Wake Forest Baptist Medical Center	Monitoring of Laboratory Environment – Refrigerator & Ambient Temperature and Humidity CCL-029	Dept: 324318	Critical Care Labs
		Effective Date:	April 2001
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature:			

1) **General Procedure Statement:**

a. **Purpose:** Ambient temperature and humidity are checked and documented daily to verify that the laboratory environment for instrument operation, reagent, QC and consumable storage is within the manufacturer's defined limits. Refrigerator temperatures are checked and documented daily to verify that the appliances are operating within defined acceptable limits.

b. **Responsible Department/Party/Parties:**

i. Procedure owner: Ann Shoffner
ii. Procedure: Critical Care Lab (CCL) Staff
iii. Supervision: Ann Shoffner
iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

2) **Procedure:**

A. Equipment:

1. SPOT monitoring – The WFBH SPOT system monitors the reagent refrigerators, ambient temperature and humidity in the ICU and OR Labs 24/7. Temperatures are recorded by SPOT every 10 minutes. In the event a temperature falls out of range, SPOT verbally notifies the ICU Lab staff and also sends an automatic email to lab management and the POCT staff.
2. Rees Monitoring System - Monitors the OR Lab triple door refrigerator 24/7.
3. Back up devices to SPOT –
   a. Streck Temp-Chex thermometers with glycol manufactured to meet NIST/DKD standards of accuracy certified traceable to NIST/DKD standards are used in the OR and ICU laboratory refrigerators as back up to the SPOT and Rees monitoring systems. New thermometers with NIST certification will be placed into use annually.
   b. Digital Hygrometer/Thermometers are used in the OR and ICU Laboratories as a back up to SPOT for humidity and room temperature monitoring. A new device with NIST certification will be placed into use prior to the current device's calibration expiration date.

B. Reading/recording temperatures:

1. First shift staff in the OR and ICU Lab performs the reagent refrigerator, ambient temperature and humidity checks. 3rd shift ICU Lab staff is responsible for performing these checks in the OR Lab on weekends and holidays when the OR Lab is closed.
2. ICU BGAS Lab - Read the temperature from the thermometer located in reagent refrigerator. Obtain the room temperature and humidity from the digital thermometer/hygrometer device. Record readings from all devices and document your initials in the respective blocks by date on the Temperature and General Maintenance Log (*CCL-F028 ICU Temp and General Maintenance Log*).
3. OR Lab – Read the temperature from the thermometer located in reagent refrigerator. Obtain the room temperature and humidity from the digital thermometer/hygrometer device. Record the readings from all devices and document your initials in the respective blocks by date on the Temperature and General Maintenance Log (*CCL-F029 OR Temperature and General Maintenance Log*). In addition to the current readings, also record the minimum and maximum ambient and humidity readings for the last 24 hour period.

C Acceptable Temperature and Humidity Ranges:

1. ICU Blood Gas Lab Room Temperature 65°F – 77°F (18.0°C – 25.0°C)
   - SPOT tolerance range: 66.2° F -76.1°F (19°C – 24.0°C)

   Humidity 5% – 90% non- condensing
   - SPOT tolerance range: 10% - 80%
2. OR Blood Gas Lab Room Temperature 65 – 77°F (18.0°C – 25.0°C)
   - SPOT tolerance range: 66.2° F -76.1°F (19°C – 24.0°C)

   Humidity 20% – 80% non- condensing
   - SPOT tolerance range: 25% - 75%
3. ICU Blood Gas Lab Reagent Refrigerator 2 - 8 °C
   - SPOT tolerance range: 2.50 – 7.00 °C
4. OR Blood Gas Lab Triple Door Reagent Refrigerator 2 – 8 °C
   - SPOT tolerance range: 2.50 – 7.00 °C
   - REES tolerance range: 2.10 – 7.90 °C

Temperature and Humidity requirements of instruments/reagents/qc/consumables

What instrument/reagent drives the acceptable ranges for ambient temp and humidity? Information obtained using manufacturer's product inserts and system specifications. The product with the tightest requirement drives the acceptable range.

- Roche Cobas e411 – humidity requirements 20% - 80%
- Rapid Lab QC - PO2 values will require a correction factor if the temperature rises above 25°C.
- iSTAT Cartridges stored at room temp – per manufacturer, results are not accurate if ambient temperature falls below 18°C.

Item	Temp °C	Temp °F	Humidity
Rapid Lab 1265 instrument	15 - 32°C	59 - 89°F	5-90% non-condensing
Wash Cartridge	2 - 25°C	36 - 77°F	n/a
Reagent Cartridge	2 - 8°C	36 - 46°F	n/a
Rapid Lab QC	2 - 25°C	64 - 77°F	n/a
High G/L	2 - 8°C	36 - 46°F	n/a
Glucose/ Lactate sensors	2 - 8°C	36 - 46°F	n/a
pH Electrode fill	4 - 25°C	39 - 77°F	n/a
Reference Electrode fill	4 - 25°C	39 - 77°F	n/a
Na/K/Ca Electrolyte fill	4 - 25°C	39 - 77°F	n/a
Conditioner	4 - 25°C	39 - 77°F	n/a
Deproteinizer	4 - 25°C	39 - 77°F	n/a
Electrodes	4 - 25°C	39 - 77°F	n/a
Hemochron Response	15 - 30°C	59 - 86°F	n/a
ACT Tubes	15 - 30°C	59 - 86°F	n/a
ACT liquid QC	2 - 8°C	36 - 46°F	n/a
hCG Combo Rapid Test Kit	2 - 30°C	36 - 86°F	n/a
hCG Stanbio tri-level serum QC	2 - 30°C	36 - 86°F	n/a
iSTAT Analyzer	16 - 30°C	61 - 86°F	n/a

Item	Temp °C	Temp °F	Humidity
iSTAT cartridges	2 - 8°C 18°C - 30°C	36 - 46°F 64 - 86°F	n/a
Cobas e411	18°C - 32°C	64 - 89°F	20-80% non-condensing
PTH STAT reagent pack	2 - 8°C	36 - 46°F	
PTH STAT CalSet	2 - 8°C	36 - 46°F	
PTH SysWash	2 - 8°C	36 - 46°F	
PTH ProCell	15 - 25°C	59 - 77°F	
PTH CleanCell	15 - 25°C	59 - 77°F	
SysClean	2 - 8°C	36 - 46°F	
PTH CalCheck5	2 - 8°C	36 - 46°F	
PreciControl Varia	2 - 8°C	36 - 46°F	
Bio-Rad Liquichek QC	2 - 8°C	36 - 46°F	

D. New Device Validation:

The performance of a new NIST traceable/certified thermometer and hygrometer should be verified prior to being placed into use by comparing the new device reading to the current in use device reading.

1. Place both devices in close proximity to each other and allow all devices to equilibrate to the surroundings (approximately 2 hours).
2. Record both device readings on the *CCL-F074 CCL Thermometer/Hygrometer Record* found electronically under G:\Lab_Shared\ICU_ORLab\ FORMS and LOGS\Temperature Monitoring\CCL-F074 CCL Thermometer record.xlsx. A paper copy of this record along with device certificates and other pertinent information can be found in the Environmental Measuring Devices Notebook located in the Lab Manager's office.

E. Thermometer recalibration/recertification:

Thermometers must be recalibrated, recertified or replaced prior to the date of expiration of the guarantee of calibration or they are subject to requirements for noncertified thermometers.

1. Obtain the Pathology Department's NIST certified thermometer.
2. Place both devices in close proximity to each other and allow all devices to equilibrate to their surroundings (approximately 2 hours).
3. Read thermometer value from the new device. Read the thermometer from the NIST reference device.
4. The two readings should agree within +/- 2°C.
7. Record both device readings on the *CCL-F074 CCL Thermometer/Hygrometer Record* found electronically under G:\Lab_Shared\ICU_ORLab\ FORMS and LOGS\Temperature Monitoring\CCL-F074 CCL Thermometer record.xlsx. A paper copy of this record along with device certificates and other pertinent information can be found in the Environmental Measuring Devices Notebook located in the Lab Manager's office.

F. Digital thermometer and hygrometer device recalibration/recertification:

When purchased, digital devices are calibrated against NIST traceable instrumentation and are indicated to be within tolerance. Digital thermometers are not recalibrated or recertified. Instead, they are replaced prior to their certification expiration date by new NIST digital thermometers that are within calibration.

F. Troubleshooting: All temperature and humidity readings falling outside the acceptable range should be documented and circled in red. Perform a comparison between our back up devices and the SPOT system. To access the SPOT temperature records for a particular refrigerator, refer to CCL-QRG-005 *Looking up SPOT Temperatures and Pulling Reports*. If temperature or humidity exceeds the tolerance range, patient testing with affected reagents/devices must be discontinued until the issue is resolved.

1. **Room Temperature:** Adjust the thermostat accordingly and check the temperature again in approximately 15 minutes. If the temperature is still out of range, notify the Hospital Engineering Department and laboratory management. If the temperature exceeds the tolerance range, patient testing with affected reagents/devices must be discontinued until the issue is resolved. Action needs to be taken to resolve the issue or to relocate temperature affected items to another location. Document all correspondence and any action taken in the troubleshooting section of the Temperature and General Maintenance log.
2. **Humidity:** Notify the Hospital Engineering Department and laboratory management. If the humidity exceeds the tolerance range, patient testing with affected reagents/devices must be discontinued until the issue is resolved. Action needs to be taken to resolve the issue or to relocate humidity affected items to another location. Document all correspondence and any action taken in the troubleshooting section of the Temperature and General Maintenance log.
3. **Refrigerator Temperature:** Inspect the refrigerator for an open door. If the problem was an open door, check the temperature of the refrigerator again in approximately 10 minutes. If the temperature is still out of range access the SPOT system and evaluate the temperature history. If it looks like the temperature is not correcting or is climbing, notify the Hospital Engineering Department and laboratory management. Once the temperature reaches 2.5°C or 7°C, immediate action must be taken in order to save the contents of the refrigerator. The contents should be relocated to an alternative NIST certified monitored refrigerator. The Hematology and Chemistry Walk In refrigerators in the Core Lab can also be used. If items are not able to be relocated by the time the temperature falls below 2°C or rises above 8°C, the contents should be individually evaluated for acceptability. Document all calls and any action taken in the troubleshooting section of the Temperature and General Maintenance log. Disposition of all the contents of the refrigerator should be documented.

   OR Lab: The temperature of the triple door refrigerator in the OR Lab is monitored 24/7 by SPOT and also the Blood Bank's Rees monitoring system. In the event of an alarm, in addition to the SPOT alerts, the Blood Bank will notify the ICU Lab. ICU Lab staff should notify the laboratory manager on call for further instruction. SPOT will notify the Engineering Department.
4. **Thermometer fluid separation** may occur and is evidenced by single or multiple breaks of fluid in the fluid column. Refrigerator thermometers can be placed in a 37°C water bath for approx 15 minutes. For other techniques, refer to the Directions for Uniting Fluid Separation in the Temp-Chex Instructional Information sheet located in the Environmental Measuring Devices Notebook located in the Lab Manager's office. Thermometers that cannot be repaired should be taken out of use and replaced. Documentation should be made on the *CCL-F074 CCL Thermometer/Hygrometer Record* found electronically under G:\Lab_Shared\ICU_ORLab\ FORMS and LOGS\Temperature Monitoring\CCL-F074 CCL Thermometer record.xlsx.

3) Related Procedures:

Department of Pathology - Thermometer/Timer Guideline
Department of Pathology – Temperature & Humidity Monitoring for Reagents, Equip, Environment

4) **Attachments:** none

5) **Related Forms:**
   - *CCL-F074 CCL Thermometer/Hygrometer Record* found under G:\Lab_Shared\ICU_ORLab\ FORMS and LOGS\TEMPERATURE Monitoring\CCL-F074 CCL Thermometer record.xlsx
   - *CCL-F028 ICU Temperature and General Maintenance Log* found in the Current Year's Maintenance, QC and Patient Log Notebook
   - *CCL-F029 OR Temperature and General Maintenance Log* found in the Current Year's Maintenance, QC and Patient Log Notebook

6) **References:**
   - *CCL-QRG-005 Looking up Temperatures and Pulling a Detailed Report in SPOT - Quick Reference Guide.*
   - Note: This procedure is a consolidation of former procedures CCL-019 *Monitoring of Temperature Related Equipment* and CCL-027 *Monitoring of Laboratory Ambient Temperature and Humidity.*

7) **Review/Revision/Implementation:**
   - Review Cycle: All procedures must be reviewed at least every 2 years.
   - Office of Record: Department of Pathology, Critical Care Laboratory

8) **Previous Revision Date(s):** 05/03, 04/05, 03/11, 03/12, 6/14, 3/15, 2/17. 3/18

9) **Revised/Reviewed Dates and Signatures:**

Reviewed/Revision Date:_____ Signature:_____

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