# Applicable Laboratory(s)):

North Carolina Baptist Hospital (NCBH)

Lexington Medical Center (LMC)

Davie Medical Center (DMC)

Wilkes Medical Center (WMC)

High Point Medical Center (HPMC)

Westchester

Clemmons

# Procedure Statement

The purpose of this procedure is to outline the policies and procedures for thawing and allocating Cryoprecipitate products.

# Scope

i. Procedure Owner/Implementer: Blood Bank Management

ii. Procedure Prepared by: Christina Warren

iii. Who Performs Procedure: Blood Bank Staff/management

# Definitions

1. Procedure: A process or method for accomplishing a specific task or objective.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
3. **AHF-** Antihemophilic Factor
4. **FFP-** Fresh Frozen Plasma
5. **Cryo AHF-** Cryoprecipitate Antihemophilic Factor. Cryoprecipitated AHF is prepared by thawing whole-blood-derived FFP, apheresis FFP, or WB derived plasma frozen within 24 hours after phlebotomy (PF24) between 1-6°C and recovering the precipitate. The cold insoluble precipitate is placed in the freezer at -18°C or colder within 1 hour after removal from the refrigerated centrifuge. Cryo AHF contains fibrinogen, Factor VIII, Factor XIII, and vWF. Each unit of Cryo AHF should contain ≥ 80 IU of Factor VIII and ≥ 150 mg of fibrinogen in approximately 5-20 ml of plasma.
6. **Pooled Cryo-** Several units of Cryo AHF have been pooled (typically 5 called “5 pack”). The volume and number of units in the pool is indicated on the label. To determine the minimum potency of this component, assume 80 IU Factor VIII and 150 mg of fibrinogen for each unit of Cryo AHF in the pool.
7. **PRCFC**—Pathogen Reduced Cryoprecipitated Fibrinogen Complex is prepared from plasma that has been processed with an FDA-approved pathogen reduction device. The PRCFC process includes thawing pathogen-reduced plasma between 1-6°C and recovering the precipitate. The cold-insoluble precipitate is placed in the freezer at -18°C or colder. PRCFC serves as an enriched source of fibrinogen, Factor XIII, and vWF. The 5 day post thaw shelf life of PRCFC is based on the retention of critical functional activities that have shown a high level of correlation with therapeutic efficacy and the reduced pathogen risk associated with pathogen inactivation. PRCFC is not intended to be used for replacement of Factor VIII. A unit of PRCFC prepared from 2 WB derived plasma units will contain about 740±166 mg of fibrinogen immediately post thaw and 686±165 mg fibrinogen after 120 hours.
8. **IFC**—Intercept Fibrinogen Concentrate see PRCFC

# Sections

1. Thawing Cryo
2. Pooling Cryo

# Policy Guidelines

1. Cryo AHF and PRCFC must be stored in a freezer at -18°C up to the expiration date until thawed for use.
2. Compatibility with recipient’s ABO group is not required; but, should be considered when the infused volume will be large relative to the recipient’s red cell mass.

*Refer to: BB-POL-0052: Selection of Blood and Blood Components*

1. Neonates should receive group AB or group specific cryo if available.
2. Single units of cryo AHF, pooled cryo AHF and pooled Pathogen Reduced Cryo are currently ordered via the American Red Cross and may be available from other suppliers as needed.
3. Pooled cryo that comes from the American Red Cross should not be pooled with other cryo (pooled products should not be double-pooled).
4. Single thawed cryo AHF (1) and pooled thawed cryo AHF (5) obtained from blood centers must be transfused within 6 hours after thawing (if pooled in a closed system).
5. Each unit of PRCFC is prepared from 2 pathogen reduced plasma products. We will be stocking FC15 from ARC.
   1. **FC10** is a single PRCFC product offered by OneBlood (comes from 2 donors). FC10 will not be kept in stock under normal circumstances. Contact management before ordering.
   2. **FC15** is a two-pool product being offered by the American Red Cross and is a pool of 2 PRCFC products (comes from 4 donors). Each FC15 is equivalent to a pooled 5 pack of Cryo AHF (low yield) even though it is technically a 4 pack.
   3. **FC20** is a pool of 3 PRCFC (comes from 6 donors). Each FC20 is equivalent to a pooled 5 pack of Cryo AHF (high yield) even though it is technically a 6 pack. This product is not readily available. Contact management before ordering.
   4. **FC30** and **FC40** are other PRCFC products in larger pools. These products will not be stocked.

Refer to Attachment 3: Pathogen Reduced Cryoprecipitated Fibrinogen Complex (IFC)

1. Thawed Pathogen Reduced Cryo must be transfused within 5 days after thawing.
2. Products prepared in an open system must be transfused within 4 hours of thawing.
3. All thawed Cryo (AHF and PRCFC) must be stored at Room Temperature between 20-24ºC and without agitation.
4. Cryo (AHF and PRCFC) is used to control bleeding associated with fibrinogen deficiency or Factor XIII deficiency. Cryo is also used as a source of surgical fibrin sealant when requested.
5. Single cryo AHF units that are pooled at Wake Forest Baptist Medical Center:
   1. do NOT pool different ABO types
   2. when pooling different Rh types, use the default “Rh mixed” for the printed label
6. One unit of PRCFC should be thawed at all times.
   1. Upon receipt of an order for cryo (5-unit order), select and issue the readily available PRCFC.
   2. Thaw another unit of PRCFC after the initial unit has been transfused.
   3. If the order was for more than 1 (5) units, fill the remainder of the order by thawing Cryo AHF.
   4. For single unit orders for neonates, etc. thaw single units of cryo AHF.
   5. PRCFC should NOT be wasted.

# Procedure

1. Thawing Cryo (Cryo AHF and PRCFC)

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Place the frozen cryo in the plastic overwrap.**     * 1. Two single units may be placed in one overwrap bag when using the Helmer   water bath. |
| **2.0** | **Thaw Cryo in a 30-37°C water bath with agitation or in the Barkey Thawer.**    *(Refer to: Helmer Plasma Thawing System-Operating Instructions Barkey*  *Plasmatherm Protocol)*     |  |  | | --- | --- | | Helmer Water Bath times | Barkey Thawer times | | Thawing time for a single unit of cryo is approximately 8-10 minutes. | The maximum thawing time for a single unit of cryo is 15 minutes. | | The minimum thawing time for frozen pooled cryo is 20 minutes and maximum of 45 minutes. | The minimum thawing time for frozen pooled cryo is 20 minutes and maximum of 45 minutes. | |
| **3.0** | **Inspect the unit for leakage and appearance.**    3.1 Acceptable criteria  a. In date  b. No holes or breakage  c. No leaking  3.2 Unacceptable criteria:  a. Fibrin will not disperse with gentle kneading.  b. Leaking or Hole or breakage – Discard contents of bag in component prep  sink.  Document on the unacceptable unit disposition log and complete  disposition. |
| **4.0** | **Take a temperature reading of the pooled cryo once it is done thawing.**  4.1 The temperature of the unit should be ≥ 30°C.     1. If the unit of pooled cryo is not ≥ 30°C then return the unit to the water bath for additional time (no more than 45 minutes). |
| **5.0** | **Click on SCC icon on the computer screen.** |
| **6.0** | **Click on Inventory>Edit>cr\_Product>Change.** |
| **7.0** | **Scan or type the cryo E code into the ‘orig’ box.** |
| **8.0** | **Select the product E code that is being made from the drop down.** |
| **9.0** | **F12 to accept.** |
| **10.0** | **Scan the unit number and product code into the computer.** |
| **11.0** | **Complete Label Check**   * Change creation time to the time the unit was placed into water bath * Click F12 to save and select printer. * A label will print from the ISBT label printer. * Place the new product code that printed in Step ‘c’ over the old product code and the new expiration date over the old expiration date on the product bag. * Click on Label verify in SCC. * Perform the label verify (check) on the unit.   + Verify the ABO/RH type, the expiration date, and time.   + During downtime, refer to CP: Label Verify (Check)   1. When single thawed cryo AHF to be issued and not pooled. * make sure the expiration time reads 6 hours from that time.   11.2 When single thawed cryo units to be pooled:  a. Go to Section II: Pooling Cryoprecipitate |

1. Pooling Cryo AHF

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Obtain a satellite transfer bag to pool cryo AHF. (Usually the 400 ml transfer bags are used.)**   1. **Do not use if the tip protectors are not in place.**   \*\*\*Note: When pooling cryo must use the same ABO group. If Rh is a mixture  then must label the pooled cryo as “Rh mixed”. |
| **2.0** | **Open the port on the first unit of Cryo AHF.** |
| **3.0** | **Remove the tip protector from the line attached to the transfer bag.** |
| **4.0** | **Insert the tip into the outlet port of the first Cryo AHF unit with a twisting motion until firmly sealed.** |
| **5.0** | **Initiate fluid transfer from one unit into another unit by holding/hanging unit of cryo above the transfer bag.**     1. Mix well before rolling the unit down to empty the contents. |
| **6.0** | **Clamp the line. Remove the tip and insert aseptically into the next unit of Cryo AHF.**   1. When pooling cryo must use the same ABO group. |
| **7.0** | **Repeat steps 5 -8 until all of the units have been pooled (max of 5 units).** |
| **8.0** | **Heat seal the tubing three times.**  11.1 Make certain that there are 2 seals to the product bag.    Empty Bag  Pooled Bag |
| **9.0** | **Click on SCC>Inventory>Edit>cr\_Product>Pool.** |
| **10.0** | **Click on F5 to enter by units on navigation pane.**  13.1 Start scanning unit numbers and product code.  a. The selected unit box will disappear but keep scanning. |
| **11.0** | **Scan all the unit numbers and product codes into the computer.**  14.1 Click F12 to accept. |
| **12.0** | **Change the TRCY E code to TPCR E code.**  15.1 Change the created/coll date/time if needed.  a. Click F12 to accept.  b. Select “NO” to Add supply for each unit.  c. Select “YES” to save changes.  15.2 If you forgot to change the NewProduct code to TPCR code:  a. *Go to Attachment 1: How to correct a pool in SCC when you forget to*  *change the final product code.* |
| **13.0** | **Select printer.**   1. The computer will issue a new unit number for the pooled unit. 2. A new ISBT label should print. |
| **14.0** | **Place the new label on the unit of pooled Cryo.** |
| **15.0** | **Perform the label verify (check) on the unit.**  Refer to CP: Label Verify (Check) |
| **16.0** | **Cut the seal closest to the empty bag.**  19.1 Discard the empty bag from the pooled cryo.  19.2 Make certain that there are 2 seals to the product bag.  (Cut here)  Empty Bag  Pooled Bag |
| **17.0** | **Select the product to the patient and order the pool instruction.**  *Refer to: How to Order Instruction in SCC.*  *Refer to: SCC CP Quick Reference Guide* |
| **18.0** | **Notify nurse when product is ready for pickup.** |
| **19.0** | **Document date, time, and name of nurse notified on the requisition.** |

# References

# Related procedures/policies

CP: Barkey Plasmatherm Protocol: BB.COMP.1039

CP: Helmer Plasma Thawing System-Operating Instructions: BB.COMP.1035

CP: Label Check Policy BB. COMP.900

Training: Cryoprecipitate Training

# Attachments/Linked documents (title 21)

Attachment 1: How to correct a pool in SCC when you forget to change the final product code.

Attachment 2: How to Order Instructions in SCC

Attachment 3: Pathogen Reduced Cryoprecipitated Fibrinogen Complex (IFC)

# Revision Dates: Review Change Summary as represented in Title 21.

**Attachment 1: How to correct a pool in SCC when you forget to change the final product code**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Go to SCC inventory:Edit:cr\_Prod:Change.** |
| **2.0** | **Scan the product code from the Original bag and then select the new product, the pooled code.** |
| **3.0** | **Scan the new pooled unit number and the Original bag product barcode.** |
| **4.0** | **F12** |
| **5.0** | **F12 again** |
| **6.0** | **Answer ‘NO’ to the supply question.** |
| **7.0** | **Answer ‘YES’ to save changes.** |
| **8.0** | **Hit F2 to open printer options box.** |
| **9.0** | **Select ISBT printer.** |
| **10.0** | **F12 to accept.** |
| **11.0** | **Double click on the unit in the Label Verify box.** |
| **12.0** | **Scan unit in Z pattern: Unit number, ABORH, Product code, Expiration date.** |
| **13.0** | **Save Changes.** |
| **14.0** | **Unit is ready to be selected.** |