



VETERANS ADMINISTRATION MARYLAND HEALTH CARE SYSTEM
BALTIMORE DIVISION
10 NORTH GREENE STREET
BALTIMORE, MD 21201

GEN00030.1

PATHOLOGY & LABORATORY MEDICINE SERVICE

Temperature monitoring version 1

General Procedure Manual # GEN00030

Purpose:

To establish a policy to ensure that laboratory defines the acceptable temperature ranges for temperature dependent equipment (e.g. refrigerators, freezers, incubators) units that contain reagent and/or patient specimens. Equipment must be monitored for temperature failures that could affect accuracy of test results.

Policy:

All sections must have an appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards or traceable to NIST Standards). The thermometric standard device must be recertified or replaced before calibration or certificate expires with new NIST certified thermometer, see Attachment A.

All refrigerators/freezers will be checked on a daily basis and the temperatures/humidity recorded on the daily log sheet that is located on or near the unit. The use of an automated temperature monitoring system is also acceptable and laboratory personnel have ongoing immediate access to the temperature data.

Each log sheet will define acceptable temperature range specific to the contents of the unit, i.e. reagents or patient specimens.

Scope:

All laboratory temperature dependent equipment

Procedure:

1. All temperatures on refrigerators, freezers, equipment, and storage rooms are monitored and recorded on a daily basis in each section of the laboratory.
2. Tolerance limits are posted on the individual pieces of equipment, room, or log sheet.



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3. If temperature are found to be outside of the acceptable range the following corrective action must be initiated:
 - a. Remove the contents of the unit and place them in an appropriate back-up unit.
 - b. Put in an electronic work request in Vista. Call Engineering at X7020.
 - c. Make a notation on the temperature chart what the problem was, the action taken, the date, and the tech's initials. Also, leave a visible note on the unit to notify others of the new location of the contents for that unit.
 - d. Notify the section supervisor or designee.
 - e. Once the problem has been resolved, the contents may be moved back into the equipment.
 - f. All reagents, calibrators, and quality control materials which may have been affected by the temperature change must be monitored for proper response; compared to the previous day's data, prior to the refrigeration unit malfunction.
 - g. Document all corrective action.

Attachments:

- A. Chemistry Procedure 1.11 Thermometer Standards and Calibration

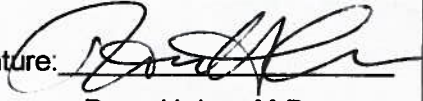
References:

College of American Pathologist, All common checklist 04/21/14

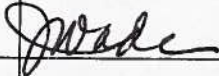


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DATE ADOPTED	Author of Procedure/Policy	Chief of Service
09/15/2015	Karla Peralta, BS MT (ASCP)	Signature:  Dong H. Lee M.D.

Policy/Procedure(s) Retired:		Date retired:
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Review Date	Version Number	Signature of reviewer
11/13/17	1	

REVISION HISTORY

Date revised	Revision #	Changes made	Signature
11/12/17	N/A	Reformatted, changed document control number from GEN00031	

Principle

Standardization and calibration of thermometers ensure appropriate temperature reading of the equipment used during processing and storage of reagents, controls, and specimens. Standardization and calibration of these thermometers should be performed at temperature close to the temperature the equipment is intended to maintain. This procedure must be performed prior to initial use of thermometers and yearly thereafter. Battery operated NIST thermometers (CAT # 4048) manufactured by Control Company, Friendswood, Texas, are sent back to the company as required for re-certification. Thermometers containing Mercury are not used in the chemistry laboratory.

Specimen Required: Not Applicable

Reagents, Instrumentation

1. Thermometers to be tested
2. NIST standard thermometer
3. Plastic bucket (Optional - dependent on range desired for testing)
4. Crushed ice (Optional - dependent on range desired for testing)
5. Waterbath set at 20C and 37C (Optional - dependent on range desired for testing)

Step-by-step Description

1. Collect all thermometers to be tested.
2. Obtain the NIST Standard thermometer from Chemistry or Blood Bank.
3. Record the thermometer number (attached to it) and thermal range of each thermometer on the Thermometer Quality Control Worksheet.
4. Determine the points at which each thermometer is to be tested.
5. If the range desired for testing includes a freezer, prepare an ice slush bath by adding crushed ice and water to a suitable plastic container. The temperature of this bath must read 0C on the NIST standard thermometer.
6. Immerse all thermometers to be checked at 0C and wait at least 10 minutes for the temperature to equilibrate. Recheck the bath temperature with the NIST standard thermometer, then read the temperature with each thermometer and record its result on the Thermometer QC Worksheet. Check the NIST standard thermometer frequently to ensure that the bath temperature does not change while testing is underway.
7. Either prepare a water bath at two different temperatures , e.g. 20C and 37C (testing at each temperature as in step 6 above.), or test at two different temperatures without a water bath if possible.

ATTACHMENT A

VAMC-Balt.-Chem

Thermometer Calibration

8. If the range of a thermometer is such that QC cannot be performed at one of the two temperatures, enter "NA" in the box designated for the reading of that temperature.
9. Every thermometer must read within +/-1C of the NIST standard. If any thermometer reads outside this tolerance limits, write "unacceptable" on its label and also on the worksheet and give the thermometer to a supervisor for disposal. All acceptable thermometers may be returned to use.
10. Document the date of testing and initial the Worksheet.

Alternative Method:

Place NIST standard thermometer with the non-certified thermometer being tested in the environment the non-certified thermometer will be used, whether it is a freezer, refrigerator, or room temperature. Let the NIST thermometer equilibrate for approximately 30 minutes before reading. Document the results as described in the previous procedure. This method takes a little longer to complete but it more accurately measures the non-certified thermometer performance for its intended use.

Record Review and Retention

Thermometer QC records are reviewed by the supervisor and kept on file for a minimum of five years. Example of Thermometer QC worksheet is attached at the end of this procedure.

References

1. Klein HG et al (eds): Standards, ed. 17. Bethesda, American Association of Blood Banks, 1996,
2. Vengelen-Tyler V et al (eds): technical Manual, Ed. 13, Bethesda, American Association of Blood Banks, 1999.

Thermometer Calibration Sheet

Date _____

Technologist _____

Reviewed _____

Standard Thermometer _____

Manufacturer _____

Serial Number _____

Test Thermometer Name	Test Thermometer ID Number	Test Thermometer Manufacturer	Test Temperature Observation	Standard (NBS) Temperature Observation	Conclusion