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|  | **Packing Whole Blood by Sedimentation and Centrifugation** BB.COMP.1012.5 | **Dept:**  | 324311 |
| **Dept Name** | Blood Bank |
| **Effective Date:** | <7/2009 |
| **Revised Date:** | Title 21 |
| **Name & Title**: CLIA Laboratory Medical Director | **Contact:** | BB Management |
| **Signature:** | Refer to Title21 | **Date:** | **Title 21** |

**1. General Procedure Statement:**

1. **Purpose:** To pack a unit of whole blood by sedimentation and/or centrifugation producing packed red blood cells.
2. **Responsible Department/Scope:**

 Procedure owner/Implementer: Julie H. Simmons/Christina S. Warren

 Procedure prepared by: Julie H Simmons

 Who performs procedure: Department staff/management

1. **Definitions:**

QC: Quality Control

1. **Sections:**
2. Whole Blood to Packed Red Blood Cells
3. Whole Blood to Packed Red Blood Cells by Centrifugation
4. Whole Blood to Packed Red Blood Cells by IBM/COBE
5. Labeling-Packed Red Blood Cells
6. Percent (%) Hematocrit of Packed Red Blood Cells Quality Control
7. Whole Blood to Packed Cells in SCC
8. **Protocol:**
9. **General Guidelines:**
	1. Group O Whole Blood is set up on a standing order to use with Traumas.
	2. Group O Whole Blood should be used by original expiration date.
	3. Group O Whole Blood will be packed around day 21.
	4. Red blood cells can be obtained by the removal of supernatant plasma from centrifuged whole blood.
	5. Packed RBCs must have a final HCT ≤ 80%, to ensure proper preservative remains.
	6. Quality control must be performed twice a year on whole blood units that are packed by each method.
	7. Plasma removed should be appropriately labeled with the unit number before separation and discarded.
	8. Transfer bag should be used from Blood Bank stock and not BMT stock.

**2.0 Expiration Date:**

**Closed system:** *Retain the same expiration as the original whole blood unit, unless the recipient requires irradiation.* Refer to procedure (COMP): Irradiation of Blood and Blood Products, BB.COMP.1022.

**Open system:** *If a unit is entered for any reason without appropriate use of a sterile connection device, a 24 hour expiration time must be assigned to refrigerated components.*

**HCT>80%:** *The expiration date should be changed to 24 hours if the final HCT is greater than 80%.*

**3.0 Methods:**

Primary method: Packing by Sedimentation

Secondary method: Packing by Thermo Scientific centrifugation

Tertiary method: Packing by IBM/Cobe centrifugation (Open System)

**4.0 Disconnecting:**

 4.1 When separating the plasma from the original unit, the packed cell needs to be labeled with the bottom

 half of the ISBT label and the plasma needs to be labeled with the unit number before physically

 separating the units.

1. Packed cell label: Unit number, ABORh, component, expiration date/time
2. Plasma label: Unit number
	1. At least two seals need to be made for each bag after clamping with a hemostat to increase the sterility of the units.
	2. The plasma will immediately be discarded once physically separated.
	3. If packing with the BMT centrifuge:
3. Then the BMT centrifuge must be cleaned per BMT procedure and the BMT cleaning form completed.

*Refer to BMT: Shared Equipment and Cleaning After Use.*

*Refer to BMT: Form: Equipment Cleaning Checklist for Non-BMT Users*

1. Express the plasma from the whole blood in BMT if the BMT centrifuge was used BUT do NOT cut the tubing until in Blood Bank and have the ISBT label. Clamp with hemostats if necessary.
2. **Leukoreduced and Nonleukoreduced Whole Bloods**

5.1 Whole blood will be used by expiration date.

5.2 Whole blood will be packed close to expiration date to utilize unit.

a. Non leukoreduced packed cells will only be used for Trauma patients.

b. Leukoreduced packed cells may be released into routine inventory.

1. **Non leukoreduced blood must be labeled with**
2. Not Leukoreduced label displayed on the front of the unit bag.

**2. Procedure:**

**I: Whole Blood to Packed Red Blood Cells**

 Chemical Risk Assessment: None

 Biological Risk Assessment: Low

 Protective Equipment: Lab coat, gloves

 **Supplies:** 400ml Transfer set**,** hemostats, scissors

 **Reagents:** NA

 **Equipment:** O’Haus Scout Pro Balance, Plasma Extractor

 **Specimen Requirements**: N/A

| STEPS | INSTRUCTIONS | CHANGE/APPROVAL |
| --- | --- | --- |
| **1.0** | **Remove unit to be separated from refrigerator.**1.1 Being careful not to disturb red cells and plasma. |  |
| **2.0** | **Determine if centrifugation is needed.**2.1 If there is a clear and definite plasma layer, with a plasma layer clear of red cells approximately ⅓ to ½ of the unit bag then - proceed to step 3.0. 2.2 If there is not a clear and definite plasma layer – Refer to Section II: Whole Blood to Packed Red Blood Cells by Centrifugation and continue onto Step 3.0 |  |
| **3.0** | **Attach a 400mL transfer bag to the unit, unless unit has bags already attached.** 3.1 Refer to procedure(COMP): Sterile docking device procedure. |  |
| **4.0** | **Use a hemostat to clamp the line to the 400 mL bag.** |  |
| **5.0** | **Place the 400 mL bag on the scale and tare the weight.**5.1 Refer to procedure (COMP): O’haus Scout Pro Balance procedure. |  |
| **6.0** | **Open the plasma extractor and hang unit on the prongs label side in.****Protective equipment: Face Shield** |  |
| **7.0** | **Break the seal on the line at the top of the whole blood bag or remove the hemostat on the 400mL attached bag.****Protective equipment: Face Shield** |  |
| **8.0** | **Close the extractor.****Protective equipment: Face Shield** |  |
| **9.0** | **Weigh the supernatant plasma to ensure the proper hematocrit.**9.1 For 500ml of whole blood collection, the removal of 200 to 260g of plasma will generally result in a red cell component with a hematocrit ≤80%.9.2 For 450ml of whole blood collection, the removal of 200 to 250g of plasma will generally result in a red cell component with a hematocrit ≤80%.9.3 **STOP when the desired volume has been reached OR when the packed red cells reach the top of the clear window of the plasma expressor (whichever is first)**

|  |  |
| --- | --- |
| Whole Blood Volume | Approximate Amount of Plasma to remove (grams)\*\* |
| 450mL | 200g – 250g |
| 500mL | 200g – 260g |

**NOTE: If whole blood was allowed to sediment (not centrifuged in refrigerated centrifuge), then try to work the buffy coat up and out towards end of extraction.****\*\*Note: These are approximate volumes. Clamp when red cells approach top of bag****Protective barrier: Face Shield** |  |
| **10.0** | **Clamp the line with a hemostat.** See Figure 1.**Protective barrier: Face Shield**http://www.marketlabinc.com/uploads/images_products/6441.jpgHeat seal twice hereHemostat hereHemostat hereFigure 1 |  |
| **11.0** | **Heat seal the tubing twice. Do not cut the bags apart until labeling is complete.****11.1 Make sure that there are 2 seals to each bag.**  |  |
| **12.0** | **Label plasma to be discarded with the unit number.** 12.1 Discard immediately the supernatant plasma in appropriate red biohazard bin. |  |
| **13.0** | **Label the Packed Red Blood Cells –** Refer to Section IV: Labeling-Packed Red Blood Cells |  |
| **14.0** | **Separate the bags by cutting with scissors after the last segment.****14.1 Make sure that there are 2 seals to each bag.**  |  |
| **15.0** | **Perform Percent Hematocrit check for quality control and document on Form *‘% Hematocrit – Packed Red Blood Cells’*.**15.1 Refer to Section V: Percent (%) Hematocrit – Packed Red Blood Cells Quality Control. |  |
| **16.0** | **Irradiate (if indicated).**16.1 Refer to procedure(COMP): Irradiation of Blood and Blood Products |  |
| **17.0** | **Gently mix unit to resuspend red cells in remaining plasma.**  |  |
| **18.0** | **Return the unit to storage (1-6C).****17.1 Place Nonleukoreduced units in BioFridge and make available only to traumas.** *Refer to Routine: BioFridge Operation.*17.2 Place **Leukoreduced** units into routine inventory (may be used for any patient or  stored in BioFridge for traumas).  |  |

**II: Whole Blood to Packed Red Blood Cells by Centrifugation**

 Chemical Risk Assessment: None

 Biological Risk Assessment: Low

 Protective Equipment: Lab coat, gloves

 **Supplies:** 400ml Transfer set**,** hemostats, scissors

 **Reagents:** NA

 **Equipment:** Sterile Docker, ThermoScientific Centrifuge (Located in BMT)

 **Specimen Requirements**: N/A

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0** | **Set centrifuge to the appropriate temperature, 1-6˚C.*** 1. Refer to the procedure (EQUIP): Refrigerated Centrifuge.
	2. Note: It takes 3-4 hours for the centrifuge to reach 4C.
 |  |
| **2.0** |  **For Blood Bank to pack red cells by centrifugation: Select Program 2.**  2.1 Press “Recall”, “2”, “Enter” on the keypad.  2.2 Check the centrifuge settings; they should read 5000RPM, 7 minutes, 4°C.  |  |
| **3.0** | **Remove unit to be separated from refrigerator and/or 1-6˚C Blood Cooler .** |  |
| **4.0** | **Attach a 400 mL transfer bag, unless unit has bags already attached.**4.1 Refer to the procedure(COMP): Sterile docking device.4.2 Do NOT spike main unit bag with transfer bag (if needed) before centrifugation. If sterile dock not available, attach transfer bag after centrifugation by spike. |  |
| **5.0**  | **Open centrifuge lid.**  5.1 Press one of the Open buttons; there is one on the main operation panel and one on the front of the centrifuge.  5.2 Lift the lid when the lid finishes unlocking; this will be indicated on the digital display. |  |
| **6.0** | **Remove centrifuge buckets from rotor and place product bag in centrifuge bucket.** |  |
| **7.0** | **Balance centrifuge buckets that will contain product bags using the two-pan balance.**  7.1 Use transfer bags filled with saline and rubber discs to balance the buckets. |  |

|  |  |  |
| --- | --- | --- |
| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| **8.0** | **Replace centrifuge buckets on the rotor.** 8.1 Always operate the centrifuge with all buckets in place. 8.2 Balanced buckets should be placed opposite each other.  8.3 ALWAYS use rotor adapters when centrifuging 400 or 600mL transfer bags.  |  |
| **9.0** | **Place sealing cover on the rotor.** |  |
| **10.0** | **Close the centrifuge lid.** 10.1 The lid will automatically lock when the lid is closed.  |  |
| **11.0** | **Press Start.** |  |
| **12.0** | **Remove product from centrifuge when finished spinning.**  |  |
| **13.0** | **Place sealing cover on the rotor.** |  |
| **14.0** | **Close lid and leave power to centrifuge “ON”.** | ` |
| **15.0** | **Press recall, program “1”, then “Enter”**15.1 This step returns the centrifuge to room temperature, which is required for BMT use. |  |
| **16.0** | 1. Return to Section I: Whole blood to Packed Red blood cells
 |  |

**III: Whole Blood to Packed Red Blood Cells by IBM/COBE**

 Chemical Risk Assessment: None

 Biological Risk Assessment: Low

 Protective Equipment: Lab coat, gloves

 **Supplies:** 400ml Transfer set**,** hemostats, scissors

 **Reagents:** NA

 **Equipment:** Sterile Docker, Cobe 2991

 **Specimen Requirements**: N/A

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0** | **Record all information on component preparation worksheet** |  |
| **2.0** | **Load the cobe set.** 2.1 Refer to procedure(COMP): Installing IBM/Cobe Processing set. |  |
| **3.0**  | **Load the blood:*****Protective barrier: Face Shield**** 1. Using red striped tubing, spike the blood bag
	2. Press BLOOD-IN to allow blood to run into the processing bag
	3. Press AIR-OUT to remove excess air from the processing bag. Do not press STOP-RESET.
	4. When air is out of line, press BLOOD-IN.
	5. Press STOP-RESET before air enters the processing bag.
 |  |
| **4.0** | **Set control panel and confirm settings:** TIMER STOP VALVE STOP RCO STO1 2 PC 1 2 3 RC**•** ο **•** ο ο ο ο ο οRPM 3000 Super Out Rate 450mL/min**On Cobe 2991:** Select program #7 on the digital panel. |  |

| STEPS | INSTRUCTIONS | CHANGE/APPROVAL |
| --- | --- | --- |
| **5.0** | **Set spin timer #1 for 5 mins. Press START/SPIN.** |  |
| **6.0** | **Press STOP/RESET at the end of 5 mins when the alarm sounds.**  |  |
| **7.0** | **Clamp off the clear tubing near the hexagonal seal with a hemostat.** See Figure 2. Figure 2  |  |
| **8.0** | **Clamp the tube from the original bag near the port.** See Figure 2. | ` |
| **9.0** | **Create at least 2 segments on the tubing with the heat sealer** (3 segments if 80% HCT QC is being done, Refer to Section V: Percent (%) Hematocrit-Packed Red Blood Cells Quality Control) |  |
| **10.0** |  **Seal off the red and purple striped tubing to the original unit and waste bag.** |  |
| **11.0** | **Cut off the tubing to the waste bag.** |  |
| **12.0** | **Lift the seal weight, open the doors, remove the centrifuge cover, and remove the alignment blocks.** |  |
| **13.0** | **Remove the processing bag and original unit. Do not cut the bags apart until labeling is complete.** |  |
| **14.0** | **Perform Percent Hematocrit check for quality control and document on Form *‘ % Hematocrit – Packed Red Blood Cells’*.**14.1 Refer to Section V: Percent (%) Hematocrit – Packed Red Blood Cells Quality Control. |  |
| **15.0** | **For labeling, go to procedure IV: Labeling - Packed Whole Blood (IBM/COBE Centrifugation, Open System)** |  |
| **16.0** | **Perform component prep function in SCC.** |  |
| **17.0** | **Label verify the unit in SCC.**  |  |
| **18.0** | **Separate the bags by cutting with scissors after the last segment.** |  |
| **19.0** | **Remove one segment and label it with the unit number for the ABO recheck.** |  |
| **20.0** | **If 80% HCT QC is being done, remove an additional segment and label it with the unit number.**  Proceed to Section V: Percent (%) HCT – Packed Red Blood Cell Quality Control. |  |
| **21.0** | **Disassemble and remove processing set.**  |  |
| **22.0** | **Discard waste bag.** |  |
| **23.0** | **Irradiate (if indicated).** |  |
| **24.0** | **Return the unit to storage (1-6C).** **24.1 Place Nonleukoreduced units in BioFridge and make available only to traumas.** *Refer to Routine: BioFridge Operation.*24.2 Place **Leukoreduced** units into routine inventory (may be used for any patient or  stored in BioFridge for traumas).  |  |

**IV: Labeling-Packed Red Blood Cells**

 Chemical Risk Assessment: None

 Biological Risk Assessment: None

 Protective Equipment: Lab coat, gloves

 **Supplies:** Base Label, ISBT Label

 **Reagents:** NA

 **Equipment:** NA

 **Specimen Requirements**: N/A

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0** | **Label the Packed Red Blood Cell unit referring to the original whole blood unit.** **1.1**

|  |  |  |
| --- | --- | --- |
|  | **METHODS:** |  |
| **UNIT TYPE** | **COBE** | **SEDIMENTATION &****CENTRIFUGATION** |
| ISBT | 1. **When component prep is completed, a full face label should print on the Hematrax.**
2. **Affix the bottom half of the label over the bottom of the original label.**
 | 1. **When component prep is completed, a full face label should print on the Hematrax.**
2. **Affix the bottom half of the label over the bottom of the original label.**
 |

 |  |
| **2.0** | **Record new expiration date/time and tech initials on label for Codabar labels.** **Reminder:** Open system:*If a unit is entered for any reason without appropriate use of a sterile connection device, a 24 hour expiration time must be assigned to refrigerated components.*Closed system:*Retain the same expiration as the original whole blood unit, unless the recipient requires irradiation.* |  |
| **3.0** | **Proceed to SCC to perform blood component prep.** 3.1 Go to Section VI: Whole Blood to Packed Cell in SCC |  |
| **4.0** | **Label verify the unit in SCC.**  |  |
| **5.0** | **Irradiate (if indicated) and allocate the unit (if applicable).** |  |

**V: Percent (%) Hematocrit – Packed Red Blood Cells Quality Control**

 Chemical Risk Assessment: None

 Biological Risk Assessment: Low

 Protective Equipment: Lab coat, gloves

 **Supplies:** Tube strippers

 **Reagents:** NA

 **Equipment:** Heat sealer

 **Specimen Requirements**: N/A

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0** | **Pack a unit of whole blood if not already done.**1.1 Refer to Sections I, II, III, IV. |  |
| **2.0** | **Using tube strippers, obtain a well-mixed segment from the Packed red blood cells and label with the unit number.** |  |
| **3.0**  | **Take this segment to the BMT Lab to obtain a hematocrit.**3.1 Attach the print of results to BB.Forms.1196: % Hematocrit – Packed Red Blood Cells.  |  |
| **4.0** | **Fill out BB.Forms.1196: % Hematocrit – Packed Red Blood Cells, using the BMT printout.**4.1 Date performed4.2 Initials of tech.4.3 List the method used. (Sedimentation or Centrifugation).4.4 List unit number packed.4.5 Fill in the % Hematocrit obtained.4.6 Make interpretation

|  |  |
| --- | --- |
| **% Hematocrit** | **Interpretation** |
| 80% or less | Satisfactory |
| 81% or greater | Unsatisfactory. |

 |  |
| **5.0** | **Give BMT lab results to management for review, along with completed 1196 Form.** |  |
| **6.0** | **Place results in Semi-Annual QC Section of Quality Control notebook.** |  |
| **7.0** | **Document on Semi-Annual checklist for this task with initials and date performed.**  |  |

**VI: Whole Blood to Packed Cells in SCC**

 Chemical Risk Assessment: None

 Biological Risk Assessment: None

 Protective Equipment: Lab coat, gloves

 **Supplies:** NA

 **Reagents:** NA

 **Equipment:** Computer

 **Specimen Requirements**: N/A

**3. Review/Revised/Implemented:**

All protocols must be reviewed as stated in the Document Control Protocol.

 All new protocols that have major revisions must be signed by the CLIA Director.

 All reviewed protocols with minor revisions can be signed by the designated section medical director or designee.

**4. Related Procedures:** NA

**5. References:**

 AABB Technical Manual, revised periodically.

Thermo Fisher Scientifc RC3BP+ Instruction Manual, release history 50113587-5, November, 2010.

**6. Attachments: NA**

**7. Revised/Reviewed Dates and Signatures:**

 Refer to archive history/title21