Wake Forest Baptist Medical Center	Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas	Document Control Number:	N/A
		Effective Date:	2/15/2018
		Revised Date:	2/2019
		Contact:	Laboratory Compliance, QA, and Safety
CLIA Laboratory Medical Director Signature:		Date Approved:	3/12/19

1) **General Policy Statement:**

It is the policy of Wake Forest Baptist Medical Center (WFBMC) to monitor temperature and humidity for all temperature dependent reagents, equipment, and environments in all clinical sites according to manufacturer instructions. Each site will monitor temperature and humidity according to their individual processes, reagents, equipment, and environment as a measure of quality assurance. All staff members who perform testing at Wake Forest Baptist Health (WFBH) clinical sites will be educated and trained appropriately to monitor temperature and humidity as necessary for their site. The purpose of this procedure is to provide guidelines for staff and ensure they are compliant with state and federal regulations in monitoring temperature and humidity in order to assure optimal performance of reagents, instruments/analyzers, and equipment.

COM.30750 Temperature Checks Phase II:
Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer.

COM.30775 Temperature Range Phase II:
Acceptable ranges have been defined for all temperature-dependent equipment and environments (including test-dependent ambient temperature) in accordance with the manufacturer's instructions.

COM.30800 Temperature Corrective Action Phase II:
There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including evaluation for adverse effects.

a) **Scope:** All staff members at WFBH clinical sites who are educated and qualified to perform duties associated with their job descriptions are responsible for following this policy.
b) **Responsible Department/Party/Parties:**
   i. Policy Owner: Laboratory Compliance, Quality Assurance (QA), Safety and Point-of-Care Testing Manager
   ii. Procedure: All staff members who are educated and qualified to perform duties associated with their job descriptions at WFBH clinical sites shall adhere to processes outlined in this document.
   iii. Supervision: The Medical Director and/or laboratory director, as indicated on covering CLIA certificate, shall supervise the person(s) performing activities outlined in this document.
   iv. Implementation: Each applicable laboratory director and/or site manager is responsible for ensuring compliance with processes stated in this document.

2) **Definitions:** For purposes of this procedure, the following terms and definitions apply:
   a) **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
   b) **College of American Pathologists (CAP):** An association composed of pathologists, certified

by the American Board of Pathologists, who is responsible for enforcing standards of quality assurance through the accreditation of laboratories under authority of The Centers for Medicare and Medicaid Services (CMS).

c) **National Institute of Standards and Technology (NIST):** A measurement standards laboratory and a non-regulatory agency of the United States Department of Commerce.
d) **Quality Assurance (QA):** A system for ensuring a desired level of quality.
e) **Intelligent InSites (SPOT):** A WFBMC centralized temperature, humidity, and environmental continuous monitoring system.

3) **Procedure:**
   A. Temperature and humidity readings are checked and recorded at a minimum of once each day for all temperature dependent reagents, equipment, and environments, using either a calibrated Min/Max thermometer or electronically through SPOT. Manufacturer requirements must be followed. A complete inventory list along with the optimal temperature and humidity for all temperature dependent reagents, equipment, and environments is maintained and reviewed annually, see Attachment A.
      1. All temperature ranges are either specified by the manufacturer or set by the laboratory will be recorded and documented, indicating that an appropriate temperature is maintained and corrective action is taken when tolerance limits are exceeded.
         a. Monitoring may be achieved by using a Minimum/Maximum thermometer/hygrometer or through SPOT.
         b. If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures, both the low and high temperatures must be recorded as well as the actual temperature, see Attachment B.
            i. After reading and recording these 3 temperatures, the min/max thermometer must be reset. To reset the min/max thermometer, press and release the "reset" button once.
            ii. The lab manager or designee should review and sign all applicable temperature logs at least once per month.
         c. If using the SPOT system, emails and /or calls alerts are sent to key individuals within the department and the Service Response Center when readings fall outside of predefined limits of acceptability.
         d. When setting up a SPOT tag, ALL labs must set the SPOT alert range one degree prior to "going out" for a buffer. (Consult all manufacturer recommendations to set this appropriately.)
         e. This will be the "caution" temp on both the high and low end. This is necessary to allow time for decision making and/or movement of product.
         f. ALL SPOT tags/probes are to be set up to ALERT the department IMMEDIATELY in the case that a temperature or humidity reading goes into "caution" range.
         g. See section below for setting up SPOT alerts.
            i. The lab manager or designee reviews alerts and responds accordingly. Temperature alerts are rounded to the nearest whole number when evaluating an out of range event.
            ii. The lab manager or designee should review all applicable SPOT temperature logs at least once per month and document review in SPOT.
      2. In the event the temperature or humidity exceeds the manufacturer requirements, investigative and corrective actions will be taken and documented. Refer to the CAPA Procedure for any temperature and/or humidity variances.

B. Thermometric Standard Device
    1. An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards or traceable to NIST standards) is available and used when necessary.
        a. Minimum/maximum thermometers/hygrometers and SPOT are traceable to NIST standards.
    2. Thermometric standard devices, including SPOT tags, must be recalibrated, recertified, and/or replaced prior to the date of expiration of the guarantee of calibration. The WFBMC SPOT team will annually calibrate all SPOT tags; however, it is also the responsibility of the lab manager or designee to ensure that reagents, equipment and/or environments are not in use if the SPOT tag has expired.
    3. Thermometers and SPOT tags should be periodically evaluated for damage, and if damage is present, be rechecked before continued use. See SPOT set up and information below for troubleshooting contact information.

4) SPOT Set-Up and Information:

A. Intelligent InSites software (SPOT)
    a. URL: http://spot.wakehealth.edu (From a Wake browser, using either Internet Explorer or Google Chrome)
    b. Contact information: SPOTSupport@wakehealth.edu or 336-716-8899
    c. When requesting SPOT monitoring for reagents, equipment, and/or environment, contact SPOT Support with locations and temperature ranges for alerts (including optimal range and range tolerance), and alert contact names and contact information (required for 24/7/365 coverage to address and resolve out of range issues).
        i. There is a HELP tab on the Home page which accesses a Contact Support tab and a Help Center tab which has information to assist with daily InSites System use.
    d. When requesting SPOT access for new staff members, email a SPOT Support Specialist with their email information and the Tag numbers they will need to receive alerts on. SPOT Support will respond with username and password, a link to the SPOT website, and, if necessary, a tutorial of temperature monitoring.

5) Review/Revision/Implementation:

a) Review Cycle: Each 2 years
    i. All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Medical Director.
    ii. Review/sign-off can be completed by the designated section Medical Director or section manager in the following circumstances:
        - Biennial review
        - Minor document revisions

b) Office of Record: Laboratory Compliance, QA, Safety and Point-of-Care Testing

6) Related Policies:
CAPA (Corrective Action/Preventative Action)
Temperature Monitoring- MD Lab- Equipment Maintenance
Temperature Monitoring- Histology and OR Path Lab- Equipment Maintenance

7) References:
CAP Lab Accreditation Program Lab, General and All Common checklists, CAP, 325 Waukegan Rd, Northfield, Illinois 60093-2750, Revised 8/17/2016

7) **Attachments:**
Attachment A: Manufacturer Recommended Temperature/Humidity Requirement Log
Attachment B: Manual Temperature and Humidity Log

9) **Revision Dates:**
2/2018, 11/2018 (Added Content) , 2/2019 (Added Alert Stipulation)

Reviewed: _____ Date: _____

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Attachment A

Wake Forest Baptist Medical Center

Manufacturer Recommended Temperature/Humidity Requirement Log

Location	Instrument, Reagent or Environment	SPOT Monitored (Y/N)	SPOT TAG # and Expiration	Optimal Temperature Range (^{0}C or ^{0}F)	Humidity Range (%)

Attachment B

Wake Forest Baptist Medical Center

Manual Temperature and Humidity Log

MONTH/YEAR: **THERMOMETER ID:** **ROOM/LOCATION:**

DATE	TEMPERATURE Acceptable range:_____	Min Temp Reading Not below <_____	Max Temp Reading Not to exceed <_____	Humidity Acceptable range:_____	Acceptable? (Y/N) If no, CAPA #	Tech
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
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If reading is not within acceptable range, a CAPA is required. Values must be recorded each WORKING DAY. Additional monitoring provided by SPOT.