ABMT-GEN-021
MONITORING TEMPERATURE AND HUMIDITY

1 PURPOSE
1.1 This procedure outlines the processes for monitoring the temperature and humidity of the supply storage areas (ABMT Clinic Storage Room and Apheresis Storage cabinets) and the Apheresis Area where cellular products are collected. These areas are not connected to a central monitoring and alarm system.

2 INTRODUCTION
2.1 It is good practice and is required by regulations to maintain control over the environment used for cellular collection and for collection associated supply storage. Temperature and humidity monitoring ensures that the environmental specifications required by the blood cell separator manufacturers are being met.

3 SCOPE AND RESPONSIBILITIES
3.1 All Adult Blood and Marrow Transplant Program collection nurses or Charge Nurse or designee will record the temperature and humidity of the Apheresis Area and supply storage areas daily.
3.2 The Apheresis nurse will be responsible for recording the collection room temperature and humidity on the ABMT-COLL-019 FRM1Optia CMNC Run Sheet at the end of collection.
3.3 All ABMT, collection personnel and ABMT Clinic Charge Nurses are responsible for the contents of this procedure.
3.4 The Apheresis Charge nurse is responsible for reporting any temperature and/or temperatures that are not within the defined ranges to the ABMT Nurse Manager for corrective action.

4 DEFINITIONS/ACRONYMS
4.1 ABMT Adult Bone Marrow Transplant
4.2 THM Thermometer
4.3 C Celsius
4.4 RH Room Humidity

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 NIST traceable thermometer and humidity monitor (THM).

7 SAFETY
7.1 NA
8 PROCEDURE
8.1 Once a day, the temperature and humidity of the Supply Room and Apheresis area must be recorded.
8.2 Press the temperature button once for the minimum temperature and again for the maximum.
8.3 Press the humidity button once for the minimum humidity and again for the maximum.
8.4 Record the temperature and humidity values on the ABMT-GEN-021 FRM1 Temperature and Humidity Log.
8.5 If the temperature is outside of 15.5°C–27.7°C in storage and Apheresis areas, contact the Apheresis Coordinator or designee and record on the back of the AMBT-GEN-021 FRM1 under the Troubleshooting Log.
8.6 If the RH is outside of 8%–75% in the storage and Apheresis areas, contact the Apheresis Coordinator or designee and record on the back of the ABMT-GEN-021 FRM1 under the Troubleshoot log.

8.6.1 If contacted because temperature or humidity is out of range:
8.6.1.1 Ensure that all values that are out of range are investigated and resolved as quickly as possible to ensure that supplies are promptly relocated, if necessary, to another storage device.
8.6.1.1.1 Determine the cause of the temperature or humidity change, and ways to handle the temporary malfunction.
8.6.1.1.2 If malfunction is longer than temporary, determine the steps to take in the event of prolonged failure.
   - Ensure proper temperature for supplies.
   - Ensure integrity of supplies
8.6.1.2 If supplies must be moved:
8.6.1.2.1 Notify Service or Maintenance personnel.
8.6.1.2.2 Contact additional staff for moving products.
8.6.1.2.3 Locate and prepare back-up storage units.
8.6.2 Review ABMT-GEN-021 FRM1 Temperature and Humidity Log at month’s end.
8.6.3 Resolve all issues that were recorded Temperature and Humidity Troubleshooting Log

9 RELATED DOCUMENTS/FORMS
9.1 ABMT-GEN-021 FRM1 Temperature and Humidity Log FRM1
10 REFERENCES

10.1 FDA, CFR Title 21, Parts 200-299, 1270, 1271


11 REVISION HISTORY

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<th>Author</th>
<th>Description of Change(s)</th>
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<tr>
<td>08</td>
<td>M. Christen</td>
<td>• Section 8.6: Updated humidity to reflect kit humidity max per Terumo BCT recommendation.</td>
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## Signature Manifest

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### ABMT-GEN-021 Monitoring Temperature and Humidity

#### Author

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#### Document Release

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