Wake Forest Baptist Health	Department of Pathology Thermometer/Timer Guideline	Document Control Number:	N/A
		Effective Date:	August 2018
		Revised Date:	N/A
		Contact:	Laboratory Compliance, QA, Safety and Point-of-Care Testing
CLIA Laboratory Medical Director Signature: 		Date Approved:	2/1/19
Name and Title: Dr. Gregory Pomper, CLIA Director			

1) **General Policy Statement:**

a) Scope: All WFBMC laboratory staff members who are educated and qualified to perform the duties in this procedure in regards to maintenance of laboratory thermometers.

b) Responsible Department/Party/Parties:

1. Policy Owner: Department of Pathology, Laboratory Compliance, QA, Safety.

2. Procedure: The Laboratory Director listed on the CLIA certificate (and/or their designee) will be responsible for the oversight of any areas performing these duties.

3. Supervision: The Laboratory Director as indicated on the CLIA certificate for the Laboratory, Laboratory Compliance and Wake Forest Baptist Department of Pathology.

4. Implementation: The Laboratory Director as indicated on the Waived CLIA certificate for the clinic/area performing the test and/or their designee.

2) **Definitions:** For purposes of this Policy, the following terms and definitions apply:
A. *NIST*- National Institute of Standards and Technology.

3) **Policy Guidelines:** Thermometers are used to measure the ambient temperature, and the temperatures of water baths, incubators, refrigerators, and freezers etc. Timers are used to measure time for various laboratory procedure. The purpose of this policy is to establish guidelines for staff to ensure tracability and/or calibration of thermometers and timers that are used in monitoring temperature and humidity in the laboratory setting as well as time intervals for laboratory procedures. This protocol also describes the procedure used to point-check the accuracy of laboratory thermometers and timers against a NIST theremometer and timer and the steps to take in case re-calibration is necessary.

A. NIST:
- Theremometer: At least two appropriate thermometric standard devices of known accuracy (certified to meet NIST Standards or traceable to NIST Standards) are available. Thermometric standard devices 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. Thermometers should be periodically evaluated for damage (e.g. separation of columns). Thermometers with obvious damage must be rechecked

before continued use. The NIST traceable thermometers should be certified annually by an outside agency.

- Timer: Multiple NIST certified timers of known accuracy are available throughout the laboratory. NIST certified timers 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 timers. Timers should be periodically evaluated for damage. Timers with obviouse dample must be rechecked before continued use.

B. Calibration of Non-NIST Glass Thermometers:
   1. All non-certified glass thermometers in use are calibrated against an appropriate thermometric standard device at least annually and before being placed into use.
   2. Follow all site specific procedures when placing a non-NIST thermometer into use, ensuring to include the following:
      a. All thermometers are calibrated using a NIST traceable thermometer.
      b. Allow the non-certified thermometer and the NIST thermometer to equilibrate with the solutions before taking the temperature reading. The temperature reading of the non-certified thermometer must fall within ±2°C of the NIST thermometer.
      c. Once the thermometer has passed calibration, a label displaying the thermometer "name/number" and date of calibration is placed around the top of the corresponding thermometer.
      d. If the non-certified theremometer does not pass calibration, it should be removed from the laboratory and marked as out of use.
      e. Record calibration information on the Laboratory Thermometers Calibration Log, or other site specific log.

C. Calibration of Digital Thermometers:
   1. On-site calibration of digital thermometers is not required.
   2. When purchased, digital thermometers are calibrated against NIST traceable instrumentation and are indicated to be within tolerance.
   3. Once the NIST calibration that originally came with the digital thermometer has expired, the thermometer will be discarded or labeled as reaserach only and no longer used in the clinical laboratory.
   4. These "disposable" thermometers are replaced by new NIST digital thermometers that are within calibration.

D. Calibration of Non-NIST Digital Timers:
   1. All non-NIST timers are calibrated against an appropriately calibrated timer annualy and before being placed into use.
   2. Follow all site specific procedures when placing a non-NIST timer into use, ensuring to include the following:
      a. All timers are calibrated using a NIST traceable timer.
      b. All timers must be calibrated for all time incriments used in the laboratory.
         i. Turn both timers on.
         ii. Set timers to specific length of time.
         iii. Simultaneously start both timers.
         iv. Record the full displayed time on the non-NIST timer. The reading must fall within 10% of the NIST timer.
      c. Once the timer has passed calibration, a label displaying the timer "name/number" and date of calibration is placed on the back of the non-NIST timer.
      d. If the non-NIST timer does not pass calibration, it should be removed from the laboratory and marked as "out of use".
      e. Record calibration information on the Laboratory Thermometer/Timer Calibration Log, or other site specific log.

4) 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

5) Related Policies: N/A

6) Governing Law or Regulations:
40 CFR 160.63 - Maintenance and calibration of equipment.
https://www.law.cornell.edu/cfr/text/40/160.63

7) Attachments:
A. Laboratory Thermometer/Timer Calibration Log

8) Revision Dates:

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Attachment A – Laboratory Thermometer/Timer Calibration

Laboratory Thermometer/Timer Calibration Log

Tolerance for Thermometer: ±2°C
Tolerance for Timer: 10% of set time

Traceable Thermometer Used: _____
Traceable Timer Used: _____

DATE	Instrument Name (Thermometer or Timer)	Reading	Within Tolerance? Y/N	Corrective Action	Initials

Manager Reviewed By:_____ Date: _____