TRAINING UPDATE

Lab Location:	GEC	**Date Implemented:**	11.28.2017
Department:	Lab	**Due Date:**	12.18.2017

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Helmer Undercounter Refrigerator and Temperature Form
Description of change(s):
1. Added requirement to bleach probe and probe bottle annually. 2. "Clean Probe Bottle" was added to the form as annual maintenance.

Electronic Document Control System

Document No.: GEC.BB06[3]
Title: Helmer Undercounter Refrigerator
Owner: LESLIE BARRETT
Status INWORKS
Effective Date: 22-Dec-2017 **Next Review Date:**

Non-Technical SOP

Title	**Helmer Undercounter Refrigerator**
Prepared by	Stephanie Codina Date: 09.30.2011
Owner	Stephanie Codina Date: 09.30.2011

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**

TABLE OF CONTENTS

---

1. PURPOSE

Red blood cells are stored at temperatures between 1-6°C. Blood product refrigerators must be equipped with a system for continuous temperature monitoring and an audible alarm. The alarm must activate at a temperature that will allow proper action to be taken before blood products reach unacceptable conditions. The temperature and alarms are frequently checked to ensure an appropriate temperature is maintained.

2. SCOPE

This procedure applies to the Helmer iSeries undercounter refrigerator.

3. RESPONSIBILITY

All Germantown Emergency Center Laboratory staff members must understand and adhere to this procedure for assessing appropriate refrigerator temperatures, performing refrigerator maintenance, and performing the steps that must be taken when a refrigerator is out of the appropriate temperature range.

4. DEFINITIONS

N/A

5. PROCEDURE

General Guidelines

Blood bank refrigerators:

1. Shall only contain blood products and reagents. For products other than blood, the temperature and alarms of the refrigerator will be adjusted to meet the manufacturer's storage recommendations (refrigerator range will be 1-6°C and the alarms will sound at ≥1.5°C and ≤5.5°C).
2. Shall be equipped with a fan for circulating air to ensure proper temperature is maintained throughout the refrigerator.
3. Shall be equipped with a visual and audible alarm system, and have continuous temperature monitoring device via a chart recorder. Alarm is set to activate at a

Form revised 3/31/00

temperature that will allow proper action to be taken before components reach unacceptable temperature. The audible alarm sounds within the laboratory where there is 24 hour coverage.

4. Shall be connected to an emergency power source, alarm system has a battery backup.
5. Shall have a verified thermometer placed on upper shelf near the door.

Daily Quality Control

Step	Action
1	Review the recording chart. A. Verify that the recording chart is positioned at the correct date and time. If not, re-adjust to the correct date and time and document the correction on **both** the front of the recording chart and the "Blood Bank Refrigerator Temperature Form." B. Ensure the temperature has been within the acceptable temperature range for the previous 24 hours.
2	Read and record the following temperatures on the "Blood Bank Refrigerator Temperature Form." The acceptable temperature range is 1-6°C. A. Chart recorder read to the nearest whole number (for example, 2 or 3). The chart recorder is always read at the point where the stylus touches the paper. B. Thermometer read to the nearest 0.5 degree (for example, 2.5 or 3.0) C. Digital display read to the nearest 0.1 degree (for example, 2.6 or 2.7)
3	Visually inspect the appearance of blood products in inventory. A. Examine blood products for hemolysis, clots, change in color or unusual color, comparison of segments with bag. B. Quarantine any unacceptable blood products in inventory. C. Record findings on the QC form.
4	Interpret the refrigerator's operation. A. If satisfactory, document "Y" for yes. B. If unsatisfactory, document "N" for no. a. Document corrective action on the reverse side of the "Helmer Undercounter Refrigerator Temperature Form." b. Notify a supervisor if unable to resolve. c. If the temperature is out of range, move the contents of the refrigerator. Refer to section, "Blood Bank Refrigerator in Alarm."

Weekly Quality Control

Step	Action
1	Weekly QC is performed each Monday.

Form revised 3/31/00

Step	Action
2	Obtain a new temperature chart. Be sure the new temperature chart is appropriate for the refrigerator and will record temperatures correctly. A. Stamp the back of the chart with the "date on" stamp. B. Record the refrigerator identification on the back of the chart to identify the storage container. C. Record the current date in the "date on" line. D. Initial the back of the chart next to "By."
3	On the chart recorder, press the "C" (chart change) button until the stylus begins to move to the left, then release the button. The LED will flash to indicate the current temperature range value.
4	When the stylus stops moving, remove the chart knob by turning it counter-clockwise, then swing it toward the top of the chart recorder.
5	Gently lift the stylus and remove the current temperature chart.
6	Press the new chart onto the chart recorder. Gently lift the stylus and turn the paper so the pen is on the correct day and time line groove.
7	Hold the chart paper to prevent it from turning while re-installing the chart knob. Turn the knob clockwise until snug.
8	Press and hold the "C" (chart change) button until the stylus starts to move to the right, then release the button.
9	Confirm the stylus is marking the correct temperature on the correct day/time. If not, repeat steps 3-9. Do not try to move or adjust the chart while it is on the recorder.
10	Record the following information on the removed chart and forward the chart to a supervisor or designee for review. A. Date off B. Tech's initials

Quarterly Quality Control

Step	Action
1	**Calibrate the chart recorder.** This task is performed to ensure the temperature being marked on the temperature chart matches that read by the chart recorder probe. A. Place a verified thermometer (preferably NIST thermometer) inside the refrigerator probe bottle along with the chart probe. B. Allow the temperature to stabilize. C. Read the temperature of the verified thermometer to the nearest 0.5°C and record on the QC form. D. Compare the reading of the thermometer to the reading of the temperature chart and adjust the temperature if necessary. a. The arrow buttons on the chart recorder indicate in which direction the stylus will move. b. Press and hold the appropriate button until the stylus has moved to the desired location (the correct temperature). c. Release the button to save the setting. d. The verified thermometer and chart recorder should be within 1°C of each other. E. Document the temperature probe calibration on the maintenance form. F. Notify a supervisor or designee immediately if a problem exists.
2	Check the **backup battery** on the chart recorder and replace if necessary. A. The color of the LED on the chart recorder changes from green to red (constant pattern) when the battery charge is low. B. Disconnect the old battery and discard. C. Press a new 9V battery into the holder and connect the leads. D. The LED indicator will change from red to green if the battery was successfully changed.
3	**Calibrate the temperature probes** to ensure accuracy. A. Place a verified thermometer (preferably NIST thermometer) inside the refrigerator probe bottle along with the temperature probe. B. Allow the temperature to stabilize. C. Read the temperature of the verified thermometer to the nearest 0.5°C and record on the QC form. D. Compare the reading of the thermometer to the setpoint of the refrigerator. E. If the temperatures are ≥1°C different, determine how much to increase or decrease the offset value to make the monitor reading match the verified thermometer. a. Read the digital temperature. b. Subtract the reading of the verified thermometer from the digital reading. c. Divide the difference in half. d. This number is the adjustment that should be made. e. Example, i. Digital = 4.0 ii. Thermometer = 5.5

Step	Action
	iii. 4.0 minus 5.5 is -1.5 iv. -1.5 divided by 2 suggests a -0.8 adjustment be made. F. Enter and save the temperature reading in the refrigerator configuration. a. Press and release the "SEL" button until the "CONTROL" lamp is lit. b. Press and hold the "SET" button. The control display shows a SET temperature, which is typically higher than the chamber temperature. c. While holding the "SET" button, use the up ▲ and down ▼ arrow buttons to adjust the refrigerator setpoint by the amount determined. The buttons change the value by + or – 0.1°C. d. Release all buttons to save the data. e. Return to monitor mode by pressing and releasing the "SEL" button until the monitor lamp is lit. G. Document the temperature probe calibration on the Refrigerator Temperature Form. H. Notify a supervisor or designee immediately if a problem exists.
4	**Test the alarms.** A. Low Alarm Test a. Place a container of water in the refrigerator until the water temperature has equilibrated. b. Attach the temperature probe to an NIST-verified thermometer with a rubber band. c. Place the probe and thermometer into the water solution. d. Constantly stir the water while watching the temperature of the monitor. e. Slowly add ice (1 teaspoon every 15 – 25 seconds). f. The alarm will sound when the temperature reaches the setpoint. Note the temperature on the thermometer when the alarm sounds. g. The alarm must sound at a temperature of 1.5°C or greater, and at a temperature consistent with manufacturer's instructions for any reagents stored in the refrigerator. h. Document the alarm check on the Refrigerator Temperature Form." i. Notify a supervisor or designee immediately if a problem exists B. High Alarm Test a. Place a container of water in the refrigerator until the water temperature has equilibrated. b. Attach the temperature probe to an NIST-verified thermometer with a rubber band. c. Place the probe and thermometer into the water solution. d. Constantly stir the water while watching the temperature of the monitor. e. Slowly add warm water so the temperature increases 0.5°C each minute.

Step	Action
	f. The alarm will sound when the temperature reaches the setpoint. Note the temperature on the thermometer when the alarm sounds. g. The alarm must sound at a temperature of 5.5°C or lower for blood products. h. Document the alarm check on the Refrigerator Temperature Form. i. Notify a supervisor or designee immediately if a problem exists
5	Test the **Power Failure Alarm** to ensure it activates in an appropriate amount of time. During a power failure, the backup battery should continue to provide power to the monitoring system. A. Disconnect the refrigerator from power, either at the wall, or using the power switch located inside the lower front panel. B. The power failure alarm should activate, causing the audible alarm to sound and "POFF" (power off) to display. C. Reconnect the refrigerator to power. The power failure alarm should clear. D. Document the alarm failure check on the Refrigerator Temperature Form. E. Notify a supervisor or designee immediately if a problem exists.
6	Test the **door open alarm.** A. The door open alarm is factory set at 3 minutes and cannot be changed. B. Note: This check requires the refrigerator door to be open for long periods of time. Protect blood products from extended exposure to adverse temperatures. C. Set a timer for 3 minutes. D. Open the refrigerator door and start the timer. E. When the timer value is reached, the door open alarm should activate with an audible alarm and the "DOOR ALARM" lamp to flash. F. Close the refrigerator door. The door open alarm should clear causing the audible alarm to clear and the "DOOR ALARM" lamp to stop flashing. G. Document the Door Open Alarm check on the Refrigerator Temperature Form. H. Notify a supervisor or designee immediately if a problem exists.
7	Clean the **condenser grill.** A. The condenser grill is located on the front of the refrigerator, inside the lower front panel (finned surface). B. Disconnect power to the refrigerator to eliminate the potential for electric shock. C. Protect blood product from exposure to adverse temperatures. D. Clean the condenser grill using a soft brush and vacuum cleaner. E. Document the cleaning on the maintenance form. F. Notify a supervisor or designee immediately if a problem exists.

Step	Action
8	Examine the probe bottles. Clean and refill if necessary. The probe bottles are filled with 10% glycerol.
9	Wipe the interior, exterior, and gasket with a damp cloth and mild soap to clean.

Annual Maintenance

Step	Action
1	Clean the probe bottles annually, when they visually appear dirty, and when the temperature alarm sounds repeatedly without an obvious cause. A. Remove the probes from the bottle. B. Remove the bottle from the bracket. C. Dump the probe bottle. Soak the bottle in a 10% bleach solution for 10 minutes then allow the bottle to dry. D. Wipe the probe with a hospital-approved bleach disinfectant wipe or a solution of 10% bleach. E. Refill the bottle with a 10% solution of glycerol and water. F. Allow the solution to cool before replacing the probes. G. Document "cleaning probe bottles" on the refrigerator chart to explain why the temperature is out of range as applicable. H. Document cleaning of probe bottles on the maintenance form.

Refrigerator in Alarm

Step	Action
1	If the refrigerator alarm activates, push the alarm silence button to temporarily stop the audible alarm.
2	Determine whether there is an obvious cause for alarm activation and correct. If corrected, make a note on the temperature chart indicating alarm activation and reason. A. Refrigerator door ajar B. Outlet power failure / unit unplugged C. Refrigerator failure D. The probe solution is empty or low

Step	Action
3	If the cause of alarm is not identified or if the problem is not immediately correctable, A. Monitor the internal thermometer temperature of the refrigerator every **15 minutes** until the alarm stops **or** until all blood products have been removed. Document the temperature on the "Manual Product Storage Temperature" form. B. If the temperature reaches a low of 1.5°C or high of 5.5°C, all blood products and reagents must be relocated to another storage container that will maintain temperatures between 1-6°C. Blood products can be moved to: a. Another refrigerator. Be sure to temporarily label the shelves so incorrect blood products are not inadvertently issued. b. Transfer to SGMC Blood Bank C. Document movement of the blood products on the temperature chart. Include the exact time and tech's initials. D. Place a verified thermometer in the temporary storage container with the blood products. E. Monitor the temperature at least every 4 hours. Document the temperature of the temporary storage container on the "Manual Product Storage Temperature" form.
4	A. Notify a supervisor or designee as soon as possible but definitely within 1 business day. B. Notify Quest biomedical engineering if the problem persists or if repairs are needed. C. Notify plant operations if there is a problem with the power supply.
5	When the problem is resolved **and** the refrigerator temperature returns to the acceptable range, A. Re-activate the alarm B. Return the blood products to the refrigerator C. Document replacement of blood products on the temperature chart with exact time and initials D. Continue to monitor and document manual temperatures every 4 hours for a minimum of 12 hours.

6. RELATED DOCUMENTS

Form: Helmer Undercounter Refrigerator Temperature Form (AG.F140)
Form: Manual Product Storage Temperature Form (AG.F51)

7. REFERENCES

1. Fung, MK, Grossman, BJ, Hillyer, CD, and Wsthoff, CM. 2014. Technical Manual of the AABB, 187th ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 2016. AABB, 30th ed. AABB Publishing, Bethesda, Maryland.
3. Helmer Inc., Temperature Chart Recorder Operation and Service Manual,360076-1/J; 2009
4. Helmer Inc., Refrigerator Service Manual 360117-1/C; 2010

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes GEC.BB04		
000	11.30.12	Section 5: Enhanced instruction for reading the temperature chart. Removed statement that power failure alarm is set for 3 min; alarm activates immediately when power fails.	SCodina	NCacciabeve
001	12.19.14	Section 5: Removed references to RhIG; changed "calibrated" thermometer to "verified" thermometer throughout SOP. Changed acceptable range from 2-6 to 1-6 and low alarm activation from 2.5 to 1.5 since RhIG is no longer stored. Section 6: moved forms from section 9 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	SCodina LBarrett	NCacciabeve
2	11.21.17	Section 5: Added annual maintenance. Section 7: Updated references.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

None

Electronic Document Control System

Quest Diagnostics

Document No.: AG.F140[4]
Title: Helmer Undercounter Refrigerator Temperature Form, GEC
Owner: LESLIE BARRETT
Status INWORKS
Effective Date: 22-Dec-2017 **Next Review Date:**

QuestDiagnostics

Germantown Emergency Center

Helmer Undercounter Refrigerator Temperature Form

Acceptable Range: 1-6°C

S/N 1002125

Month/Yr _____

All temp readings agree ≤ 2 °C

Day	CHECK DAILY					Tech
	Verified Temp Chart Recorder Operation	Chart Temp 1-6°C	Digital Temp 1-6°C	Internal Thermometer Temp 1-6°C	Appear of Blood Products Satisfactory?	
		°C	°C	°C	Y/N	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Circle unsatisfactory item/s. Document corrective action on back sheet.

Reviewed By: _____

Quarterly Maintenance

___ Check (√) if quarterly maintenance not due during current month.

Calibrate Chart Recorder Therm_____ Chart_____ Tech____Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Calibrate Temperature Probe Therm_____ Digital_____ Tech____Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Power Failure Alarm Tech____ Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Door Open Alarm Tech____ Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Backup Battery Tech____ Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Wipe Clean Interior, Exterior, and Gasket and Clean Condenser Grill Tech____ Date____	□ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Alarm Test Tech____ Date____	High Activation_____ Low Activation_____ (High ≤ 5.5 and Low ≥1.5) □ Acceptable □ Unacceptable If unacceptable, document resolution on back.
Clean Probe Bottle (Annual)	Tech____ Date____