GUNDERSEN HEALTH SYSTEM®

Standard Operating Procedure

Subject	Temperature Recording and Maintenance of Temperature Dependent Equipment
Index Number	Lab-0265
Section	Laboratory
Subsection	Laboratory-General
Category	Departmental
Contact	Kamprud, Elizabeth A.
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References

Required document for Laboratory Accreditation by the College of American Pathologists (CAP), Centers for Medicare and Medicaid Services (CMS) and/or COLA.

Applicable To

Employees of GLMC clinical laboratories, Gundersen St. Joseph's Hospital laboratories, Gundersen Tri-County Hospital laboratories, Gundersen Boscobel laboratories, Gundersen Moundview Hospital and clinic laboratories and Gundersen Palmer Lutheran Hospital and Clinic laboratories.

Scope: This procedure applies to all laboratory sites, all temperature dependent equipment and environments (not instrumentation), with the exclusion of blood bank blood storage equipment, plasma thawers, and incubators. Temperature monitoring records, with corrective action, will have active review by lab leadership to ensure compliance with this policy.

Detail

PRINCIPLE:

To ensure the proper functioning of temperature dependent equipment and environments, such as refrigerators, freezers, heating blocks, water baths, incubators, and test-dependent ambient temperature, the temperatures will be taken daily, recorded and acted upon in the event of failure. In laboratories that are not operational every day, minimum & maximum temperatures will be recorded using a device designed for monitoring temperatures over a period of days.

Implementation

The temperature of each refrigerator, freezer, any walk-in refrigerator/freezer, or ambient/room temperature that affects testing should be taken daily, recorded, and initialed on an appropriate temperature log. The temperatures of heating blocks, water baths, and incubators or ovens (when temperature control is necessary for a procedure) should be taken and recorded on each day of use. Record temperature readings on appropriate form. Acceptable ranges must be defined for all temperature dependent equipment or environments, in accordance with the manufacturer instructions and must be listed on the form.

The laboratory uses a few types of temperature monitoring devices. Besides physically taking the temperature visually each day, Minimum/Maximum thermometers may be used in areas that do not provide testing each day (Referral Lab, Clinic and regional locations). An electronic monitoring system is used for monitoring the walk-in refrigerators (Microbiology, Chemistry and some Regional locations) and the refrigerators in the Courier room on first floor of the La Crosse Clinic. The La Crosse 4NW lab also has an alarm board that will sound if temperatures go out of range for some units in Blood Bank, Histology,

Immunology and Chemistry. If problems occur after normal business hours – the Manager on call should be notified.

1. Refrigerators, Freezers, Incubators; there must be evidence of corrective action taken if unacceptable temperatures are obtained on any piece of temperature dependent equipment, including evaluation for adverse effects. If the temperature does not fall within the acceptable range, the temperature should be retaken in one hour.
    a) If the temperature still does not fall within the acceptable, range, remove the contents to a suitable refrigerator, freezer or incubator (as appropriate).
    b) When the acceptable range has been exceeded (refrigerator, freezer or incubator), any stored specimens must be evaluated and any untested samples with orders for labile constituents must be redrawn or recollected. Any stored reagents, kits, calibrator or quality control materials will be checked to confirm viability based on the test or product. Refer to the test procedure and consult with technical leader, supervisor, or manager to determine a documented plan of verification.
    c) If after a period of time, the equipment is unable to achieve or maintain an acceptable temperature follow protocol for requesting repair or replacement. A maintenance request can be placed on Gladiator, Popular Links, Requests for Service/Work Orders or contact your Facilities Services if Gladiator is not available. Ensure that a stable, acceptable temperature is achieved before returning contents.
    d) Document all unacceptable conditions and corrective actions taken on the back of approved temperature form.
    e) Notify Technical Leader, Supervisor, or Manager of a condition and action taken. Communicate status between staff and shifts.
2. Heating Blocks, Water Baths: If unacceptable temperatures are obtained, do not use the equipment for testing. If the temperature does not fall within the acceptable range, the temperature should be retaken in one hour.
    a) If the temperature still does not fall within the acceptable range, remove the piece of equipment from service.
    b) Follow site protocol for requesting repair or replacement.
    c) Document all unacceptable conditions and corrective actions on back of approved temperature form.
3. In areas where room temperature tests are performed or reagents are affected by temperature or humidity, the monitor must be recorded each day of testing. Record temperature or humidity on approved form. Document all corrective action on the back of the form.
4. Vacutainer Blood Collection Tubes are to be stored at optimal temperatures ranging from 4°C to 25°C. However, BD sent a letter dated Nov. 19, 2013 stating the following excerpt: "*BD Vacutainer Tubes are designed (and shelf life is established) to tolerate and allow for exposure to temperature conditions that may be typically encountered within the global distribution chains year round. Performance characterized by additive stability and maintenance of required additive-to-blood ratio, have been evaluated on the subject products in controlled temperature exposure studies. These studies indicate that the products will perform as intended after exposure of up to 4 weeks at temperatures ranging from -30°C to 40°C*". Extended exposures (beyond 10 days) to temperatures beyond 40°C are not recommended for gel tubes (SST and PST). In summary, BD designed these products to

tolerate these typically encountered temperatures. The letter can be viewed as an attachment to this policy.

5. Temperature recording, Blood Bank. Refer to standardized blood bank quality control procedures and forms per location. (LaCrosse Hospital Policy is: Lab-3522 with attached forms),
6. Maintenance: Refrigerators and Freezers.
   a) All temperature related issues are to be documented on the back of the form.
   b) Any spills must be cleaned up immediately with Oxivir TB or approved cleaning solutions, wearing appropriate personal protective equipment.
   c) Routine scheduled maintenance is performed by Facility Operations or designee.
   d) Documentation of maintenance will reside in Facility Operations, Lab Equip Records share file or onsite.
7. Maintenance: Incubators, Heating Blocks, and Water Baths.
   a) Turn off and, if possible, unplug the unit.
   b) Remove contents of the unit and place the contents in an alternate monitored incubator, heating block or water bath.
   c) Wipe the interior and exterior of the unit with 10% bleach or approved detergent solution. Use detergent for dirt and bleach solution for biological contamination.
   d) Dry the unit.
   e) Plug in and turn the unit on.
   f) When the temperature is within acceptable range, restock the contents.
   g) Check the temperature of the unit within one (1) hour of restocking the contents to verify that the proper temperature is being maintained. If the temperature is not acceptable, troubleshoot and assess quality of contents.
   h) Document incubator, heating block or water bath maintenance on appropriate log per section.
8. Verification of Thermometers
   a) An appropriate thermometric standard device of known accuracy, guaranteed to meet NIST Standards, is available.
   b) All non-certified thermometers in use are checked against a standard device before initial use. (excluding Blood Bank)
   c) All non-certified thermometers in use, including blood-warmer thermometers, are checked before being placed in service, and at least annually thereafter, against an appropriate standard device.
   d) Thermometers used to measure room temperature must be verified at least every two years, or replaced.

REVIEW & CHANGES:

This document and all attached forms should be reviewed optimally on an annual basis, with 2 years as the maximum review date. Review will be done by the Technical Leader, Supervisor, Manager, Medical Director or designated person. Changes require retyping document or form and review by the Medical Director.

REFERENCES: N/A