For Leukodepleted Red cells, Plasma and Platelet collection, separation and storage of human blood components.

GENERAL PREPARATIONS BEFORE USAGE

1. Open the outer wrap at the tear notches and remove one blood bag system
2. Apply blood pressure cuff or tourniquet on donor’s arm, identify venipuncture site and release the cuff or tourniquet.
3. Disinfect the venipuncture site. Cover the area with sterilized gauze strip and do not touch until the time of venipuncture

CAUTION: Beware of iodine sensitive donors!

4. Before venipuncture, inspect the blood bag system; tubing, and needle for visual defects and discoloration
5. Signs on the needle protector and hub should be in the same line. Apply some pressure to determine any leakages.
6. Place the collection bag below the level of donor’s arm
7. The anticoagulant and additive solutions should be checked for containing appropriate volume, color or particle contaminants.

CAUTION: While opening the blood bag system, blood taking tube should be held from needle protector not from the needle safety cover. Pay attention not to lock the needle safety cover before collection of blood by mistake.

DESCRIPTION

1. Blood samples; sampling tubes are inserted into the tube holder and necessary blood is taken (Figure 1, No: 3).
2. The clamp on the tubing to the bag is opened and blood taking starts. (Figure 1, No: 1)
3. Take blood to the sampling bag (Figure 2, No: 5).
4. The clamp on the tubing to the sampling bag is closed. (Figure 2, No: 2)
5. The clamp on the tubing to the bag is opened and blood taking starts. (Figure 2, No: 1)

CAUTION: Sample blood in the sampling bag should immediately transferred to the tubes otherwise they get coagulated.

COMPONENT SEPARATION

1. After sampling complete, break the breakaway part on the tubing to collection bag for the systems with donor line breakaway (Figure 3 and 4), for others (Figure 1 and 2), open the clamp.
2. The tube with the tube holder is hanged on to donor’s wrist in a way not to compress the needle, continue with number 9.
3. Mix blood and anticoagulant gently and periodically (approx. every 45 seconds) during collection. If a mixer or a collection system is used, please refer to their operator’s manual.
4. Make sure there is continuous blood flow. If there is continuous, adequate blood flow and constant agitation, blood collection is expected to be completed under 12 minutes. CAUTION: It is a above 12 minutes, collected blood may not be suitable for Platelets, Fresh Frozen Plasma or Cryoprecipitate AHF.
5. Collect the quantity of blood within the limits indicated on the bag label. Monitor the blood being drawn.

After blood collection is finished, blood collection mixer collects the desired blood and stops the collection by clamping the blood collection tube.

Stop the blood taking and-agitating device, and after opening the clamp of the device;

Loosen the tourniquet or deflate the pressure cuff.

When blood taking is done, to remove the needle hold the hub with one hand between the thumb and index finger while the other hand holding the sterile gauze and pull the hub without exerting pressure completely. Let the donor keep sterile gauze on the point of entry of the needle into veins.

Hold the needle with one hand as it tip stay at the upper position; wait for flowing off the blood to bag in the blood taking tube

The clamp on the tube to the bag is closed after that step. Put a knot on the systems without sampling bag. CAUTION: When the needle is locked if the clamp is not closed there is risk of blood flushing from the needle safety cover.

For the blood bag systems with needle safety cover, while holding the needle with one hand hold the needle safety cover with the other one, than leave the needle, pull the needle to the safety cover by pulling the tube under the cover and be sure that it is locked (Figure 5, No:6). CAUTION: To prevent accidental injuries or contamination of the personnel, insert the needle into the locked system or throw it to the medical waste.

The blood taking tube is closed from under the Y port with tube sealing device and the needle is removed from the system. CAUTION: Throw locked needle kit to the medical waste.

Strip donor tubing as completely as possible into bag, starting at seal. Work quickly, to prevent the blood from clotting in the tubing. Invert bag several times to mix thoroughly; then allow tubing to sit in medical waste.

Reverse the whole kit, hook redcell bag to the top and the SAG-M bag will be on the bottom. (Figure 9).

COMPONENT SEPARATION

CLASSICAL Triple Bag Sets

1. Load the full blood filled bag system in the centrifuge buckets. Caution: Proper positioning of the bags will prevent burst of the bags during centrifugation.
2. Centrifuge at 2500 g for 15 minutes under +22 °C. Caution: Centrifuge settings may vary according to the centrifuge brand used.
3. Place the centrifuged bag to the blood component extractor.
4. Clamp all tubing except for the tubing of transfer bag used in plasma separation. Meanwhile put a clamp on the tubing connected with filter to prevent leakages of plasma into filter.
5. Place the plasma in accordance with the extractor operation manual.
6. Break the break-off part at the opening of the bag by turning left and right (Figure 7) and transfer the plasma into the transfer bag labelled 5.
7. The transfer bag labelled 5 contains plasma and the transfer bag connected to it are removed from the bag system. Check number 19 for continue with production gaining.
8. Hook the SAG-M bag to filter hanger from a height of 150 cm (Figure 8).
9. Break the breakaway part at the output of SAG-M bag by turning left and right. (Figure 7).
10. SAG-M solution flows through the filter.
11. After SAG-M process is finished the tube is clamped under leukocyte filter with temporary clamp. CAUTION: Beware to put the clamp to the closest point of redcells bag.
12. Rinse the redcells bag before up. Caution: Rinsing the bag decreases filtration time.
13. Reverse the whole kit, hook redcell bag to the top and the SAG-M bag will be on the bottom. (Figure 9).
14. Unlock the temporary clamp. Redcells flow into the filter and leukocytes are filtered and they are collected in the SAG_M bag.
15. Caution: Be sure that the tube is flat to avoid remaining of air in the filter and to increase the filtration speed, pull the clamp at once.
16. Filtration time is around 25 minutes at controlled room temperature. Caution: Do not use the product if the filtration time is less than 5 minutes!
17. After the procedure seal the tube under filter.
18. Samples for cross-match can be taken from tube of the bag. Invert bag several times to mix thoroughly; then allow tubing to refill with anticoagulated blood from the bag. Repeat this procedure twice (Figure 5). Closest segment to collection bag always remains with the bag for identifying.
19. Red cells should be placed into blood bank refrigerators under 1-6°C.
20. If PLTs will be separated, plasma is re-centrifuged at 3000 g for 10 mins.
21. After centrifuge, PLTs remain at the bottom, and plasma on the top of the bag.
22. Place the plasma bag to the blood component extractor, and unlock the clamp.
23. Transfer plasma to the empty transfer bag.
24. PLTs can be stored up to 5 days in incubator under agitation if they are transferred into the transfer bag from PVC (TOTM).
25. Store the plasma in the freezer. If the separation takes place within 6 hours after collection, it can be stored at -18°C/-25°C for 3 months, -30°C/-40°C for 6 months and at lower temperatures for 12 months.

TOP&BOTTOM Triple and Quadruple Bag Sets (Intended for PLT separation by BC)
1. Place the bags into centrifuge bucket as the breakaway part stands on above. Caution: Place the filter into the housing. Proper positioning of the bags will prevent burst of the bags during centrifugation.
2. If the blood will be used as a whole blood, break the breakaway part on the main bag and transfer whole blood into 500 ml capacity transfer bag.
3. Centrifuge at 3500 g for 15 mins at 22° C. Caution: Centrifuge settings may vary according to the centrifuge brand used.
4. Place the centrifuged bag to the blood component extractor. If quadruple bag is used, seal the PLT bag’s tube.
5. Use the blood component separator according to the separator using manual.
6. Firstly, break the main bag’s breakaway part, then the transfer bags. (Figure 7)
7. Separator transfers plasma to the plasma bag, redcells to the transfer bag while keep Buffy-Coats remaining in the main bag.
8. When the procedure is done, seal transfer bags with plasma and redcells; then remove them from the kit.
9. Store plasma as identified in number 24.
10. Hook the SAG-M bag to filter hanger from 150 cm high (Figure 8).
11. Break the breakaway part at the output of SAG-M bag by turning left and right (Figure 7).
12. SAG-M solution flows through the filter.
13. After SAG-M process is finished lock the tube under leukocyte filter with clamp. Caution: Beware to put the clamp to the closest point of redcells bag.
14. Rinse the redcells bag before hook up. Caution: Rinsing the bag decreases filtration time.
15. Reverse the whole kit, hook redcells to the top and leave the SAG-M bag on the bottom (Figure 9).
16. Unlock the temporary clamp. Redcells flow into the filter and leukocytes are filtered and they are collected in the SAG_M bag.
Caution: Beware not to lose air, and a flat tube for increasing filtration, and lock the clamp at one time.
17. Filtration time is 25 mins in average at a room temperature.
18. Invert bag several times to mix thoroughly; then allow tubing to refill with anticoagulated blood from the bag. Repeat this procedure twice. (Figure 6)
19. If quadruple bag is used, lock main bag with BC with PLT clamp, rinse the bag and rest it for an hour.
20. Centrifuge main bag and 57 transfer bag at 500 g for 6 mins at 20°C. Caution: Centrifuge settings may vary according to the centrifuge brand used.
21. Separator transfer PLTs to the transfer bag. Caution: PLTs are separated after centrifuge.
22. PLTs can be stored in a TOTM transfer bag up to 5 days in incubator under agitation. 9

TRANSFUSION
1. Inspect the container and blood for any defects.
2. Before transfusing the blood, make sure that serological test results are acceptable, cross match test results match with the recipient. If appropriate, apply cross match again at bed side.
4. Hold the top part of T port with one hand and bag from the bottom part of T port with other hand, and twist of the upper part by 270°(Figure 10).
5. Keep holding the bag from T port, remove the cap of the transfusion spike with other hand.
6. Insert the spike by ¼ of its length into outlet port. Do not touch the spike of the transfusion set and open outlet port to prevent contamination.
7. After inserting the spike, squeeze the bag to the level that transfusion set filter is filled with blood.
8. Hook the bag from its holder.

GENERAL CAUTIONS
During storage and transportation:
1. During shipment, up to two blood bags shippers shall be carried at the same time manually or on a trolley. Parcels should not be dropped and/or crushed and should be loaded in a way to prevent fall over.
2. In the warehouse, up to seven parcels can be stored on top of each other and in a way to prevent fall over.

Before opening overwrap:
3. Store the overwrapped bags at clean, dry and cool places.
4. Do not use if there is visible sign of deterioration on the overwraps.
5. Blood bags are packed with sterilized.

After opening overwrap:
6. Store the bags in their outer wraps at clean, dry and cool places.
7. Bags should be used within 10 days after removal of the transparent overwrap.

Before usage:
1. This product is intended to be used by certified Blood Bank personel in the Blood Bank.
2. Store the closed overwraps at clean, dry and cool places.
3. Intended for human blood and blood components.
4. Sterile and non pyrogenic - Steam sterilization.
5. Do not use unless solutions are clear.
6. Do not use if there is visible sign of deterioration on the bags.
7. Protect the bag and tubing from sharp objects.
8. Do not use if needle protector is opened. Bars on the needle should be in the same line. (Figure 11).
9. Do not recap the opened needles.
10. Do not use if fluid path closures are loose and not intact
11. Do not vent.
12. Store blood between 1–6°C.
13. Do not add medication to blood.
14. Cross match the contents of the bag with recipient before transfusion.
16. Mix thorougly before use and if necessary, store under controlled conditions to achieve the appropriate temperature.

When frozen, plastic is more fragile.

After usage:
Single use only, Throw to medical waster after use. Caution: In case of reuse, there is infection risk.

CAUTION: This medical device contains di(2-ethylhexyl) phthalate (DEHP). Some studies indicate that of patients may be at increased risk due to exposure to DEHP following transfusions, these patients are infants undergoing exchange transfusion, children undergoing certain medical procedures and adults undergoing ECMO (extracorporeal membrane oxygenation). It has been indicated by animal experiments that nonhuman primates are less sensitive than rodents to DEHP exposure following oral administration also. Medical procedures should not be avoided however, as the benefits outweigh any possible health risks associated with DEHP exposure. Please refer to current literature to make an informed decision.