BEST PRACTICES GUIDE FOR SELECTING LABORATORY FREEZERS

Important guidelines to consider when purchasing a freezer for storage of patient specimens and reagents.

BY HELMER SCIENTIFIC

IMPORTANT GUIDELINES TO CONSIDER

To ensure compliance with the College of American Pathologists (CAP) All Common Checklist, and to implement best practices for reagent storage, there are important considerations for the design and features of a Laboratory Freezer. The following checklist can help ensure all critical aspects are considered when selecting a freezer for storage of reagents and patient specimens.

COM.30250 Reagent Handling/Storage - Waived Tests, Phase II

For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc.

NOTE: There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.

If the laboratory identifies a problem with a reagent that was used for patient testing (eg, expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

Evidence of Compliance:

Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring.

Considerations for Implementation

- ☐ The freezer should be designed to maintain the temperature range listed on the manufacturer’s instructions
- ☐ To support quick temperature recovery after door openings, the freezer should utilize forced-air circulation
- ☐ For storage within the range of -15°C to -30°C, the freezer should be capable of automatically defrosting the refrigeration system with only a minimal temperature increase

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COM.30350 Reagent Storage and Handling, Phase II

All reagents and media are stored and handled as defined by the laboratory and following the manufacturer's instructions.

NOTE: Reagents and media must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded.

If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.

If the laboratory identifies a problem with a reagent that was used for patient testing (eg, expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

Evidence of Compliance:

Records of reagent and media storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring.

Considerations for Implementation

- ☐ The freezer should be designed to maintain the temperature range listed on the manufacturer’s instructions
- ☐ To support quick temperature recovery after door openings, the freezer should utilize forced-air circulation
- ☐ For storage within the range of -15°C to -30°C, the freezer should be capable of automatically defrosting the refrigeration system with only a minimal temperature increase

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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.

NOTE: Temperature-dependent equipment (eg, refrigerators, freezers, incubators) containing reagents and/or patient/client specimens must be monitored daily, as equipment failures could affect accuracy of patient/client test results. Items such as water baths and heat blocks used for procedures need only be checked on days of patient/client testing. For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature.

If specific instruments, equipment, kits, or supplies have specified ambient temperature ranges for proper operation, storage, or use, there must be records that the specified ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.

Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording the temperature(s) must be recorded (initials of the individual are adequate).

If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the system.

If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (eg, laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised. Storage conditions must remain within the specifications of the manufacturer of the reagent or control. Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer. Thermal containers within the freezer may be used. Patient samples may be stored in a frost-free freezer only if protected from thawing. The laboratory must retain records showing that the temperatures stay within the defined range.

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Considerations for Implementation

- ☐ The freezer constantly monitors the temperature inside the cabinet
- ☐ For storage within the range of -15°C to -30°C, a frost-free freezer should be capable of automatically defrosting the refrigeration system with only a minimal temperature increase
- ☐ High temperature alarms activate if the temperature exceeds the alarm limit
- ☐ The freezer monitors and activates alarms for other factors that could impact the temperature, such as door openings and power failure
- ☐ A freezer that includes minimum/maximum temperature display and reset functionality provides an additional level of continuous monitoring
- ☐ Additional freezer features, such as an onboard temperature graph, event log, and downloadable temperature and event files can help support these requirements

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.

Evidence of Compliance:

Temperature log or record with defined acceptable range

Considerations for Implementation

- ☐ A freezer that features a downloadable temperature graph showing the defined high and low limits can help support this requirement

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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.

NOTE: If acceptable temperature ranges are exceeded, stored reagents, controls, calibrators, etc. must be checked to confirm the accuracy or quality of the material before use, with records retained. The check should follow a defined procedure.

Considerations for Implementation

- ☐ A freezer that features a downloadable event log with event acknowledgement can help support this requirement

Additional Considerations for Best Practices

- ☐ The freezer's storage configuration supports organization for efficient stock rotation and better inventory management
- ☐ The freezer is designed with self-closing doors to prevent temperature excursions caused by users inadvertently leaving the door open
- ☐ The freezer should be designed with remote alarm contacts and a probe port to enable monitoring and recording with 3rd party systems

Laboratory Freezers from Helmer Scientific are designed for the critical demands of storing reagents and patient specimens. The use of Helmer freezers supports clinical laboratories in their efforts to comply with regulatory requirements. They are also designed to facilitate best practices for laboratory storage.

Reference: CAP All Common Checklist, College of American Pathologists, CAP Accreditation Program, 2020

About the Author:

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Helmer designs, manufactures, and markets specialized medical and laboratory equipment to customers in more than 125 countries. With an extensive background in Helmer products, Colleen's focus is on the Clinical Laboratory and Blood Bank segments.