

PROCEDURE

Corewell Health East - Equipment - Helmer Plasma Thawing System - Blood Bank

This Procedure is Applicable to the following Corewell Health sites:

Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to:	N/A
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Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Blood Bank

1. Principle

A. The purposes of this procedure are:

1. To describe the quality control (QC) and preventative maintenance for the Helmer Plasma Thawing System
2. To provide procedures to perform the QC and preventative maintenance
3. To provide policies relating to the required QC, including the steps that should be taken in the event that QC fails.
4. To provide the Blood Bank staff with instructions for the use of the Helmer Plasma Thawing System

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Contents

- A. [Supplies/Equipment Needed](#)
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Entities will reference associated Documentation contained within this document as applicable
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4. Definitions

- A. Corewell Health Biomedical: Performs repairs and some maintenance of equipment for Corewell.
- B. Daily: On a given calendar date.
- C. Weekly: Within 7 days \pm 2 days.
- D. Quarterly: Every 3 months \pm 2 weeks; typically, in the calendar months January, April, July and October.
- E. FFP: Plasma prepared from a whole blood or apheresis collection and placed at less than -18°C within the time frame required for the anticoagulant or collection process. When frozen, the unit expires within 12 months.
- F. PF24: Plasma prepared from a whole blood or apheresis collection and placed at less than -18°C within 24 hours of collection. Clinically, it is the equivalent of FFP; however, there is a decrease in the labile clotting factors (Factors V and VIII). It has the same expiration dates as FFP.
- G. PF24RT24: Plasma prepared from a whole blood or apheresis collection that is held for up to 24 hours after collection at room temperature and then stored at less than -18°C . Clinically, it is the equivalent of FFP; however, there is a decrease in the labile clotting factors (Factors V and VIII). It has the same expiration dates as FFP.
- H. Thawed Plasma: Plasma (FFP, PF24 or PF24RT24) product that is thawed, relabeled as thawed plasma and stored at 1°C - 6°C for up to 5 days from the original thaw date (day zero being the day it is thawed). All frozen plasma products at Corewell Health are modified and relabeled as thawed plasma prior to issue.
- I. THAW24: Plasma product that is thawed, relabeled as thawed plasma and will expire in 24 hours. To be used when product will be split into aliquots. Refer to [Corewell Health East - Aliquot Preparation - Blood Bank - All Beaumont Hospitals](#) for additional information.

5. Supplies/Equipment Needed

- A. NIST (National Institute of Standards and Technology) Certified Thermometer
- B. Helmer CleanBath (plasma bath additive)
- C. Disinfectant (suitable for stainless steel)
- D. Lightweight oil (e.g. 3-IN-ONE Multi-Purpose Oil)
- E. Distilled or tap water
- F. Plastic tubing
- G. PPE - Gloves must be worn when handling products during or after thawing until it is established that no breakage has occurred.
- H. Plastic overwrap bags - each component that is placed in the plasma/water bath must be first placed in a plastic overwrap (or sealed biohazard bag for frozen RBCs) to protect the component from potential contamination and to isolate a broken component.

6. Quality Control and Preventative Maintenance

- A. The Helmer Plasma Thawing System Operation-Service-Maintenance Manual recommends the following to keep the Helmer Plasma Thawing System in optimum performance condition.
 - 1. Cleaning of the chamber bath and basket assemblies shall be performed weekly.
 - 2. A high alarm test and temperature controller calibration test should be conducted on a quarterly basis.
 - 3. On a quarterly basis, the moving parts shall be lubricated.
 - 4. Bearings on each basket shall be checked for wear and replaced as necessary.
 - 5. The fan on the 100V version of the DH8 Plasma Bath shall be cleaned on a quarterly basis.
- B. Daily Quality Control
 - 1. The Daily Quality Control consists of a temperature check and visual inspection.
 - 2. Documentation of Daily Quality Control:

- a. Dearborn: Day Shift Daily Checklist, refer to [Corewell Health East - Blood Bank Quality Activities - Dearborn](#)
 - b. Farmington Hills: *Daily Temp Equipment QC Record*, refer to [Corewell Health East - Blood Bank Quality Activities - Farmington Hills](#)
 - c. Grosse Pointe: *Daily Inspection Log*, refer to [Corewell Health East - Blood Bank Start-Up and Routine Maintenance - Grosse Pointe](#)
 - d. Royal Oak: 33902-1 *Daily Temp and QC record*, refer to [Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak](#)
 - e. Taylor: Attachment 33906-2 *Helmer Plasma Thawing System Daily and Weekly PM Log*
 - f. Trenton: 33951 *Daily Temp Chart record*, refer to [Corewell Health East - Blood Bank Quality Activities - Trenton](#) and attachment 33906-2 *Helmer Plasma Thawing System Daily and Weekly PM Log*
 - g. Troy: 33961-1 *Daily Temperature and Quality Control Record*, refer to [Corewell Health East - Blood Bank Quality Performance Activities - Troy](#)
 - h. Wayne: 34004-02 *Temperature Log*, refer to [Corewell Health East - Shift Responsibilities in the Blood Bank - Wayne](#)
3. Temperature check
 - a. Observe the temperature of the plasma/water bath as it appears on the digital display. The temperature is recorded on the site-specific daily log listed above or continuous monitoring system.
 - b. If the temperature is:
 - 1) $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (acceptable)
 - a) Proceed to step 4.
 - 2) Greater than 37.0°C or less than 35.0°C
 - a) Refer to [Failing Daily Quality Control](#) section below.
 4. Visual Inspection of water bath
 - a. Observe the water level of the Helmer plasma bath by observing the slotted lines (= = =) on the inside back wall of the bath. A satisfactory water level should not exceed the upper slotted line when the baskets are in the lowered position but still cover the baskets completely.
 - b. If the water level exceeds the limit drain excess water.
 - c. If the water level does not cover the baskets completely when in lowered position add distilled or tap water.
 - d. Document whether the appearance and level are satisfactory or unsatisfactory (S or U) on applicable log in the appearance column.
 - e. Observe the water for contamination, cloudiness, and odor. If the appearance is unsatisfactory proceed to [Failing Daily QC](#) section below.
 5. Failing Daily Quality Control
 - a. If the temperature is higher than acceptable, then:
 - 1) The water bath must not be used until the temperature is appropriately calibrated and is within the acceptable range as described in the Procedure section of this document.
 - 2) The Equipment Out of Service form shall be completed and attached to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).
 - 3) Proceed to the [Calibration of the Temperature Controller](#) before proceeding to step 4.
 - 4) Record the post calibration temperature later in the day on the Daily Temperature and QC Record after verifying that the temperature is acceptable. Remove the Equipment Out of Service form.
 - b. If the temperature is too low, then:
 - 1) It is acceptable to continue to use the water bath if the reason that the temperature is low relates to the instrument's recent use / consecutive cycles.

- 2) However, if the instrument has not been used recently, the temperature must be calibrated as described in the [Calibration of the Temperature Controller](#) procedure below.
- 3) The temperature must be rechecked later in the day and documented on the Daily Temperature and QC Record to verify that the temperature is acceptable.
- c. If the water is cloudy or has an odor, then the following apply:
 - 1) The Equipment Out of Service form shall be completed and attached to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#)
 - 2) If possible, the plasma bath should not be used until it is cleaned.
 - 3) If the plasma bath must be used ensure that the blood components are protected with a plastic overwrap and submit a variance.
 - 4) The plasma bath should be cleaned as soon as possible as described in the [Basket and Chamber Cleaning](#) procedure below.
- C. Weekly Preventative Maintenance
 1. Documentation of Weekly preventative maintenance:
 - a. Dearborn: *Day Shift Daily Checklist*, refer to [Corewell Health East - Blood Bank Quality Activities - Dearborn](#)
 - b. Farmington Hills: Attachment 33906-3 *Helmer Plasma Thawing System Weekly Cleaning Log*
 - c. Grosse Pointe: Attachment 33906-3 *Helmer Plasma Thawing System Weekly Cleaning Log*
 - d. Royal Oak: 33902-1 *Daily Temp and QC record*, refer to [Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak](#)
 - e. Taylor: Attachment 33906-2 *Helmer Plasma Thawing System Daily and Weekly PM Log*
 - f. Trenton: Attachment 33906-2 *Helmer Plasma Thawing System Daily and Weekly PM Log*
 - g. Troy: Attachment 33906-3 *Helmer Plasma Thawing System Weekly Cleaning Log*
 - h. Wayne: Attachment 33906-3 *Helmer Plasma Thawing System Weekly Cleaning Log*
 2. Basket and Chamber Cleaning - On a weekly basis, the Helmer plasma baths will be cleaned as described below. The performance of this task shall be documented on the applicable form.
 - a. Attach an Equipment Out of Service form to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).
 - b. Turn the power to the unit off by pressing the Power button.
 - c. Place one end of the plastic drain tube into a sink drain.
 - d. Attach the other end of the plastic drain tube to the valve on the lower left rear of the unit. Water will begin to drain immediately. Let all the water in the bath drain out.
 - e. Press the button on the top of the drain plug to disconnect the drain hose.
 - f. Remove the plasma basket assemblies from the unit by unscrewing the top and lifting them out.
 - g. Thoroughly clean the interior chamber bath walls, basket assemblies, and the instrument's exterior with a mild disinfectant solution and a soft cloth or sponge.
 - 1) If stains or discoloration remain after general cleaning, use a stain, scale, or rust remover suitable for stainless steel.
 - h. Reattach the basket assemblies.
 - i. Refill the chamber with distilled or tap water to the appropriate level as described in the [Acceptable Range](#) section of this document.
 - j. Optional: Add 12 drops of Helmer Cleanbath inhibitor per gallon of water in the bath to help inhibit bacterial growth.
 - 1) DH8 – approximately 3 mL
 - 2) DH4 – approximately 1.7 mL
 - 3) DH2 – approximately 0.8 mL
 - k. Turn the power on and observe the temperature after allowing time for the temperature to stabilize. Confirm that the temperature returns to 36°C ± 1°C. If the temperature does not

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return to this acceptable range, then the temperature controller must be calibrated as specified in the [Temperature Controller Calibration](#) procedure below.

- I. Document the cleaning of the water bath on the applicable site-specific form.
 - m. Remove the Equipment Out of Service form from the plasma bath.
- D. Quarterly Preventative Maintenance
 - 1. The following preventative maintenance tasks will be performed quarterly. The performance of these tasks shall be documented on form 33906-1 *Helmer Plasma Thawing System Quarterly PM*.
 - a. The calibration of the temperature controllers shall be checked and recalibrated if necessary.
 - b. The rails and bearings on the Helmer Plasma Bath are lubricated for optimal performance.
 - c. The bearings on the baskets are checked for wear.
 - d. A high temperature alarm system check shall be performed.
 - e. 100 V DH8 model only: Fan cleaning. The fan must be kept clean to maintain airflow and prevent the agitation motors from overheating.
 - 2. Temperature Controller Calibration Procedure
 - a. Attach an Equipment Out of Service form to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).
 - b. Insert a certified thermometer into the chamber water bath. Do not allow the thermometer to touch the sides or bottom of the chamber. Allow the thermometer to stabilize.
 - c. Record the thermometer reading and the temperature on the unit's temperature controller display on form 33906-1 *Helmer Plasma Thawing System Quarterly PM*. If the temperature controller temperature matches the certified thermometer reading:
 - 1) Within 0.5°C:
 - a) No additional action is required.
 - 2) Does not match within 0.5°C, then:
 - a) The Temperature Controller needs to be adjusted. Reduce or increase the Temperature Controller to match the certified thermometer reading.
 - d. To recalibrate the Temperature Controller, see the Helmer Operations Manual. For example:
 - 1) Temperature Controller = 36.5°C
 - 2) Calibrated Thermometer = 35.5°C
 - 3) Action to take: Reduce Temperature Controller by 1°C
 - e. Allow the chamber temperature to stabilize after making any calibration changes to the Temperature Controller and take a new reading to verify that the controller is properly calibrated.
 - f. Continue to make adjustments until the temperature readout is properly calibrated.
 - g. Record any adjustments and the final stabilized temperature on the form.
 - h. Remove the Equipment Out of Service form from the plasma bath.
 - i. Note: If the temperature controller cannot be calibrated after a reasonable number of adjustments take the following actions:
 - 1) Take the plasma bath out of service.
 - 2) Contact Corewell Health Biomedical and request service.
 - 3) Update the Equipment Out of Service form on the plasma bath with the work order # and details of the PM failure.
 - 3. Component Lubrication
 - a. Attach an Equipment Out of Service form to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).
 - b. After removing any blood components from the plasma bath, confirm the basket assembly(ies) are raised (press LIFT OUT if necessary).
 - c. Unscrew the finger knobs securing the basket(s) to the lift-out system and remove the basket(s) from the lift-out system.
 - d. Place no more than 3 drops of lightweight oil on your finger. Note: do not use grease.

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- e. Spread the oil along the length of all 4 sides of each lift-out rail. (Lubricating all 4 sides ensures the bearing is properly lubricated.)
- f. Document the lubrication on form 33906-1 *Helmer Plasma Thawing System Quarterly PM*.
- g. Remove the Equipment Out of Service form from the plasma bath.
4. Bearings Wear Check
 - a. Signs of worn bearings include noisy or rough agitation, and markings on the chamber walls where the bearings make contact with the chamber.
 - b. Document the wear check on form 33906-1 *Helmer Plasma Thawing System Quarterly PM* as Satisfactory or Unsatisfactory (S/U).
5. High Temperature Alarm System Check
 - a. Attach an Equipment Out of Service form to the plasma bath. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).
 - b. Document the steps followed below on form 33906-1 *Quarterly Preventative Maintenance of the Helmer Plasma Thawing System*.
 - c. Remove any plasma or cryoprecipitate products from the unit.
 - d. Verify the temperature controller display has been calibrated.
 - e. Document the initial temperature ($36.0^{\circ}\text{C} \pm 1^{\circ}\text{C}$).
 - f. Confirm the High Alarm is set to 36.9°C . Document on the form with a check mark (✓).
 - g. Temporarily increase the Set Temperature value to 37.0°C to allow the unit to raise the temperature of the water to the upper limit of acceptable levels for use and document on the form with a check mark (✓). (Reference the Helmer Operation Manual for detailed directions on adjusting the Set Temperature value.)
 - h. Watch the chamber temperature digital readout until it reaches the High Alarm setting (36.9°C). Document with a check mark (✓) to indicate that each of the following visual and audible alarms activated:
 - 1) Audible alarm.
 - 2) Visual alarm displays "HI" or "AL".
 - 3) Basket assembly lifts out of the chamber.
 - 4) Digital agitation timers blink "E1".
 - i. Reset the chamber Set Temperature to 35.9°C and allow the chamber temperature to stabilize before using.
 - j. Indicate the temperature at which the alarms were activated (must be $<37.0^{\circ}\text{C}$).
 - k. Document with a check mark (✓) to indicate the temperature set point was reset to 35.9°C .
 - l. Document the temperature after it has re-stabilized ($36^{\circ}\text{C} \pm 1^{\circ}\text{C}$).
 - m. Technologist's initials, date, and interpretation of the Alarm System Check (Pass or Fail).
 - n. If the Alarm System Check passed:
 - 1) Remove the Equipment Out of Service Form from the plasma bath and place back in use.
 - o. If the Alarm System Check failed:
 - 1) Contact Corewell Health Biomedical for service.
 - 2) Update the Equipment Out of Service Form with the work order number and a note that the Alarm System Check failed.
 - 3) Submit a variance. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#)
6. 100 V DH8 Fan Cleaning (only applies to the 100 V version of the DH8 model)
 - a. Press the AC ON/OFF button to power the plasma thawer (and fan) OFF.
 - b. Clean the fan using a soft brush and a vacuum cleaner.
 - c. Press the AC ON/OFF button to power the plasma thawer ON.
- E. Taking a Plasma Bath Out of Service
 1. If a plasma bath needs to be taken out of service for any reason:
 - a. Attach an Equipment Out of Service form to the bath.
 - b. Submit a Biomedical Service Request here: [BioMedical Requests](#).

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- c. Contact Corewell Health East Facilities and Biomed at 248-551-6300 if an emergent repair/service is required.
- d. Document a variance. Refer to [Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals](#).

7. Procedure for Use of the Helmer Plasma Thawing System

- A. Thawing Blood Products using a Helmer Plasma Thawing System
 1. Check the water temperature by visually observing the digital read out of the independent thermometer.
 - a. The temperature must be $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ at the start of the thawing process.
 2. Remove the plastic cover from the bath and press the LIFT OUT button (up arrow) to raise the basket assembly.
 3. Place the frozen product in an overwrap and hang it on the basket assembly.
 4. Press the CYCLE TIME button to advance through the pre-programmed cycles to reach the desired cycle time:
 - a. 25 - 40 minutes for plasma
 - b. 10 - 15 minutes for cryoprecipitate
 5. Press the CYCLE START button (curved arrow) to start the agitation, the basket will lower to the appropriate level in the water bath. When the cycle is complete, the basket will rise and a tone will sound.
 6. If Hi-alarm ($>37^{\circ}\text{C}$) sounds, then notify the Blood Bank leadership. Move the products to an alternative plasma bath that is within the correct temperature range.
 7. Inspect the product for thawing. If the product is not thawed repeat steps 4-6 in 5-minute increments.
 8. Remove the thawed unit from water bath and dry the ports.
 9. Press the LIFT OUT button to lower the arm and replace the plastic cover.
 10. Inspect the unit for any breakage or damage and ensure that thawing is complete.
 - a. No breakage or damage
 - 1) Thawing is complete.
 - a) The product is ready to be modified in the BBIS and labeled to reflect thawing. Proceed to [Results/Interpretation section](#).
 - 2) Thawing is incomplete.
 - a) Return to step 6.A.2. and repeat until product is completed thawed.
 - b. Product is broken or damaged
 - 1) Complete a status change in the BBIS to Waste. Refer to Transfusion Medicine policy, [SafeTrace \(Blood Bank\) Application](#).
 - 2) Complete a credit request with the blood supplier, if applicable.
- B. Royal Oak campus only - Thawing Cryopreserved Cellular Therapy Product (CTP)
 1. Remove the basket assembly from the water bath or section of water bath to be used for thawing the CTP.
 2. Check the water temperature by visually observing the digital read out of the independent thermometer.
 - a. The temperature must be $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ at the start of the thawing process.
 - b. Document the temperature on the applicable Chain of Custody form. Refer to applicable CAR T Receipt, Inspection, Storage, Transport and Release of Cellular Therapy Products for Infusion procedure.
 3. After confirming patient identity, load the CTP into a plasma overwrap bag as described below:
 - a. While wearing appropriate personal protective equipment for handling cryopreserved CTPs, remove metal cassette from dewar and open it, inspecting infusion bag for any breaks or cracks prior to thawing. If the bag is compromised, do not infuse the contents. Call the applicable CTP manufacturer.
 - b. Insert the CTP bag into an overwrap bag, ports pointing up, to protect from potential contamination and to isolate a broken bag.

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4. Cryopreserved CTP bags are thawed without using the agitation feature. **Verify agitation is turned off.**
 5. On control panel, press the “LIFT OUT” button, if needed, to lower the arm.
 6. Attach a metal clip to the bottom of the overwrap bag, making sure the clip is attached to the overwrap bag and is not clipped to the CTP.
 7. Place overwrapped CTP bag in the water bath. Hook the slot at the top of the overwrap bag over the top of the arm. The metal clip should help to submerge the CTP product in the water.
 8. Document the thaw start time on the applicable Chain of Custody form.
 9. Approximate thaw time for cryopreserved CTP bags with volume 10 – 50 mL is 3 - 5 minutes.
 10. Inspect thawed CTP bag periodically to confirm product is thawed. It is adequately thawed when there is no visible ice in the infusion bag.
 11. Document the thaw end time on the applicable Chain of Custody form.
- 8. Results/Interpretation**
- A. Blood Product BBIS Modification to Reflect Thawed Product
 1. All thawed plasma and cryoprecipitate products are modified in the computer immediately after thawing in accordance with Transfusion Medicine policy, [SafeTrace \(Blood Bank\) Application](#), within a maximum of one hour of the thaw start time.
 - a. To modify plasma that will be aliquoted use the THAW24 modification to modify and relabel as a 24-hr thawed plasma.
 - b. For cryoprecipitate and all other plasma usage use the THAW modification to modify and relabel. This will give a 5-day expiration for the thawed plasma and 6-hour expiration for thawed cryoprecipitate.
 2. If the technologist is unable to immediately modify the product in the computer, a downtime modification form indicating the actual time and date at the end of the thawing process needs to be attached to the product so this can be recouped and modified in the BBIS when the system is available/time permits.
 - a. Thawed plasma product shall be placed in a site-specific area of the refrigerator.
 - b. Thawed cryoprecipitate product shall be placed on the counter in the site-specific area defined for room temperature storage of thawed cryoprecipitate.
 - c. Refer to site specific Transfusion Medicine Computer Downtime/Manual Operation procedures.
 3. Label Verification
 - a. If a component is modified and new labels are applied, the labeling process shall include a method to ensure the accuracy of all labels including the donor identification number, ABO/Rh, expiration date, and blood product code.
 - b. Label verification is a validated process in the Blood Bank Information system (BBIS) where each bar code quadrant of the component label is scanned and compared to the electronic record in the laboratory computer system.
 - c. In the case of a BBIS downtime, if possible, 2 technologists will verify that the appropriate label(s) have been updated. Refer to site specific Transfusion Medicine Computer Downtime/Manual Operations procedures.
 - d. Refer to Transfusion Medicine policy, [Corewell Health East - Labeling Blood Components - Blood Bank - All Beaumont Hospitals](#) for additional information.
 - B. Blood Product Expiration and Storage
 1. Refer to the table below for thawed product expiration date/time and storage temperature. Thawed expiration date/time must not exceed the original product expiration date/time.

Thawed Product Type	Expiration Date/Time	Storage Temperature
Thawed Plasma	At 23:59 on day 5 after thawing (day of thaw = day 0)	1°C – 6°C
Thaw 24 Plasma*	24 hours from time of thaw	1°C – 6°C

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Cryoprecipitate, Single	6 hours after thawing	20°C-24°C
Cryoprecipitate, Pre-pooled**	6 hours after thawing	20°C-24°C

*Thaw 24 Plasma Product that remains unused for a neonate after 24 hours, and remains in a closed system may have the expiration extended to 23:59 on day 5 after thawing (day of thaw = day 0).

**Pooled by the blood supplier in a sterile, closed system

9. Limitations

ACCEPTABLE RANGES:

Daily QC	
Temperature of the plasma/ water bath	36°C ± 1°C
Appearance of the water	Clear, not cloudy and without an odor or other signs of contamination.
Water level	Helmer: The water level should not exceed the upper slotted line when the baskets are in the lowered position but still cover the baskets completely.
Helmer Alarm System Check	
Initial Temperature	36°C ± 1°C
Temperature set point increased to:	37.0°C
Audible alarm	Should alarm at or before the temperature reaches 36.9°C
Visual alarm	Should alarm at or before the temperature reaches 36.9°C
Basket assembly	Should automatically lift at or before the temperature reaches 36.9°C
Digital timers	Should blink at or before the temperature reaches 36.9°C
Temperature at which alarms must activate	36.9°C
Temperature set point reset to 35.9°C	Yes
Temperature re-stabilized	36°C ± 1°C

10. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

11. Procedures Superseded and Replaced:

This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [31691 Corewell Health East – CAR T Use of Helmer Scientific Waterbath and Thawing of Cryopreserved Cellular Therapy Products, 33969 Corewell Health East – Helmer DH4 Plasma Thawing System Quality Control and Preventative Maintenance – Blood Bank – Troy, 33999 Corewell Health East – Helmer Water Bath Maintenance – Blood Bank – Wayne, 33801 Corewell Health East – Quality Control & Preventative Maintenance of

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the Helmer DH4 Plasma Thawing System – Blood Bank – Dearborn, 33854 Corewell Health East – Quality Control & Preventative Maintenance of the Helmer DH8 Plasma Thawing System – Blood Bank – Farmington Hills, 33775 - Corewell Health East - Thawing Fresh Frozen Plasma and Cryoprecipitate].

12. Resources

- A. Helmer Plasma Thawing System Operation-Service-Maintenance Manual, Noblesville, IN 46060.

13. Procedure Development and Approval

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14. Keywords

Not Set