HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Red Cells 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 **Primary Bag:** for donor blood collection. It contains a standard anticoagulant CPD (63 ml) or CPDA-1 (63 ml).
- 2.1.1 CPD: It contains Citrate, Phosphate and Dextrose.
- 2.1.2 CPDA-1: It contains Citrate, Phosphate, Dextrose and Adenine.

2.2 **Satellite bag:** either is empty or contains additive solution (100 ml) which is added to the red cells, thus providing nutrients to red cells for improved viability. Additive solutions;
- 2.2.1 SAGM: It contains Saline, Adenine, Glucose, and Mannitol.
- 2.2.2 ADSOL: It contains Adenine, Dextrose, Saline, and Mannitol.
- 2.2.3 AS-5: It contains Saline, Adenine, and Dextrose.

2.3 **Pre storage leukoreduction filtration:** leukocyte reduction using in-line filters during the process of blood/blood component preparation.

2.4 **Post storage leukoreduction filtration:** leukocyte reduction using bedside filters connected to the storage container after the process of blood/blood component preparation.

3. POLICY:

3.1 Donor whole blood (WB) is collected in double, triple or quadruple bags with integral tubing within 10-15 minutes.

3.2 Whole blood will be processed and separated into the following single donor components: packed red blood cells. (PRBC's), platelet concentrate (P.C.), and/or Fresh Frozen plasma (FFP) (according to inventory).

3.3 Most of whole blood bags are separated into its components (PRBC's, Platelet, and FFP) within 8 hours of collection.
- 3.3.1 No components other than RBC are made from:
  - 3.3.1.1 A low-volume collection; with whole blood volumes of 300-404 ml (whole blood weight: 316-425 grams).
  - 3.3.1.2 Slow bleed (more than 15 min).
  - 3.3.1.3 Aspirin ingestion by the donor.
  - 3.3.1.4 Units kept more than 8 hours before separation.

3.4 The sterility of all components shall be maintained during processing by use of aseptic methods, equipment and material that allows transfer of components without breakage of the seal.

3.5 To ensure maximum patient benefit, the packed red cells component should be prepared and stored, according international standards.

3.6 RBC components are prepared by separating the RBC from plasma protein.

3.7 RBC components are stored under properly controlled conditions between 1 and 6°C. They are stored in a variety of different anticoagulant/preservative solutions. The resultant RBCs components have different haematocrits and shelf lives.

3.8 The expiration policy of blood and its components depend upon the nature of preservative and maximum storage for achieving the desired increments.

3.9 RBC components are assigned an expiration date according to the manufacturer's recommendations or:

- 3.9.1 21 days for RBC in CPD.
- 3.9.2 35 days for RBC in CPDA-1.
- 3.9.3 42 days for RBC in additive solution.
- 3.9.4 24 hours post opening the RBC unit.

3.10 All blood components should be used only during the permissible period of storage.

3.11 RBC components are transported in properly insulated container between 1 and 10°C.

- 3.11.1 Different blood components transport and shipping will be discussed later.

3.12 RBC bags are filtered using inline filters (when using bags associated with filters).

3.13 Additive solution (AS) is added to almost all RBC units when using bags attached with AS satellite bags.

- 3.13.1 The additive solution should be added to red cells within 72 hours since phlebotomy.

3.14 Red Blood Cells without additive solutions is prepared to result in a final hematocrit of <80%.

- 3.14.1 RBCs stored in additive solutions (AS) have haematocrit of 52 -60 % whereas,
- 3.14.2 RBCs stored in CPD or CPDA-1 have haematocrit of 70-80 %.

3.15 Pre storage leukoreduction filtration:

- 3.15.1 Almost all RBCs units having in-line filters are pre storage leucocyte reduced.
  - 3.15.1.1 Anticoagulated whole blood or the red cells in additive solution may be filtered.
  - 3.15.1.2 Non leukocyte-reduced red cells may also undergo leukocyte reduction after preparation by attaching a leukocyte reduction filter connected to a storage container using a sterile connection device (i.e. post storage leukoreduction filtration).
- 3.15.2 Leucocyte-reduced packed red blood cells (LR-PRBCs) are prepared by a method known to retain 85% of the RBCs in the original product and a residual WBC count of less than $5X10^6$ WBC/ unit.
- 3.15.3 Leukocyte reduction filters: They are typically component-specific;
  - 3.15.3.1 A filter intended for one component type should not be used with other component types.
  - 3.15.3.2 Leukocyte reduction filters intended for bedside filtration should not be used for pre-storage leukocyte reduction.
- 3.15.4 Re-filtration: Components that fail to leukocyte reduce appropriately are not re-filtered, unless re-filtration is specified as appropriate by the device manufacturer in the instructions for use.
- 3.15.5 Requirements for RBC preparation, storage, transport and expiration are applied.

3.16 All components are stored in "Unscreened" storage equipment until getting TTD screening results, then released for cross match and transfusion (for free bags).

3.17 Access to component storage area and authorization for removal of contents is restricted to assigned blood bank personnel.

3.18 No apheresis process is made in MCH blood bank.

3.19 No irradiation process is done in MCH blood bank.

4. PROCEDURE:

4.1 Whole blood that is collected in donor room is transported as soon after collection as possible to the component preparation room.

4.2 Units, from which platelets will be made, are allowed to cool toward room temperature (20-24 °C).

4.3 Units, destined for Fresh Frozen Plasma (FFP), are transported with sufficient refrigeration to allow them to cool toward 1 to 10 °C. Plasma must be placed in the freezer within 8 hours.

4.4 The whole blood bags are received by blood bank technician/ specialist in the component preparation room. He has to check that the satellite bags have the same donor number as that on the primary

bags. He has also to review the donor form and blood bag label regarding any recommendation regarding blood component separation.

4.5 Blood bank technician/ specialist in the processing room starts blood component preparation (RBC, FFP, and Platelet) within 8 hours of whole blood collection.

4.6 Centrifugation: Centrifuge freshly collected whole blood (within 8 hours) at speed, temperature, and time of each centrifuge specified for separation of platelet rich plasma "PRP" (First spin = soft spin).

- 4.6.1 Balance units in pairs using electronic scale.
- 4.6.2 Place the balanced units in plastic centrifuge cups and place the cups opposite one another in the refrigerated centrifuge.
- 4.6.3 Adjust the speed, temperature, and time of each centrifuge as specified for separation;
  - 4.6.3.1 In RBCs/ FFP separation, centrifuge using heavy spin (3500 RPM for 7 minutes) with a temperature setting at 1-6 °C.
  - 4.6.3.2 In the case of preparing platelets (RBCs/ PRP) , use a soft spin (2650 RPM for 5 minutes) with a temperature setting of 20-24 °C.

4.7 After completion of centrifugation, remove the units gently from the centrifuge using the ports at the top of the bag.

4.8 Place the primary bag containing centrifuged blood on plasma expresser. Release its spring allowing the plate of the expresser to contact the bag.

4.9 Apply the clip/clamp to the satellite bags leaving the platelet collection bag (if platelets to be prepared) /or plasma collection bag (if plasma to be prepared). Penetrate the closure of the primary bag. Using the plasma expresser, platelet rich plasma (PRP) is expressed into 5-day expiry satellite bag or plasma is expressed into plasma bag. The use of an additive solution allows removal of a greater volume of plasma.

4.10 Reapply the clip/clamp closing the plasma bag when the desired amount of supernatant plasma has entered the satellite bag.

- 4.10.1 In case of additive solutions, remove all plasma from original bag (i.e. plasma-depleted PRBC's) before adding AS. Stop the flow once the red cell level is almost touching the port on the top of the primary bag by placing a tubing clip/clamp.
- 4.10.2 A scale may be used to measure the expressed plasma.

4.11 Additive solution: If use a red cell additive solution:

- 4.11.1 For bags without filters:
  - 4.11.1.1 Open the valve on the additive satellite bag and allow all of its content to flow only into the red cell unit. Mix well. Reapply the clip (closing the additive satellite bag).
  - 4.11.1.2 Seal the tube the primary bag and the satellite bags in two places 5 cm in between.
- 4.11.2 For bags with filters:
  - 4.11.2.1 Seal the tube between 'the primary bag and AS satellite bag' and 'PRP and FFP satellite bags' in two places 5 cm in between.
  - 4.11.2.2 Open the valve on the additive satellite bag and allow all of its content to flow only into the red cell unit. Mix well.
  - 4.11.2.3 Start filtration by hanging the container (PRBC's mixed with additive solution) upside down and by allowing the RBCs to flow through an in-line filter by gravity into a secondary container.
  - 4.11.2.4 Red cells that are leukocyte-reduced are labelled "LR-PRBC"
  - 4.11.2.5 Make the tube segments (used for cross matching) from the.

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

4.13 Cut the tubing between the two seals.

4.14 For RBCs units, the integrally connected tubing must be filled with an aliquot of RBCs, and sealed to be available for subsequent compatibility testing. In bags with filters, post-filter tubing is used.

4.15 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 PRBCs bag

4.15 The details of component separation are stored in hematos system of blood bank .

4.16 Specifications:

4.16.1 Packed red blood cells (PRBCs):

4.16.1.1 Crossmatch: Required.

4.16.1.2 Approximate Volume: 280 ± 60 ml.

4.16.1.3 Expiration: as specified before in 3.8.

4.16.1.4 Hematocrit: about 52 -60 % with additive solutions and about 70-80% with CPDA-1.

4.16.1.5 Storage Conditions: 1-6 °C in a monitored blood refrigerator.

4.16.1.6 Transport Conditions: 1-10°C in ice box during transportation in properly insulated container.

4.16.1.7 Description: Contains red cells from one unit of whole blood plus a small amount of plasma and anticoagulant and approximately l00 ml of additive solution (if used). The transfusion of one unit of red cells is expected to increase the haemoglobin 1-1.5 g/dl in the 70 kg patient.

4.16.1.8 Minimum Preparation Time: 35 minutes (if blood group of patient is known)

4.16.1.9 Maximum administration Time: Complete transfusion within 4 hours of commencement.

4.16.1.10 Dose Adult: 1 unit per 1 gm Hb rise desired in the 70 kg patient (or as prescribed by the treating physician).

4.16.1.11 Paediatric dose: 5-15 ml/kg body weight (or as prescribed by the treating physician).

4.16.1.12 Indications:

4.16.1.12.1 Symptomatic anaemia.

4.16.1.12.2 Acute blood loss > 15% of blood volume.

4.16.1.12.3 Pre-operative Hb < 8 g/dl and operative procedure associated with major blood loss.

4.16.1.12.4 Evidence of inadequate oxygen delivery Hb 7-l0 g/dl.

4.16.2 Leukocyte-Reduced Packed Red Blood Cells (LR-PRBC) (through pre-storage filtration:

4.16.2.1 Crossmatch: Required.

4.16.2.2 Approximate Volume: 280 ± 60 ml.

4.16.2.3 Expiration: as specified before in point no 3.8.

4.16.2.4 Hematocrit: about 52 -60 % with additive solutions and about 70-80% with CPDA-1.

4.16.2.5 Storage Conditions: 1-6 °C in a monitored blood refrigerator.

4.16.2.6 Transport Conditions: 1-10°C in ice box during transportation in properly insulated container.

4.16.2.7 Description: Contains red cells from one unit of whole blood plus a small amount of plasma and anticoagulant. and approximately l00 ml of additive solution (if used). Prepared by a method known to retain 85% of the RBC in the original product and a residual WBC count of less than $5X10^6$ WBC/ unit. The transfusion of one unit of red cells is expected to increase the haemoglobin 1-1.5 g/dl in the 70 kg patient.

4.16.2.8 Minimum Preparation Time: 35 minutes (if blood group of patient is known)

4.16.2.9 Maximum administration Time: Complete transfusion within 4 hours of commencement.

4.16.2.10 Dose Adult: 1 unit per 1 gm Hb rise desired in the 70 kg patient (or as prescribed by the treating physician).

4.16.2.11 Paediatric dose: 5-15 ml/kg body weight (or as prescribed by the treating physician).

4.16.2.12 Indications:

4.16.2.12.1 Symptomatic anaemia.

4.16.2.12.2 Acute blood loss > 15% of blood volume.

4.16.2.12.3 Pre-operative Hb < 8 g/dl and operative procedure associated with major blood loss.

4.16.2.12.4 Evidence of inadequate oxygen delivery Hb 7-l0 g/dl.

4.16.2.12.5 Such processing reduced the risk of CMV transmission.

4.16.2.12.6 Patients with history of febrile non-haemolytic transfusion reaction.

4.16.2.12.7 Postoperative infection or bacterial contamination.
4.16.2.12.8 Immunosuppression, or immunocompromised patients.

4.17 Initial labelling of blood/blood components:
- 4.17.1 The original label and added portions of the label must be attached to the container and must be in clear, eye-readable type.
- 4.17.2 The labelling process must ensure the accuracy of affixed label(s).
- 4.17.3 The label contains information about the following items:
  - 4.17.3.1 Identification of the collecting facility.
  - 4.17.3.2 The unique unit number.
  - 4.17.3.3 The ABO group and Rh type of the donor.
  - 4.17.3.4 Collection and expiration date of the product.
- 4.17.4 Handwritten additions or changes must be legible and applied with permanent, moisture proof ink.
- 4.17.5 On the label of the bag, there must be place for recording transfusion transmitted disease (TTD) results.

4.18 Expiration:
- 4.18.1 The shelf life and hence the expiration of blood and its components depend upon the nature of preservative and maximum storage for achieving the desired increments.
- 4.18.2 All blood components should be used only during the permissible period of storage.
- 4.18.3 Day of collection is considered day zero.
- 4.18.4 Expiration time is the midnight of the last day of shelf life.
- 4.18.5 Whole blood/RBC components are assigned an expiration date according to the manufacturer's recommendations or:
  - 4.18.5.1 For whole blood:
    - 4.18.5.1.1 ACD/CPD/CP2D: 21 days.
    - 4.18.5.1.2 CPDA-1: 35 days.
  - 4.18.5.2 For RBCs:
    - 4.18.5.2.1 ACD/CPD/CP2D: 21 days.
    - 4.18.5.2.2 CPDA-1: 35 days.
    - 4.18.5.2.3 Additive solution: 42 days.
  - 4.18.5.3 For open pack or washed RBC's:
    - 4.18.5.3.1 24 hours post opening or washing the unit.

4.19 Aliquoting:
- 4.19.1 Indications:
  - 4.19.1.1 Neonatal and paediatric transfusions.
  - 4.19.1.2 Patients with severe chronic anaemia, overt heart failure, or moderate to severe renal failure may be candidates for transfusions of divided RBC units.
- 4.19.2 Procedure:
  - 4.19.2.1 Mix the original unit well before dividing it. Use a welding machine to attach the original unit to the transfer bag (if no empty satellite bags are attached)
  - 4.19.2.2 To the transfer bag (s), deliver the needed amount. Consider the weight of the empty bag and the density of component transferred. 1 ml of PRBC's equal 1.09 gm.
  - 4.19.2.3 Accurate labelling of the satellite bags is a must before detachment from the original bag. Labelling must include the whole information like the product name, number, collection and expired date…….etc.

4.20 Welding:
- 4.20.1 If a sterile connection device is used to produce sterile welds between two pieces of compatible tubing, the weld must be inspected for completeness;
  - 4.20.1.1 If the integrity of the weld is complete, the component retains the original expiration dates.
  - 4.20.1.2 If the integrity of the weld is incomplete, the container is considered an open system and may be sealed and used with a component expiration as indicated as open system.

4.21 Leukocyte Depleted Blood Components:

4.21.1 Reduction of leukocytes in transfused blood components may reduce the risk of:

4.21.1.1 Febrile non-haemolytic transfusion reaction (FNHTR).

4.21.1.2 CMV transmission.

4.21.1.3 HLA allo-immunization.

4.21.1.4 Platelet refractoriness.

4.21.1.5 Immune-modulation, cancer recurrence and bacterial infections in some surgical procedures.

4.21.1.6 Prion disease (CJD).

4.21.1.7 Yersinia enterocolitica contamination of RBC's.

4.21.2 Acceptable leukoreduction level in blood components:

4.21.2.1 RBC's < $5X10^6$.

4.21.2.2 Random platelets < $8.3X10^5$

4.21.3 Methods for leukoreduction:

4.21.3.1 Blood component washing (e.g. by saline).

4.21.3.2 Post storage leukoreduction filtration: using bedside filters.

4.21.3.3 Pre storage leucoreduction filtration.

4.21.4 Blood component Washing:

4.21.4.1 Methods:

4.21.4.1.1 Automated: Expensive and Time consuming.

4.21.4.1.2 Manual.

4.21.4.2 Saline Washed Red Blood Cells:

4.21.4.2.1 Description:

4.21.4.2.1.1 Contain 10 to 20% less RBCs than the original units.

4.21.4.2.1.2 Have a hematocrit of 70%.

4.21.4.2.1.3 Have been depleted of 99% of the plasma proteins and 85% of the leukocytes.

4.21.4.2.1.4 RBC metabolites, cytokines are almost entirely removed.

4.21.4.2.1.5 Saline washed RBCs must be used within 24 h after washing since:

4.21.4.2.1.5.1 The original collection bag has been entered, which breaks the hermetic seal and increases the possibility of bacterial contamination.

4.21.4.2.1.5.2 Removal of the anticoagulant-preservative solution also limits cell viability and function.

4.21.4.2.2 Indications:

4.21.4.2.2.1 Febrile transfusion reactions not prevented by leukocyte reduction.

4.21.4.2.2.2 IgA deficiency with documented anti-IgA antibodies and IgA deficient donor not available.

4.21.4.2.2.3 History of a previous anaphylactic transfusion reaction.

4.21.4.2.3 Procedure:

4.21.4.2.3.1 Using welding machine, attach RBC unit to a transfer bag.

4.21.4.2.3.2 Centrifuge the unit of RBC by light spin and subsequently express the plasma or AS and buffy coat manually to the transfer bag using a plasma expressor leaving packed RBC's in the collection bag.

4.21.4.2.3.3 Heat seal the tube between the two bags and detach the transfer bag and discard it.

4.21.4.2.3.4 Using welding machine, attach RBC unit to IV

transfusion set attached to 500 ml of saline. Allow the saline to pass to RBC unit.

4.21.4.2.3.5 Heat seal the tube between the RBC bag and saline container and detach saline container and discard it.

4.21.4.2.3.6 Using welding machine, attach saline-RBC unit to a transfer bag.

4.21.4.2.3.7 Centrifuge again by light spin, and the supernatant manually removed using an expressor, leaving washed RBC's.

4.21.4.2.3.8 Repeat the washing process another two times.

4.21.4.2.3.9 Label "washed RBC" and record the new expired date (24 hours).

4.21.4.3 Saline washed Platelets:

4.21.4.3.1 Description:

4.21.4.3.1.1 Loss of 33 % of platelet.

4.21.4.3.1.2 No changes in leukocyte content.

4.21.4.3.1.3 Remove 99 % of plasma.

4.21.4.3.1.4 Must be transferred within 4 hours.

4.21.4.3.2 Advantages:

4.21.4.3.2.1 Decrease prophylaxis in IgA deficient patients.

4.21.4.3.2.2 Decrease FNHTR

4.21.4.3.3 Procedure:

4.21.4.3.3.1 Like saline washed RBC.

4.21.4.3.3.2 Label "washed platelets". It must be transferred within 4 hours.

4.21.4.3.3.3 Note: Cellular washing does not prevent HLA alloimmunization

4.21.5 Pre storage leucoreduction filtration:

4.21.5.1 Advantages:

4.21.5.1.1 More effective in preventing risk of Febrile non-haemolytic transfusion reaction (FNHTR).

4.21.5.1.2 More effective in multiple platelet transfusion.

4.21.5.1.3 Easy QC performance in blood bank.

4.21.5.1.4 No hypotensive reactions noticed.

4.21.5.2 Timing: It is often within 24 hours of collection but can be up to 5 days or as directed by the manufacturer of the filter.

4.21.5.3 Requirements for RBC preparation, storage, transport and expiration are applied.

4.21.5.4 Notes:

4.21.5.4.1 If the collection system does not include an in-line filter, a sterile connection device can be used to attach a leukocyte reduction filter to the collection system. The filter should be used according to the manufacturer's directions.

4.21.5.4.2 If filters become blocked, attach the two bags using welding machine and keep RBC in one bag and label (unfiltered RBCs).

4.22 Procedure notes:

4.22.1 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.

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

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

4.22.2.2 "QNS" units weighing less than 316 gm.

4.22.2.3 Heavy units weighing more than 521 gm.

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

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

4.22.4 In case of bags without filter:

4.22.4.1 If only the plasma to be separated, seal the tubing near the plasma bag leaving the other satellite bag connected to PRBC's primary bag with a loose overhand knot (to be used later as satellite PRBC's bag). The plasma will be placed at -18 °C or colder to ensure it is frozen solid within 8 hours of phlebotomy and stored for one year.

4.22.4.2 If the platelets to be prepared, seal the PRBC's primary bag leaving the PRP bag connected to the additive or empty satellite bag (keeping a clip in between).

4.22.5 If the whole blood couldn't be separated within 6-8 hours (under certain circumstances), the whole blood bag is kept inside blank bank refrigerator at 1 to 6 °C to be separated within 24 hours. PRBC's is used (after addition of additive solution) while the plasma is discarded.
Soft spin: (according to QC of the machine):

4.22.5.1 Soft spin: (according to QC of the machine):

4.22.5.1.1 Speed: 2650 RPM.

4.22.5.1.2 Time: 5 minutes.

4.22.5.2 Heavy spin: (according to QC of the machine)

4.22.5.2.1 Speed: 3500 RPM.

4.22.5.2.2 Time: 7 minutes.

4.22.6 If the seal is broken during processing, components shall be considered to have been prepared in an open system with component expiration as indicated as open system.

4.22.7 Blood clots in RBC units are often too small to be detected by visual inspection. Clots are sometimes revealed during transfusion when they clog the filter or during the component preparation when the units are filtered through a leukocyte reduction filter. Units known to have clots should not be released for transfusion.

4.22.8 A unique number is imprinted on each tube segment. A sticker with the donation number is wrapped around the segment archived for investigative purposes in case any transfusion reactions occur. Retention segments are held at the blood bank for 2 months.

4.22.9 Hemolysis identified in a segment by visual inspection often does not correlate to the presence of hemolysis in the unit.

4.22.10 Abnormal color caused by bacterial contamination may be observed in segments that may appear lighter than the color of the bag.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Components preparation sheet

5.1.2 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.

8. REFERENCES:

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8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.
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8.7 Modern Blood Banking & Transfusion Practices, 6th edition, 2012.
8.8 U.S. Department of Health and Human Services; Food and Drug Administration (FDA), September 2012: Guidance for Industry; Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion.
8.9 http://www.mahasbtc.com/preservation-and-storage-blood.

9. APPROVALS:

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