THAWING OF FROZEN PLASMA PRODUCTS

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PURPOSE

To provide background and instructions for the thawing of various frozen plasma (FFP) products having a 5-day expiration date from the date of thaw. SAH, SCH, SEH and SFH receive delivery of FFP directly from the supplier and thaw, modify and issue product at their location.

BACKGROUND

FFP is a generic term commonly used in Transfusion Services for several different types of frozen plasma components. The differences between them are the method of collection, how long after collection they are frozen, and whether or not a single apheresis collection has been divided into different containers. The different types of frozen plasma components each have a different product code. These components include:

- Fresh Frozen Plasma (FFP) (frozen within 8 hours of collection)
- Plasma Frozen within 24 hours of collection (FP24)
- Apheresis FFP - single
- Apheresis FFP – divided (1st container, 2nd container, 3rd container, 4th container)
- Apheresis FP24 - single and divided

Note: Apheresis plasma is commonly collected from AB donors in large volumes and divided to maximize the availability of this universal plasma type.

Plasma is used to treat bleeding associated with clotting factor deficiencies in situations where factor concentrates are not available or are not indicated. It is also used to replenish clotting factors during a massive hemorrhage. It is never to be used for the purpose of volume expansion.

Extensive studies on the stability of coagulation factors are found in the literature and demonstrate that the difference in the activity of various clotting factors found in thawed plasma products at 1-day and at 5-days post-thaw are relatively minor, with the exception of heat labile Factor V and Factor VIII. These two factors' activity levels do decline more rapidly, but are still found to be within the surgical hemostatic range for treatment at five days post-thaw.

RELATED DOCUMENTS

M-W-TS-0338	Batch Thaw of FFP -- For Inventory
M-W-TS-0337	Autothaw FFP and Cryoprecipitate – Assigned to Patient
M-W-TS-0336	Component Label Verification
R-W-TS-0350	Quarantine Status – Assignment to Blood Components

SPECIMEN

A valid patient ABORH type from the current admission must be on file before giving type-specific plasma. In emergent cases, type AB plasma may be given since it is compatible with all blood types. The SJMC transfusion service will perform patient ABORH testing. Always notify SJMC TS when a STAT specimen is being sent. Specimen type and degree of testing is dependent upon prior history as shown below:

PATIENT HISTORY	PRIORITY LEVEL	ACTION or TESTING REQUIRED	PRODUCT CHOICE
ABO/RH results	All	New Specimen for ABORH required per each current admission	See below
No ABO/RH results	**Emergency**	Request specimen for Type and Screen or ABORH testing and send to SJMC Transfusion Service.	Give AB FFP. Switch to type-specific FFP once typing is complete.
No ABO/RH results	Routine	Request specimen for Type and Screen or ABORH testing and send to SJMC Transfusion Service.	Give ABO-compatible once typing is complete
Neonates	All	Request pre-transfusion specimen for ABORH testing for patient history, but do not wait to transfuse in emergency.	Give only AB FFP

FFP COMPONENT BLOOD TYPE SELECTION

Type-specific or type-compatible plasma is to be given to the patient as outlined in the chart below:

Patient type	FFP ABO type (Rh is not important)			
	1st Choice	2nd Choice	3rd Choice	4th Choice
O	**O**	**A**	**B**	**AB**
A	**A**	**AB**		
B	**B**	**AB**		
AB	**AB**			
Unknown	**AB**			

EQUIPMENT / SUPPLIES

- Plasma Thawing System
- Thawing Overwrap Bags

Steps

1. When an order for FFP has been placed in EPIC, a notification label will print to the designated printer in the Lab (Prepare Plasma). This label is reviewed by a Tech who will check in EPIC to verify the number of products needed, and whether an ABORH or TNS orders/specimens are needed.

2. Call the Floor and determine when the product is needed and whether or not this is an emergency situation for the patient.

    a. Emergency situations require the thawing of AB plasma if no blood type is on file from the current admission.
    b. Non-emergent situations allow time for the patient to be typed for ABORH and whether there are any previously thawed units – either in house, or at SJMC are available in inventory to use for the patient

3. Following the guidance in the table above, select and remove appropriate FFP units from Plasma Freezer.

6. Inspect each unit for:
   - Discoloration (a clear greenish color is due to birth control pills and is acceptable)
   - Evidence of partial thawing
   - Breaks, or cracks in the tubing, administration ports, or outside seam

7. Quarantine any questionable or cracked units for return to supplier.
   - Fill out a Quality Form
   - Send Component Complaint Form to BWNW
   - Quarantine/Discard the unit in Safetrace TX

8. At SJMC only: Allow unit(s) to sit at room temperature for five minutes. This helps prevent breakage when the unit is put into the thawer from the ultra-low temperature freezer.

9.. Gently place the unit(s) in a thawing overwrap bag (to protect the entry ports from exposure to possible contamination).

10. Press the appropriate Lift Out Button to raise and open the basket assembly.

11. Place FFP/overwrapped bag in basket, hooking top overwrap slots around top basket tab.

    NOTE for SJMC only: The DH8 plasma thawer basket assembly gates overlap on each side, so the thickest bags must be placed in the front baskets or the assembly gate will not close completely. The dividers between each compartment are removable to allow for larger sized bags.

12. Press the Time Set Button to advance through the pre-programmed times until the desired cycle time is selected. A 300 ml FFP bag takes about 20 minutes to thaw.

13. Lower the basket assembly by pressing the Lift-Out Button. The basket will close and agitation will automatically begin. Remaining cycle time (in minutes) will display on the corresponding indicator.

14. Thaw the component completely at 30-37°C so that no ice is present. Total time in the thawer should not exceed 30 minutes.

    Note: In an emergent situation, the cycle may be paused by raising the basket. The FFP in its overwrap bag may be removed to inspect for ice. The bag may be gently kneaded to break up ice chunks and speed the thawing. Lowering the basket will restart the cycle and agitation process.

15. When the timed cycle is complete, the basket will stop agitation, lift out, and open. "End of process" alert sounds and cycle time indicator resets itself.

16. Remove plasma from the thawer and overwrap. Inspect the unit for any leakage. If it has leaked into the overwrap bag:
    - Discard in biohazard trash
    - Write a Quality Form
    - Send Component Complaint Form to BWNW
    - Quarantine/Discard the unit in Safetrace TX

17. Proceed with Batch Thaw or Autothaw procedures in Safetrace TX to electronically modify, label-verify, assign and/or issue the thawed product(s). In Emergency Situations use, Emergency Release – Known.

NOTE: Be sure to affix a "Filter All Products" Label to all thawed products and add a "Neg for ZIKA VIRUS by Investigational NAT" label when applicable.

18. If Product is not being issued right away, store the thawed plasma unit(s) at 1-6°C in the designated, monitored refrigerator.

MANUAL LABELING OF THAWED UNIT (in case of Label-Print failure or Safetrace TX Downtime)

1. Place label "Filter All Products" on front of unit above the face label.

2. Transfer volume recorded on the FFP product label to the selected thawed product label

3. Affix the appropriate Thawed Plasma, Thawed Apheresis Plasma, or Thawed Apheresis Plasma (1st, 2nd3rd or 4th container) Product Label to the lower left quadrant of the base label, covering the old frozen component product label. (See table below)

    - ***Note***: It is extremely important that the container number on the new label (1st, 2nd, 3rd, or 4th) match the container number on the original label for the Apheresis Plasma (1st, 2nd, 3rd, 4th container) units. The container number is part of the product code and can also be found below the storage temperature on the label.

4. Correct the expiration date in the lower right quadrant of the unit label to a 5-day (120 hour) outdate

    - Draw a line through the original expiration date on the label, and record Tech ID
    - Record the new expiration date/time – 5 days from today's date @ 2359

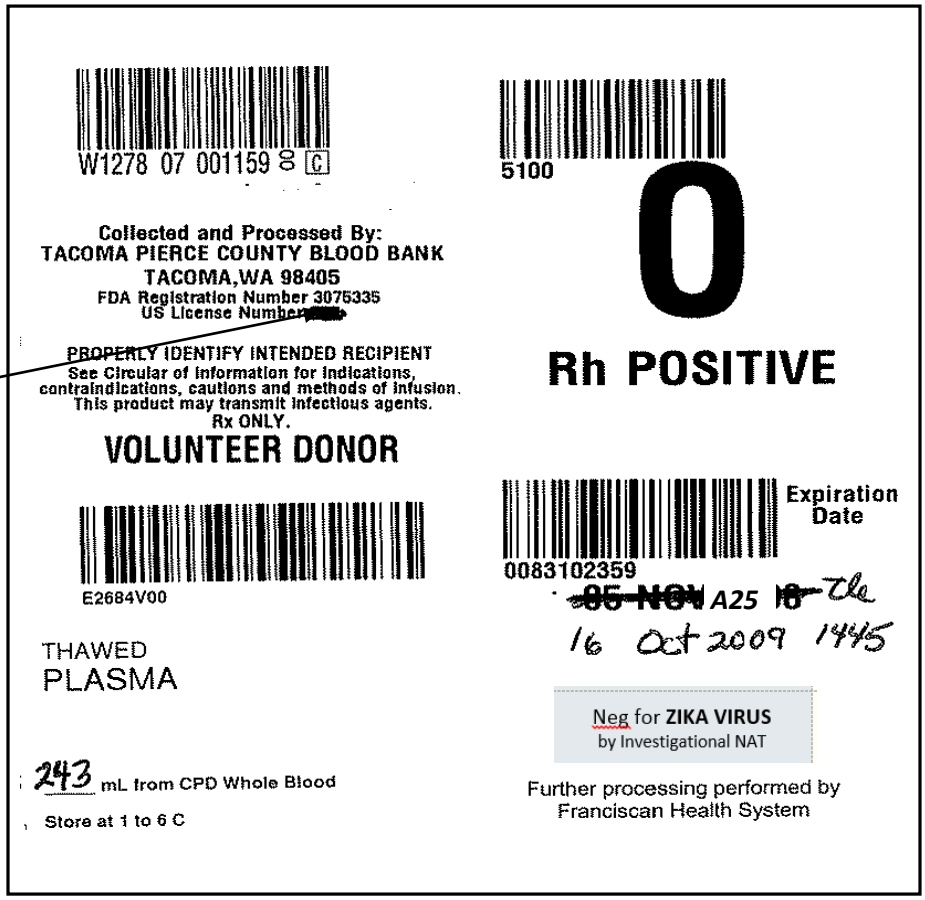
5. Affix label "Further Processing by Franciscan Health System, Tacoma, WA 98405" to the lower right quadrant of the base label so as not to obscure any other information present.

6. Deface the license number of the collecting facility (upper left) so that it is not visible.

7. Add the "Neg for ZIKA VIRUS by Investigational NAT" label if Zika testing was performed

8. See example of completed manual label below:

FILTER ALL PRODUCTS



Effaced License Number

Use the table below to guide the selection of the correct product code label.

Original –BWNW Frozen Product Code	Product Description	Modified - Thawed Product code
E0713V00	Thawed Plasma (CP2D)	E2720V00
E0869V00	Thawed Apheresis Plasma (ACDA)	E2121V00
E0869VA0	Thawed Apheresis Plasma (ACDA) Part A0	E2121VA0
E0869VB0	Thawed Apheresis Plasma (ACDA) Part B0	E2121VB0
E0869VC0	Thawed Apheresis Plasma (ACDA) Part C0	E2121VC0
E0869VD0	Thawed Apheresis Plasma (ACDA) Part D0	E2121VD0
E1624V00	Thawed Plasma Frozen Within 24 Hours (ACDA)	E2284V00
E1624VA0	Thawed Plasma Frozen Within 24 Hours (ACDA) Part A0	E2284VA0
E1624VB0	Thawed Plasma Frozen Within 24 Hours (ACDA) Part B0	E2284VB0
E1624VC0	Thawed Plasma Frozen Within 24 Hours (ACDA) Part C0	E2284VC0
E1624VD0	Thawed Plasma Frozen Within 24 Hours (ACDA) Part D0	E2284VD0
E2619V00	Thawed Plasma Frozen Within 24 Hours (CP2D)	E2737V00
E3587V00	Thawed Pooled Cryoprecipitated AHF	E3591V00
E2617V00	Thawed Plasma CRYO REDUCED (CP2D)	E2736V00

ISBT Codes - Safetrace TX ver 3.11
Apr 19, 2017

Use the table above to guide the selection of the correct product code label.

REFERENCES

AABB Standards for Blood Banks and Transfusion Services, current edition

AABB Technical Manual, current edition

Yazer, M., Cortese-Hassett, A., Triulzi, D. "Coagulation factor levels in plasma frozen within 24 hours of phlebotomy over 5 days of storage at 1 to 6C", Transfusion, Vol 48, December 2008, pg. 2525-2530.

Scott, E., Puca, J., Gottschall, J., Friedman, K "Evaluation and comparison of coagulation factor activity in fresh-frozen plasma and 24-hour plasma at thaw and after 120 hours of 1 to 6C storage, Transfusion, Vol 49, August 2009, pg. 1584-1591.