TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	3.28.2014
Department:	Blood Bank	**Due Date:**	4.15.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Plasma Thawer Quality Control (ThermoGenesis MT204)

Description of change(s):

Updated form and procedure in response to CAP/AABB deficiency.

- Added both requirements for monthly QC to the form:
  - Check water level and fill as needed
  - Check the power cord for splits or frays
- Added quarterly QC to the "Daily Temperature Quality Control" form.
  - Form contains boxes to document thermometer serial number, thermometer temperature, plasma thawer temperature, difference, and interpretation
  - Form also contains a spot to document that the plasma thawer water was changed and water conditioner was added.

The procedure was updated to reflect changes to the form.

Electronic Document Control System

Quest Diagnostics

Document No.: WAH.BB84[1]
Title: PLASMA THAWER QUALITY CONTROL (THERMOGENESIS MT204)
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 25-Apr-2014 **Next Review Date:**

Non-Technical SOP

Title	**Plasma Thawer Quality Control (ThermoGenesis MT204)**	
Prepared by	Stephanie Codina	Date: 3/30/2011
Owner	Stephanie Codina	Date: 3/30/2011

Laboratory Approval

Print Name and Title	Signature	Date
Refer to the electronic signature page for approval and approval dates.		

Local Issue Date: Local Effective Date:

Review:

Print Name	Signature	Date

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1. PURPOSE

Frozen plasma and cryoprecipitate products are thawed a temperatures between 30-37°C in an FDA-approved device. This procedure outlines the preventive maintenance and quality control that is performed on the ThermoGenesis MT204 plasma thawer.

2. SCOPE

This procedure applies to the ThermoGenesis MT204 plasma thawer.

3. RESPONSIBILITY

All blood bank staff members must understand and follow this procedure when performing maintenance and quality control requirements for the plasma thawer.

4. DEFINITIONS

N/A

5. PROCEDURE

Daily Maintenance

Step	Action
1	The temperature of the plasma thawer is read and recorded on the quality control form daily. The temperature must be between 30-37°C. If the plasma thawer is outside of the acceptable temperature range: A. Remove the plasma thawer from service. B. Notify the Biomedical Engineering department or a supervisor.

Document:WAH.BB84[1] Status:INWORKS,Effective:4/25/2014, Check Version Before Use

Monthly Maintenance

Step	Action
1	Check the water level: A. Remove the round cover from the fill port at the right rear of the thawer by pulling it straight up. B. A clear horizontal rod is located inside the fill port. Verify that the water level reaches the bottom of the rod. Add additional tap water until the water level reaches the bottom of the rod, if indicated. C. Record all actions on the quality control form.
2	Check the power cord for splits or frayed spots. Contact Biomedical Engineering to replace the cord if necessary.
3	Document completion of monthly maintenance on the quality control form.

Quarterly Maintenance

Step	Action
1	Verify the temperature of the plasma thawer. A. Obtain a thermometer that has been verified at 37°C. B. Document the serial number of the thermometer on the QC form. C. Remove the button cap near the left-most thawing pocket. D. Insert the thermometer. E. Start a 5-minute cycle and read the thermometer when the thawing fluid surrounds the pocket. F. Record both the thermometer reading and the digital temperature of the thawer and record on the QC form. The operating range must be between 30-37°C. a. If the readings are within 1°C of each other, no further action is required. b. If the readings are greater than 1°C from each other, adjust the thawer. i. On the keypad, enter "200" and press the "Reset" button. ii. The display will flash "00.0." iii. Enter the temperature of the calibrated thermometer reading using the keypad. For example, if the reading of the calibrated thermometer was 35.0°C, enter "350." iv. Press the "Start" key to save the temperature setting. v. Verify that the thawer temperature on the digital display is correct. If not, press "Clear" and start over.

Step	Action
2	Change the water inside the thawer. A. Drain the thawer. a. Turn off the plasma thawer. b. Slide the thawer on the counter so that the left side of the thawer hangs over the sink edge by approximately 2 inches. **Do not attempt to lift the thawer.** c. There are 2 drain fittings underneath the left side of the unit; one to drain the reservoir and one to drain the product chamber. The arrows on the side of the thawer will show the positions of the drain fittings. d. Place the discharge end of the drain hose into the sink or a suitable container. e. Press the metal tab of the drain fitting in and push the drain hose into the drain fitting. f. Drain both the reservoir and the product chamber. B. Fill the thawer with 8 gallons of tap water (up to the clear, horizontal rod). C. Run the thawer through 1 thaw cycle to flush all residuals from the system. D. Drain and discard the rinse water following step A above. E. Refill the thawer with 8 gallons of fresh tap water. F. Add 5 mL of waterbed conditioning liquid. G. Remove the drain adapter. a. Press down on the metal tab of the drain fitting. b. Pull the drain hose from the fitting. H. Document the water change on the quality control form.

Blood Product Leaks (As Needed Maintenance)

Step	Action
1	If a blood product leak occurs, determine whether the blood product spill was contained in the membrane pocket or if it leaked into the water chamber.
2	If the blood product only leaked into the membrane pocket: A. Pull the pocket assembly loose from the thawer and remove the pocket weight. B. Wash and rinse the pocket and weight to remove all visible signs of blood product. C. Soak the pocket and weight in a 10% bleach solution for 20 minutes. Soaking the pocket for longer than 20 minutes can damage the pocket. D. Rinse the disinfected pocket, inside and out, and the weight with running tap water. E. Reinstall the pocket into the thawer. a. Place the pocket weight into the pocket. b. Place the pocket into the chamber.

Step	Action
	c. Staring on the flat side, press the snap ring into the keeper. d. Working toward one corner, press the snap ring into place as you go. e. Work around the corner and along the opposite side, pressing the snap ring into place. Install a new pocket if the thawer must be used before the decontamination process can be completed. The cleaned pocket can then be stored for future use.
3	If both the blood product and membrane pocket leaked, A. Remove the pocket assembly and discard the broken pocket into the biohazard trash. B. Install a new pocket membrane. C. Drain 3 quarts of water from the chamber and replace with 3 quarts of bleach. This will result in a 10% bleach solution in the reservoir. D. Push the "Start" button and allow the pumps run for approximately 1 minute to mix the bleach. E. Allow the bleach solution to remain in the thawer for 30 minutes. Do NOT leave the bleach in the thawer for over 30 minutes, it may damage the thawer. F. Drain the contents of the chamber. G. Change the water per "Quarterly Maintenance, step 2" above.

6. RELATED DOCUMENTS

Form: Daily Temperature QC (AG.F237)

7. REFERENCES

1. Roback, J.D., Combs, M.R., Grossman, B.J., Hillyer, C.D. 2008. Technical Manual of the AABB, 16th ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 2014. AABB, 29th ed. AABB Publishing, Bethesda, Maryland.
3. Operation and Service Manual, MT204 Plasma Thawer, ThermoGenesis, Rev A, March 2000.
4. Technical Services Bulletin, ThermoGenesis, Thawer Disinfectant Change, Nov 1, 2002.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAB519.01		
000	3.26.14	Section 5: Updated SOP to reflect that all QC is now documented on the Daily Temperature QC form. Changed wording of "calibrated thermometer" to "verified thermometer." Updated reference for AABB standards. Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

None

Quest Diagnostics

Washington Adventist Hospital
Takoma Park, MD

Daily Temperature Quality Control

Month:	Year:	Reviewed:

Date	Heat Block SN SA1B09444 (36-38C)	Hole	HemoTempII Activator SN 000017 (39-41C)	Plasma Thawer SN TD1372 (30-37C)	Room Temp (20-24C)	Interp S or U	Tech
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Legend:
(S)atisfactory
(U)nsatisfactory

Monthly Plasma Thawer Maintenance:

Date	Tech	Task
		Check water level and fill as needed
		Check power cord for splits or frays

Quarterly Plasma Thawer Maintenance:

Date	Tech	Change Water/Add Conditioner	Temperature Verification				
			QC Therm SN	QC Therm Temp (°C)	Plasma Thawer Temp (°C)	Difference? Range = <1°C	Interp? S or U