic patient who is not bleeding is not indicated if the platelet count exceeds 10 x 10^9/L and >20 x 10^9/L in the presence of risk factors (e.g. fever, anticoagulants, evidence of systemic haemostatic failure).
4.5.9.1.2 Adjustment of the transfusion threshold may be necessitated by unusual clinical situations.
4.5.9.2 Patients undergoing major operative procedures generally should have platelet counts above 50 x 10^9/L for effective hemostasis .
4.5.9.2.1 Each unit of random donor platelets will raise the platelet count of an adult approximately 5-10 x 10^9/L under optimal conditions, although clinical response to platelet transfusions is diminished by fever, hypersplenism, infection, and preformed antibodies to platelet antigens .
4.5.9.3 In case of massive haemorrhage/ transfusion, Use should be confined to patients with thrombocytopenia and/or functional abnormalities who have significant bleeding from this cause. It may be appropriate when the platelet count is <50 x 10^9/L.
4.5.10 Contraindications:
4.5.10.1 Transfusion of platelets to patients with thrombotic thrombocytopenic purpura (TTP) or heparin-induced thrombocytopenia is absolutely contraindicated, except in cases of life-threatening haemorrhage, because fatal intravascular coagulation may occur .
4.5.10.2 Transfusion of platelets in idiopathic thrombocytopenic purpura (ITP) or post-transfusion purpura is ineffective because of their shortened intravascular survival time, although they may be used at the time of splenectomy.
4.5.11 Compatibility:
4.5.11.1 ABO and Rh compatible platelets will be selected and released for transfusion. If this is not available, ABO and/or Rh incompatible platelets may be issued.
4.5.12 Specifications of leukocyte-reduced platelets (LR-PC) units:
4.5.12.1 The same as those of ordinary PC units except that LR-PC units are prepared by a method known to retain recovery rate of more than 85% of the original platelet cell content and a residual WBC less than 8.3X 105 WBC/unit (or a residual WBC less than 5 X106 WBC/pool of six units). The product may be leukocyte-reduced by the use of special leukocyte reduction filters at the bedside.

4.6 **Procedure notes:**
4.6.1 Exception units are identified by donor room staff, and handled by component preparation staff as follows:
4.6.1.1 Low volume (300 – 404 ml) labelled. (Low volume AS - Red Cells)
4.6.1.2 "QNS" units weighing less than 316 gm.
4.6.1.3 Heavy units weighing more than 521 gm.
4.6.1.4 QNS and heavy units are disposed after the serology result becomes available.
4.6.2 Platelets and FFP should not be prepared from low-volume units.
4.6.3 Platelet products that containing visible RBC's. should be issued to recipient with the same ABO type
4.6.4 Most of the platelet clumps seen on day 0 disappear on day 1 of storage with continuous agitation.

4.6.5 Platelet pH level (6.2 or more) usually requires a minimum of 35 ml of plasma when storage is at 20 to 24 °C , but 50 to 70 ml is preferable.

4.6.6 Platelets should be inspected before issue to ensure that no platelet aggregates are visible.

4.7 **Volume-Reduced Platelets**:

4.7.1 Principle:

4.7.1.1 The amount of plasma is reduced by centrifugation of the platelet units to pellet the platelets. Supernatant plasma is removed, and the pelleted platelets are subsequently resuspended into a smaller volume of plasma resulting in a final volume of 15 to 20 mL/unit after the volume reduction.

4.7.2 Indications:

4.7.2.1 May be needed for patients in whom the amount of plasma in platelet units may cause cardiac overload.

4.7.2.2 For patients who are transfused with ABO- incompatible platelets.

4.7.2.3 For neonates and for intrauterine transfusion.

4.7.3 Procedure:

4.7.3.1 Single platelet concentrates may need volume reduction for pediatric recipients.

4.7.3.2 A sterile connection device is used to attach a satellite bag to the original bag for removing plasma from the platelet concentrate.

4.7.3.3 Centrifuge at 20 to 24 ^{0}C, using one of the following protocols:

4.7.3.3.1 580 × g for 20 minutes

4.7.3.3.2 2000 × g for 10 minutes

4.7.3.3.3 5000 × g for 6 minutes

4.7.3.4 Without disturbing the contents, transfer the bag to a plasma extractor. Remove all leaving 10 to 15 mL plasma from single units. After sealing, detach the satellite bag.

4.7.3.5 Leave bag at 20 to 24 ^{0}C without agitation for 20 minutes if centrifuged at 580 × g, or for 1 hour if centrifuged at 2000 or 5000 × g.

4.7.3.6 Resuspend platelets.

4.7.4 Notes:

4.7.4.1 If a sterile connection device is used for removing plasma from individual platelet concentrate, the unit can be considered sterile and it is not necessary to impose the 4-hour expiration interval required for entered platelets. However, no data exist to support storage of reduced-volume platelet concentrates; therefore, it is preferable to transfuse them as soon as possible.

4.7.4.2 The volume- reduced platelets may be stored in either 10- mL or 15-mL capacity plastic syringes for up to 6 hours. Under such storage conditions, the platelet concentrate pH seems to be maintained above 6.0 for up to 6 hours of storage.

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 plasma Freezer.

5.2.7 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:

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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:

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