

MDHHS Guidance on Temperature Monitoring

This handout provides guidance on temperature monitoring for all providers. Temperature monitoring is imperative to effective vaccine management. The Michigan Department of Health and Human Services (MDHHS) follows recommendations set forth by the Centers for Disease Control and Prevention (CDC). Michigan Vaccines for Children (VFC) providers **must** follow additional guidelines outlined in the Michigan VFC Provider Manual found at: www.michigan.gov/vfc. Refer to the manufacturer's product information for the most up-to-date storage equipment guidance.

Storage Unit Temperatures

- Required temperature ranges for storage units are:
 - Refrigerator should maintain temperatures between 36.0°F and 46.0°F (2.0°C and 8.0°C); aim for 41.0°F (5.0°C)
 - Freezer should maintain temperatures between -58.0°F and +5.0°F (-50.0°C and -15.0°C)
 - Set at the factory-set or midpoint temperature to assure appropriate frozen temperatures
 - Ultra-Cold freezers should maintain temperatures between -130°F and -76°F (-90°C and -60°C)

Safeguard Temperatures Inside Storage Units

- Only the vaccine coordinator or back-up coordinator should adjust the temperature
- Place warning signs on each unit stating, "Do not unplug!"
 - Signs are available in the CDC Storage and Handling Toolkit:
www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- Place water bottles on the top shelf, floor, and in the door racks of vaccine storage units to help maintain stable temperatures that might be disrupted by frequently opening and closing unit doors. (Note: Water bottles are sometimes not recommended for use in ultra-cold freezers or in all purpose-built or pharmaceutical-grade units – review manufacturer guidance for all your storage equipment)
- Limit the number of times the unit door is opened and check the door during the day and at the end of each workday to ensure it is closed tightly and sealed
- Remove any deli, fruit, and vegetable drawers from the storage unit to allow room for water bottles (do not store any vaccine in these areas)
- Be familiar with manufacturer freezer defrost guidance; if using a manual defrost freezer, develop a plan for defrosting the unit while appropriately storing and monitoring vaccine in another freezer
- Thermometer placement is **important**; place thermometer probe in the center of the unit surrounded by the vaccines
- Do a daily visual inspection to ensure temperature monitoring device is properly positioned and functioning

Digital Data Loggers

- It is required for VFC providers to only use calibrated digital data loggers (DDLs) with a Certificate of Traceability and Calibration Testing that has not expired
- CDC and MDHHS recommend digital data loggers (DDLs) with:
 - An active temperature display that can be easily read from the outside of the unit
 - The capacity for continuous monitoring and recording capabilities where the data can be routinely downloaded and analyzed for review

- Must download and save data weekly and anytime an alarm is triggered, or out-of-range temperature is identified
- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures display
- Low battery indicator
- Accuracy of +/- 1°F (+/- 0.5°C) or less
- Logging interval that can be programmed by the user to measure and record temperatures at least every 30 minutes (every 5 minutes is highly recommended)
- Use of buffered probe that best reflects the temperature of the vaccine (e.g., buffered with glycol, glass beads, sand, or Teflon®)
 - Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested
- Some Pharmaceutical Purpose-Built Units may have a temperature device like digital data loggers (DDLs). Before utilizing for primary temperature monitoring/documentation, this must be approved by the LHD. If not approved, a separate DDL must be utilized
- For an Ultra-Cold freezer, it is essential to use an air-probe, or a probe designed specifically for ultra-cold temperatures

Monitor Temperatures

- Assess and record current temperatures **twice** a day at minimum on a temperature log. Once in the AM when clinic opens, before vaccinating any patients, and 30-60 minutes before leaving for the day, ensuring temperatures are maintained and consistent
 - **AM Check:**
 - **Check and record** current temperature (with decimal point, including the tenth's place (i.e., 40.1°F), do not round up or down), initials, and **exact** time; assess if temps are in range; if out of range act immediately; follow your Emergency Response Plan
 - **Check and record** min/max reading, assess if all temps are in range; if min/max is out-of-range, an excursion occurred at some point since last check—you must act immediately; follow your Emergency Response Plan
 - When using a DDL: assess, record, and **RESET** (if required) the minimum/maximum temperatures every AM
 - For further guidance, review “MDHHS Digital Data Logger Tip Sheet”
 - **PM Check:**
 - **Check and record** current temperature (with decimal point, including the tenth's place (i.e., 40.1°F), do not round up or down), initials, and **exact** time; assess if temps are in range: if out of range act immediately; follow your Emergency Response Plan
- Post logs on each storage unit. If a reading is missed, leave a blank entry in the log. Such entries should be distinguished from entries in which the DDL failed to display a reading
- Download and assess stored temperature data from the DDL weekly and with every temperature excursion
- All temperature data should be stored for at least 3 years, including temperature logs and .txt files

See CDC's "Vaccine Storage and Handling Toolkit" at www.cdc.gov/vaccines/hcp/admin/storage/index.html. MDHHS guidance for vaccine storage and handling can be found at www.michigan.gov/vfc.

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Out-of-Range Temperatures

- If **any** temperature monitoring device shows an out-of-range temperature, take **IMMEDIATE** corrective action
 - Notify primary and backup coordinator; determine the cause, correct it, and document actions taken
- Follow your Emergency Response Plan; for further guidance, refer to the MDHHS and CDC websites at www.michigan.gov/vfc and www.cdc.gov/vaccines/recs/storage
- If vaccines are involved in a temperature excursion, immediately separate all compromised vaccine in a separate storage container, mark “Do Not Use,” and place in the proper storage unit at manufacturer recommended temperatures
- Do **not** discard vaccine; **ALWAYS** call the vaccine manufacturer and contact your LHD if VFC vaccine is involved

Key Points to Remember

- VFC providers are required to follow the guidelines within the Michigan VFC Provider Manual at www.michigan.gov/vfc
- Routine monitoring will identify out-of-range temperatures quickly and allow you to take immediate action, preventing loss of vaccines and potential revaccination of patients
- Temperatures can vary in storage units based on contents, how often the door is opened, and power interruptions
- Thermometers not recommended by CDC are alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial; bi-metal stem thermometers; food thermometers; chart recorders; infrared thermometers; and non-calibrated thermometers
- Remember storage units can slowly become non-functioning; if thermostat must be turned colder and colder or you notice a pattern in temperature data, it may be time to look at new equipment
- Consider an alarm/notification system in addition to DDLs; these systems alert staff to temperature changes, however, should never be used as the control temperatures for vaccine temp logs documentation
- All temperature data, including temperature logs, should be stored for at least 3 years
- Know your resources; review [MDHHS VFC Provider Manual](#) & [CDC’s Storage and Handling Toolkit](#) for current information
- Complete the “Checklist for Safe Vaccine Storage and Handling” at the Immunization Action Coalition at www.immunize.org to be sure you are safeguarding your vaccine supply