

MDHHS Guidance on Vaccine Storage and Handling

It is essential to store and handle vaccines correctly. Too much exposure to heat, cold, or light can damage vaccines, resulting in loss of vaccine potency. By following the three main elements below, you can assure vaccines are stored and handled properly and that when administered, the vaccines will be effective in preventing diseases. Always refer to the manufacturer's product information for the most up-to-date storage equipment guidance. Michigan Vaccines for Children (VFC) providers are required to follow additional guidelines outlined in the Michigan VFC Provider Manual, which can be found at: www.michigan.gov/vfc.

1. General Vaccine Management

To ensure the safety of vaccines, the following equipment is recommended:

- Pharmaceutical-grade or purpose-built refrigerator and freezer
- Commercial-Grade Units (Stand-Alone)
- Digital data logger (DDL) with a current and valid certificate of calibration for each vaccine storage unit and at least one backup in case of a malfunctioning device or to be used while primary device is out for re-calibration
- If you have an ultra-cold freezer, use a DDL with an air-probe or a probe designed specifically for ultra-cold temperatures
- A portable vaccine refrigerator/freezer or qualified container and pack-out (i.e., Cool Cubes, TempArmour, etc.) for transport of refrigerated/frozen vaccine
- It is not recommended to transport varicella-containing vaccine, but if it must be transported use a portable freezer; for detailed transport guidance, see "MDHHS Guidance on Vaccine Transport"

NOTE: Your units must have room to store the largest inventory a provider may have, without crowding (e.g., flu season, back-to-school, etc.)

To ensure the safety of vaccines, the following equipment is not recommended:

- Do **NOT** store any vaccine in a dormitory or bar-style refrigerator/freezer unit under any circumstances
- A household combination refrigerator/freezer is NOT recommended. ONLY the refrigeration section of a combination household unit can be utilized for vaccine storage, and ONLY as long as temperatures are maintained in both sections. A separate stand-alone freezer must be utilized for frozen vaccine

2. Accurate Vaccine Inventory Management

Temperature Documentation and Ranges:

- Refrigerators 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)
- Standard freezers should maintain temperatures between -58.0°F and +5.0°F (-50.0°C and -15.0°C)
- Ultra-Cold freezers should maintain temperatures between -130°F to -76°F (-90°C to -60°C)
- Check and record current refrigerator and freezer temperatures twice a day
 - In the am when the clinic opens
 - Check and record minimum/maximum temperatures from each DDL at the start of each workday
 - Some devices require that min/max be physically CLEARED after each assessment of min/max (ex: VFC5000). Please ensure you understand these intricacies of your device features

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- Some devices automatically “clear” or reset the min/max at a time period such as at midnight. Ensure that your staff toggle back to review all data since last min/max was assessed
 - In the pm, attempt to check 30-60 minutes before leaving for the day
- Document on a temperature log for all vaccine storage units:
 - Temperatures: with decimal point, including the tenth’s place (e.g., 40.1°F), do not round up or down
 - The exact time, and
 - Staff initials
 - 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
- Keep the current log posted on each storage unit; keep temperature data for 3 years
- Download digital data logger at least weekly and save the files; immediate download and review must also occur anytime an out-of-range temperature is identified

Storage Unit Setup:

- Good air circulation on the outside of the unit is important; place storage units in a well-ventilated area, leaving space between the unit, ceiling, and any walls
- Nothing should block the cover of the motor compartment
- The unit should be firm and level
- Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit
- Most units work best in an area with standard room temperatures, 20°C to 25°C (68°F to 77°F)
- Check the manufacturer-supplied owner’s manual for additional guidance on placement and spacing

Power Supply:

- Use an outlet cover to prevent the unit from being unplugged
- Post “DO NOT UNPLUG” warning signs at outlets and on storage units
- Label fuses and circuit breakers to alert people not to turn off power to the storage units
- **Do not use** power outlets that can be tripped or switched off (e.g., multi-outlet power strips, built-in circuit switches with a reset button)
- **Do not use** extension cords

Organizing and Storing Vaccine in Storage Units:

- Store vaccine in the original box with lids closed to protect from light until it is ready to be used
- Clearly label the bins and/or shelves to decrease errors; be sure to clearly differentiate between VFC and privately purchased vaccine if you are a VFC provider (Private stock vaccines must be stored, handled, and inventory managed in the same manner as VFC)
- Place vaccines and diluents in the center of the storage unit in rows, with 2-3 inches from walls, ceiling, floor, and door allowing space for air circulation
- Avoid storing vaccines and diluents on the top shelf near cooling vent
- Do not store vaccines in deli, fruit, or vegetable drawers or in the door (remove all drawers from unit)
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates
- Do not pack a storage unit too tightly; allow space for good air circulation

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- Place water bottles against walls, back, floor, and in the door to help stabilize temperatures
 - Note: water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units; always follow the manufacturer's guidance
- Place buffered probe of the DDL in the center of the unit with the vaccines surrounding it with the display placed on the outside of the storage unit
- Food and beverages should never be stored in the unit with vaccines
- Store diluent with corresponding vaccine
 - Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness; even if diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it
 - Refer to manufacturer's package insert on how to store and handle supplied diluent
 - **NEVER** store diluent in the freezer

Out-of-Range Temperatures:

- Take **IMMEDIATE** action and notify the vaccine coordinator, backup coordinator or supervisor whenever an alarm or temperature excursion is noticed, and document actions taken
- Label the exposed vaccines "DO NOT USE," store at manufacturers recommended temperature, and place in a separate container apart from other vaccines in the storage unit (**do not discard these vaccines or remove from the storage unit unless the storage unit is not capable of maintaining appropriate temperatures and you need to relocate your vaccine**)
- Contact your LHD and vaccine manufacturer for further guidance on the viability of the affected vaccine; **be prepared to provide documentation of the event (e.g., data logger temperature data) to ensure you receive the best guidance**
- **Never** allow vaccines to remain in a nonfunctioning unit for an extended period; if you believe the unit has failed, begin to implement your [emergency response plan](#)

Vaccine Deliveries:

- Ensure vaccines are delivered during office hours. Revise your [shipping hours](#) in MCIR for the holidays if you will be closed
- Providers must never refuse a vaccine delivery
- Never leave a vaccine shipping container unpacked and/or unattended
- All staff who might accept deliveries must be trained and aware of the importance of maintaining the "cold chain"

Unpacking Deliveries:

- Examine the shipping container and vaccines for signs of physical damage
- Check the contents against the packing slip to be sure they match (maintain packing slips for three years)
 - For varicella-containing (frozen) vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date
- Store vaccines at the recommended temperatures **IMMEDIATELY** upon arrival
- If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents
 - Diluents for varicella-containing (frozen) vaccines are stored in the lid of shipping containers; upon receipt, store diluent according to manufacturer's guidance, do **NOT** freeze diluent

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- Check the cold chain monitor (CCM) for any indication of a temperature excursion during transit; note: CCMs are for one-time use and should be thrown away after being checked, a CCM may not be included when vaccines are shipped directly from the manufacturer
- If there are discrepancies between the contents and the packing list or other concerns about shipments:
 - **Private vaccine:** contact the manufacturer
 - **VFC vaccine:** contact your LHD within 1 hour of receipt of shipment

Emergency Plan:

- Develop an emergency response plan for emergency situations such as equipment malfunctions, power failure, or natural disasters; an emergency plan is critical in protecting vaccine supply and ultimately your patients
- Ensure 24-hour access to the building where vaccines are stored, and designate responsible personnel
- Set up a system to notify the vaccine coordinator and/or backup coordinator during power outages
- Identify steps to assure proper storage and handling of vaccines during an emergency
- Identify an alternate power source (generator) if the clinic does not have one, or identify alternate storage units or facilities (nearby hospital, pharmacy, other provider's office); identify procedures that allow 24-hour access to alternate facilities
- Keep a portable vaccine refrigerator or qualified container and transport supplies in the office
- Follow and complete the Emergency Response Plan (post on refrigerator and inside the transport cooler)
- Do **NOT** automatically discard the vaccine that has been compromised, label "DO NOT USE" and store at the manufacturers recommended temperature in a separate storage container
- Communicate the vaccine management plan and where to find it to all staff

3. Well-Trained Staff

Staff Training:

- All staff who receive vaccine deliveries, handle vaccines, and/or administer vaccines should be familiar with the facility's vaccine storage and handling policies and procedures
- Designate a person to be the primary vaccine coordinator and backup coordinator
- Conduct training in the following situations:
 - New employee orientation
 - Annually as a refresher for all staff involved in immunization activities
 - When new vaccines are added to the inventory
 - When recommendations are updated
 - When new vaccine storage equipment is purchased