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Beaumont

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Document Contact	Kimberly Cole: Spec, Operations
Area	Laboratory-Operations
Applicability	Dearborn, Taylor, Trenton, Wayne

Temperature of Laboratory Refrigerators, Freezers, and Storage Devices

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To establish guidelines and procedure for monitoring the proper storage temperature of laboratory reagents, controls and testing materials thereby assuring the overall quality of our testing.

II. POLICY:

A. The temperature will be read and recorded a minimum of once daily for each day of operation on designated refrigerators, freezers, and any other temperature regulated devices within in the department.

B. When acceptable temperature ranges for temperature dependent equipment and environmental temperatures are exceeded an evaluation of the contents must be performed to evaluate adverse effects.

C. Thermometers are traceable to National Institute of Standards and Technology (NIST) standards. Expiration of calibration dates will be reviewed semiannually by the Laboratory Managers, Supervisors, or Lead Medical Technologist.

D. Refrigerator and freezer temperatures must be read and recorded each day of operation.

E. Temperature charts will be reviewed monthly by a Lead Medical Technologist, Manager, or Supervisor and documented.

III. GENERAL INFORMATION:

A. Read the thermometer.

B. Record the current temperature (including minimum & maximum if applicable) on the appropriate labeled device log located on/near the device.

C. If a minimum/maximum thermometer is used, reset the thermometer by pressing the reset button.

D. Verify that the temperature is within the acceptable range as stated on the specific device temperature log.

E. In the event that temperature is found outside of the acceptable range

    1. If temperature deviation is slight and/or cause is known (i.e. door open too long, thermostat set incorrect, probe not centrally placed), minimize access to the device for at least one hour. Repeat reading. If there has been no change, proceed to step E 2.

    2. Remove reagents, samples and contents from the malfunctioning device and place in alternative storage device (i.e. another refrigerator/or freezer) immediately.

        a. Quarantine/Label these contents as “Do not use” until the contents are evaluated for any adverse effects or decreased stability. (see step 6)

        b. Temperatures should be taken on the alternative device and documented as in this procedure for as long as reagents/controls/samples are stored inside.

    3. Notify Clinical Engineering/Facilities Department, Manager and/or designee of malfunctioning equipment.

    4. Record corrective actions taken under comment section of applicable temperature/ maintenance log. Suggestive corrective action may include any of the following:

        a. Thermostat Adjustment

        b. Defrosting/ Cleaning

        c. Proper placement of probe

        d. Service and Repair

    5. Once malfunctioning device is repaired or adjusted, check and record the temperature.

    6. Before quarantined reagent/control inventory can be returned for use, they must be evaluated for adverse effects as follows:

        a. Check one bottle/pack for each lot/shipment of reagents by testing with appropriate control.

        b. If control results are within acceptable ranges, the contents may be taken out of “quarantine”.

c. If control results are not acceptable do not use reagents/control material and notify manager.

d. Control/Calibrators used on automated equipment must pass manufacturer's calibration criteria.

e. Verify stability requirements of any stored samples. Those that fall outside are to be discarded and reported to manager for follow up and incident reporting.

f. The results of this evaluation are documented using "Temperature Failure Evaluation and Report Form"

F. Results of temperature checks are reviewed and documented monthly by Lead Medical Technologist, Manager, Supervisor, or designee.

IV. PROCEDURAL NOTES:

A. For those departments not staffed seven days a week, including Cytogenetics, Histology, Cytology, and the Patient Service Centers (PSC) minimum and maximum thermometer readings **must be utilized.** Prior to the department being closed daily, the temperature should be taken and the thermometer should be reset. On the following day that the department is open (after a day the department is closed such as a weekend or holiday), both the minimum and maximum temperature should be recorded in the space for the day(s) the department was closed. If temperatures fall out of range during closure, the department manager will make the decision on the integrity of the refrigerated products and document corrective action accordingly on the reverse side of the log sheet for regulatory documentation purposes. If products fall out of pre-established manufacturer temperature ranges in comparison to the min/max readings, they will be discarded immediately.

B. Those devices that are used to store Glucola for Tolerance testing and orange juice for patient consumption are not required to use min/max thermometers, nor is documentation of ambient temperature inside or out of the refrigerator required for these units.

Attachments

Temperature Failure Evaluation and Documentation Form

Approval Signatures

Step Description	Approver	Date

Medical Directors	Jeremy Powers: Chief, Pathology	5/13/2024
Medical Directors	Muhammad Arshad: Chief, Pathology	5/7/2024
Policy and Forms Steering Committee Approval (if needed)	Kimberly Cole: Spec, Operations	4/23/2024
Site Laboratory Leaders	Christopher Ferguson: Dir, Lab Operations B	4/22/2024
	Kimberly Cole: Spec, Operations	4/22/2024

Applicability

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