COVID-19 Vaccine Storage and Handling Guidance

Tennessee Vaccine-Preventable Diseases and Immunization Program

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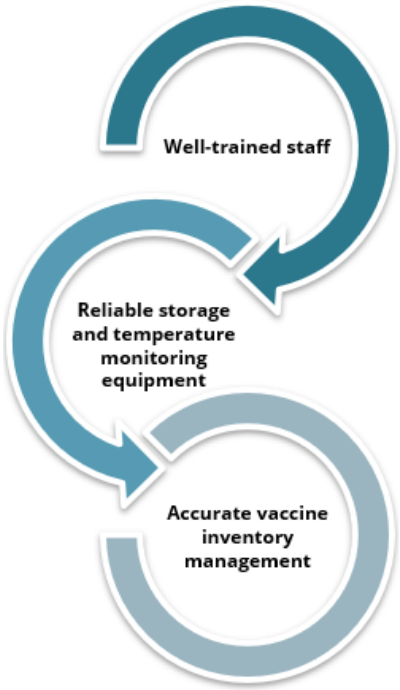
Section One: Introduction

Vaccines must be stored and handled properly in order to prevent and eradicate vaccine-preventable diseases. Failure to properly store and handle vaccines results in financial loss, revaccination, and reduced public confidence in vaccines. Vaccines that have been exposed to improper conditions have reduced potency, resulting in inadequate immune response and poor protection against disease.

The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the **vaccine cold chain**. The cold chain begins with the storage unit at the manufacturing plant, extends to the transport and delivery of vaccine and storage at a clinic, and ends with administration of the vaccine to a patient.

An effective vaccine cold chain relies on…



Every time a vaccine is exposed to improper conditions (e.g., overexposure to heat, cold, or light), its potency is reduced. If a refrigerated vaccine is exposed to freezing temperature just once, its potency can be destroyed.

This document is designed to assist providers in properly storing and handling federal COVID-19 vaccine as part of the Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) COVID-19 Vaccination Program. It is a modified version of the CDC's Storage and Handling Toolkit, which you are highly recommended to review in order to fully understand the breadth of information, recommendations, and resources available to assist you in properly storing and handling your vaccine supply. CDC's You Call the Shots Module Ten is also a recommended training for understanding vaccine storage and handling.

Always refer to the manufacturer information and package inserts or contact the manufacturer directly for detailed storage and handling protocols for individual vaccines.

The Tennessee Department of Health are not authorized to assess, validate, verify, or endorse products or services of private companies. When purchasing storage and handling equipment, keep in mind that products labeled as "CDC-compliant" have not been reviewed by the CDC or the Tennessee Department of Health.

Always contact the Tennessee Vaccine-Preventable Diseases and Immunization Program if you are unsure if a specific product meets requirements.

Section Two: Staff and Training

Clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should be maintained near vaccine storage units where staff can find them. Additionally, well-trained staff are necessary for implementing SOPs at the facility. Staff should be trained on storage and handling procedures as part of new employee orientation, annually, whenever new vaccines are added to the inventory, and whenever storage and handling recommendations change. When training is completed, document the dates and participant names.

At a minimum, SOPs should contain plans and information for three major areas:

1) **General:** contact information for vaccine manufacturers, equipment service providers, and important facility staff; job descriptions; regularly used forms; and staff training requirements
2) **Vaccine inventory management:** ordering vaccines, monitoring storage, etc
3) **Emergency:** steps to take in the event of equipment malfunctions, power failures, or other emergencies that can compromise storage conditions

A **primary vaccine coordinator** should be designated for ensuring all vaccines are stored and handled correctly. A **back-up vaccine coordinator** should also be appointed to act in the absence of the primary coordinator. Both coordinators should be responsible for:

- Ordering vaccine and overseeing receipt/storage of deliveries
- Maintaining all documentation, such as vaccine inventory and temperature logs
- Monitoring operation of vaccine storage equipment and systems
- Organizing vaccines in storage units, including rotating stock at least weekly so vaccines with earlier expiration dates are used first and removing expired vaccines
- Monitoring temperature data on storage units, including:
    - Setting up temperature monitoring devices (TMDs)
    - Checking minimum/maximum temperatures for the last 24 hours in the morning and checking current temperatures in the morning and afternoon
    - Reviewing temperature data weekly for shifts in temperature trends
    - Responding to and reporting temperature excursions
- Organizing vaccine-related training and ensuring staff complete training
- Overseeing vaccine transport when necessary
- Overseeing emergency procedures, such as tracking inclement weather conditions and ensuring appropriate handling of vaccines during a disaster or power outage

Section Three: Equipment

Vaccine Storage Unit Recommendations

Purpose-built or pharmaceutical grade units are designed specifically for storing biologics such as vaccines. These units:

- Can be compact, under-the-counter style or large
- Often have microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistant temperature detector [RTD], or thermistor)
- Often have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature

Household grade units can be an acceptable alternative under the right conditions. When using these units, the freezer compartment of a combination unit may not be used to store vaccines, and certain areas of the refrigerated compartment should be avoided as well. **Separate standalone freezers are necessary for storing frozen vaccine.**

If a **manual defrost freezer** is used, a back-up freezer must be available to store vaccine in when the main freezer is being defrosted. A defrost plan should be included in the storage and handling SOPs, and the unit should be defrosted when the unit has accumulated to a thickness of approximately 1 cm.

Dormitory-style and bar-style units may **never** be used to store vaccine. These units have a single external door and evaporator plate (cooling coil) that is usually located in the "freezer" within the refrigerator. These units place vaccine at high risk of freezing.

Storage Unit Placement

Vaccine temperature stability requires air circulation around the outside of the storage unit. Recommendations for where to place refrigerators and freezers include:

- Unit should be in well-ventilated room with standard room temperatures (between 20°C and 25°C [68°F and 77°F]) and space between the unit, ceiling, and walls
- Nothing should block the cover of the motor compartment
- Unit should be firm and level, with bottom of unit above floor
- Door should be able to open and close smoothly and fit squarely against unit body

Stabilizing Temperatures in New and Repaired Units

Prior to storing vaccines in a new or repaired unit, check and record the minimum and maximum temperatures each workday for two to seven days. Once you have **two**

consecutive days of temperatures within the recommended range, the unit is stable and can be used for vaccine storage.

Recommended Temperature Ranges

Different COVID-19 vaccines have different recommended temperature ranges.

Refrigerated vaccines should be stored in refrigerators maintained at temperatures between 2°C and 8°C. **Frozen vaccines** should be stored in freezers maintained at temperatures between -25°C and -15°C. **Ultra cold vaccines** should be stored in freezers or dry ice shipping container in which product is received between -80°C and -60°C.[1]

Temperature Monitoring Devices (TMD)

All storage units must be equipped with a specific type of TMD known as a digital data logger (DDL). DDLs provide details on all temperatures the unit has reached at preset intervals. DDLs should have the following features:

- Detachable, buffered probe (or digitally buffered device that mimics buffered probe)
- Alarms (audible or visual) for out-of-range temperatures, with parameters set as:
    - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°C
    - Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes or longer above 8.0°C
    - Freezer high alarm (too warm) set to trigger after 60 consecutive minutes or longer above -15°C
- Low-battery indicator
- Active display outside of unit that allows current, minimum, and maximum temperatures to be monitored without opening unit door
- Recommended uncertainty of +/- 0.5°C
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures **at least every 30 minutes**
- Ability to easily download data for review
- Ability to report temperatures in Celsius
- A current and valid Certificate of Calibration

A **back-up DDL with a valid and current Certificate of Calibration** must also be available on-site and readily available in case a primary DDL malfunctions or requires re-

[1] These temperatures are based on information available as of 9/4/20. Updated information will be provided as it becomes available.

calibration. The back-up DDL should be stored outside of the storage unit until needed, and it should have a different calibration re-testing date than the primary DDLs so that one may be used while the other is being replaced or sent out for re-calibration.

Certificate of Calibration Testing

Calibration testing ensures the accuracy of DDLs against nationally accepted standards. Calibration testing should be done every one or two years or according to the manufacturer's suggested timeline. Certificates of Calibration testing should indicate one or more of the following about the testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Manual Recognition Arrangement (MRA) signatory body
- Traceable to standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Certificates of Calibration Testing should also include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less

The following TMDs should not be used

- Alcohol or mercury thermometers
- Bimetal stem TMDs
- TMDs used for food
- Chart recorded
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration testing

Temperature Probe Placement

The DDL probe should be placed in the middle area of the storage unit with the vaccines. Anchoring the probe will prevent it from being moved. It should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit as temperatures in these locations may differ significantly from the temperature in the zone where vaccine is stored.

Monitoring Vaccine Temperature and Equipment

Daily Checks

Current temperatures should be reviewed for each storage unit **twice a day** (once in the morning and once in the afternoon). During the morning temperature check, the minimum and maximum temperature for the past 24 hours should also be reviewed.

If your DDL can record twice daily readings, use this function and document readings on the Vaccine Storage Unit Digital Data Logger Sign-off Sheet. If your DDL can document the initials of the person that completes the reading, the sign-off sheet does not need to be completed. If your DDL cannot document readings on the DDL report at all, use the Refrigerator and Freezer Temperature Logs to document checks.

Weekly Checks

Additionally, DDL reports must be printed, reviewed, and signed by the Vaccine Coordinator each week and maintained with temperature logs for three years.

Power Supply

The following precautions must be taken to protect the unit's power supply:

- Plug in only one unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged
- Post "DO NOT UNPLUG" signs at outlets and on units
- Post "DO NOT TURN OFF" signs on fuses and circuit breakers
- Use caution when using power outlets that can be tripped or switched off and avoid using built-in circuit switches which may have reset buttons, outlets that can be activated by a wall switch, and multi-outlet power strips
    - If built-in current switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer.

Organizing and Storing Vaccine

Store vaccines in their original packaging with lids closed until ready for administration. Loose vials or syringes may be exposed to unnecessary light and may be more difficult to track for expiration dates. Not storing vaccines in the original packaging affects inventory management and increases the risk of administration errors. Best practices for correct storage of vaccines within a refrigerator or freezer include:

- Store each type of vaccine/diluent in original packaging and in a separate container
- Position vaccines/diluents 2-3 inches from unit walls, ceilings, floor, and door.
    - If using a household-grade unit, do not store vaccines/diluents directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves. These areas may expose vaccines to unstable temperatures and insufficient air flow.
- Label shelves/containers to identify where each type of vaccine/diluent is stored.
- Store vaccines/diluents with similar packaging/names or with pediatric/adult formulations on different shelves.
- Store diluents with the corresponding refrigerated vaccine. Never store diluent in a freezer. Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
    - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccine.
    - Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
    - The freezer of a combination household-grade unit may be used for non-vaccine, medical storage, as long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- Arrange vaccines/diluents in rows and allow space between them to promote air circulation.
- Place vaccines/diluents with the earliest expiration dates in front of those with later expiration dates.
- Place water bottles on the top shelf, floor, and in the door racks. Putting water bottles help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.

- Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Regular Maintenance of Equipment

Vaccine storage units and DDLs require regular maintenance to ensure proper operation. On a regular basis, check seals and door hinges, clean coils and other compartments per manufacturer direction, defrost manual-defrost freezers when the frost exceeds either 1cm or the manufacturer's suggested limit (when defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures), clean the interior of each unit to discourage bacterial and fungal growth, and test any back-up generator quarterly and have it served annually.

Section Four: Temperature Excursions (TEs)

Temperature excursions (TEs) occur when there is a temperature reading outside of the recommended temperature range for a vaccine. When a TE occurs, VPDIP must be notified as quickly as possible at 800-404-3006 during business hours or the next business morning (Monday – Friday, 8:00 AM – 4:30 PM CT) and before any vaccine is administered.

Notify VPDIP if one of the following occurs

- Refrigerated vaccines reach temperatures below 2°C for ≥15 consecutive minutes or above 8°C for ≥60 consecutive minutes
- Frozen vaccines reach temperatures below -25°C for ≥15 consecutive minutes above -15°C for ≥60 consecutive minutes
- Ultra-cold vaccines reach temperatures below -80°C for ≥15 consecutive minutes above -60°C for ≥60 consecutive minutes
- TE is part of a pattern of frequent excursions, regardless of duration
- TE concerns regardless of one of the above criteria

If a TE occurs, follow these steps**:**

1. Troubleshoot to see if you can identify why unit went out-of-range (e.g., unit is unplugged, unit door is open or not sealed adequately, thermostat is set incorrectly, probe has been moved from center of unit, or coils and vents have excess dust) and attempt to return vaccine to proper storage conditions if still out-of-range by.
    a. If outside of business hours and temperature is still out-of-range and cannot be restored to proper temperatures, execute emergency plan.
2. Label vaccines "Do not use until notified by VPDIP," and do not use until approved.
3. Call VPDIP for further instruction.
4. Download DDL report, noting how long the temperature has been out of range and the minimum/maximum temperatures.
5. Send the DDL report/temperature log by fax to (615) 401-6829 or by email to Temperature.Health@tn.gov. Include facility PIN and name on report.
6. Wait for notification from VPDIP whether the vaccine can be used.

Section Five: Vaccine Inventory Management

The vaccine cold chain becomes the provider's responsibility once delivery is made to the facility. The following section provides information on ensuring that vaccines are unpacked, stored, prepared, administered, and transported correctly.

Scheduling and Receiving Deliveries

Staff members who may accept deliveries should be trained to immediately notify the vaccine coordinator or other designated personnel when deliveries arrive.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after arrival. Check the shipment to ensure:

- No damage occurred to the package during transport
- The correct types and quantities of vaccines (and diluents, if applicable)
- No expired or soon-to-expire products were shipped
- No TEs occurred during transit (using the cold chain monitor [CCM])

Unopened/unpacked boxes should not be placed in a storage unit because the cool packs shipped with the vaccine can make the vaccine too cold if placed inside the storage unit.

Ultra-cold vaccine may be shipped in coolers packed in dry ice. These coolers should be repacked with dry ice within 24 hours of receipt and repacked again within 5 days.

Stock Rotation and Removal

On a regular basis, vaccine stock should be rotated and checked for expired doses. Expired vaccines and diluents should be removed immediately to avoid inadvertent administration. Vaccines with earlier expiration dates should be placed in front of those with later expiration dates.

Preparing Vaccines for Administration

Preparing vaccines is the final step in the cold chain before administering to the patient. Best practices for handling vaccines include:

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared.

Section Six: Vaccine Transport

Vaccines from should not be routinely transported. However, emergencies and off-site clinics may require vaccine transport; in these instances, ensure precautions are taken to protect your supply by using the appropriate packing materials and procedures. CDC's Packing Vaccines for Transport during Emergencies is a useful tool that details proper procedures for doing so. Highlights include:

- Vaccines should not be in transport for more than eight (8) hours.
    - This time includes the length of the clinic workday if transporting vaccine for an off-site clinic.
- Diluents should be included with their corresponding vaccines during transport to ensure there is always an adequate amount for reconstitution.
    - If diluents typically stored at room temperature (20°C to 25°C [68°F to 77°F]) will be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines. Diluents should **never** be frozen, even during transport. When packing vaccines and diluents for transport, place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.
- Maintain a sufficient supply of materials needed for vaccine transport of your maximum inventory. Materials include:
    - Portable vaccine refrigerators/freezer units (preferred)
    - Qualified containers and packouts
    - Hard-sided insulated containers or Styrofoam™
    - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4°C to 5°C
        - Follow manufacturer's instructions for use to reduce the risk of freezing vaccines during transport
    - Insulation materials such as bubble wrap and corrugated cardboard – enough to form two layers per container
    - DDLs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures. In an emergency situation, a system with conditioned water bottles can be used.

Never use commercially available soft-sided food or beverage coolers, and only use the original shipping materials that vaccines were initially shipping on or conditioned water bottle transport systems as a last resort in emergencies. In **no situation** should the frozen gel packs or coolant packs from the original shipments be re-used.

Planning and Preparing for Transport

Vaccine packing and transport protocols should be included within your facility's SOPs to ensure you are prepared for a situation in which your vaccine supply must be transported.

- Staff should be trained to pack vaccines correctly.
- A refrigerated truck may be necessary if you have a large quantity of vaccines or need to transport vaccines an extended distance. If using a company or personal vehicle, only transport vaccines inside the passenger compartment as the trunk or bed of a truck may be too hot or cold. The vehicle should already be at a comfortable temperature and not too hot or cold when containers are moved.
- Prior to transport, take an inventory of vaccines and records actions to protect vaccines during transport.
- When in transport, only open unit doors when necessary and only after all preparation for packing and moving vaccines has been completed.
- Avoid leaving containers where they may be exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.

Transporting Open Multidose Vials

Partially used vials may be transported to or from an off-site clinic operated by the same provider if necessary, if the cold chain is properly maintained. They may never be transferred from one provider to another or across state lines.

Transporting Frozen Vaccines

A portable vaccine freezer unit or qualified container and packout that maintains temperatures between -25°C and -15°C must be used if frozen vaccines must be transported. Follow these steps:

- Place a DDL (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a standalone freezer at a temperature range between -25°C and -15°C.

- Record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

Dry ice should not be used as it may expose vaccines to temperatures colder than -25°C.

Monitoring Temperatures During and After Transport

While in transport, vaccines should still be continuously monitored using a DDL. DDLs used in vaccine transport have the same requirements as the ones used during routine storage and handling. Upon arrival at the destination, vaccines should be immediately stored in a storage unit with a DDL.

If vaccines cannot be stored in an approved unit after transport, they should be kept in a portable vaccine storage unit with a DDL as close as possible to the vaccines and the container closed. The temperatures should be checked and recorded hourly.

Section Seven: Emergency Vaccine Storage and Handling

Equipment failures, power outages, severe weather conditions, and natural disasters can happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, additional plans should be in place for emergencies.

You may choose to have a backup storage unit within your facility where vaccine can be stored if the primary storage unit fails. Additionally, you may have a generator that is activated if power is compromised to the facility. However, even if a generator is available, additional backup plans should be in place for transport out of the facility.

Alternative Storage Facility

A working agreement should be established with at least one alternative storage facility as part of emergency vaccine storage and handling planning. This agreement should include 24-hour access to this facility.

After Hours Facility Access

A relationship with your facility's building manager and/or security staff should be maintained to ensure that you are able to access your vaccine supply outside of normal business hours. Relevant staff should maintain copies of information regarding building access and security procedures at home.

Section Eight: Satellite, Temporary, and Off-Site Clinics

In addition to vaccine transport planning, additional oversight and enhanced storage and handling practices are required for satellite, temporary, and off-site clinics:

- Quantity of vaccine transported to satellite, temporary, or off-site COVID-19 vaccination clinics should be based on anticipated number of patients and ability of provider to store, handle, and transport vaccine appropriately.
- Ultra-cold vaccines may not be used in satellite, temporary, or off-site clinics.
- Vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transport guidelines outlined in Section Six.
- Satellite, temporary, or off-site may only be conducted within the state of Tennessee.
- Vaccine must be stored to maintain appropriate temperature throughout the day.
    - If available, store vaccine in approved units.
    - Prior to transferring vaccine to a satellite, temporary, or off-site clinic, units that will store vaccine during the day must be operational with temperatures in-range. DDLs that are routinely stored outside of a unit should be placed in a functioning unit at least six hours prior to the clinic.
- Remove only one multidose vial or ten doses at a time for preparation and administration for each person administering vaccines.
- Every hour, temperature data from the DDL must be reviewed and documented using the Hourly Vaccine Temperature Log
- At the end of the day, a DDL report must be printed. Vaccine Coordinator should review the temperature logs and sign the Hourly Vaccine Temperature Log prior to vaccine being returned to primary storage units.
- Report any TEs that occur following procedures outlined in the Temperature Excursion section.
- Store DDL reports and temperature logs from satellite, temporary, or off-site with primary clinic logs and maintain them for three years.