

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.

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.

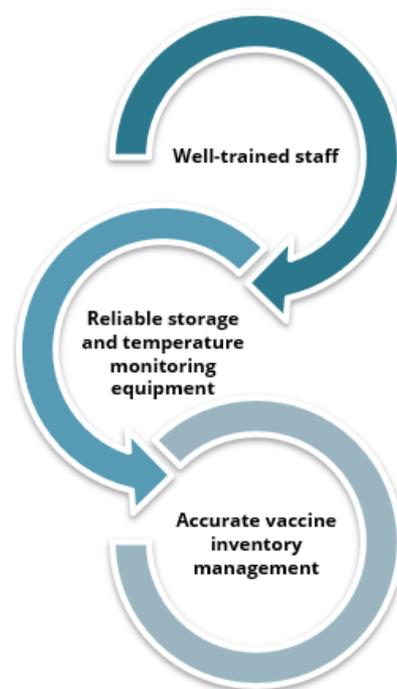
This document is designed to assist providers in properly storing and handling federal COVID-19 vaccine as part of the Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) COVID-19 Vaccination Program. It is a modified version of the Centers for Disease Control and Prevention (CDC) [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.

An effective vaccine cold chain relies on...



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. A template Routine and Emergency Vaccine Management Plan (REVMMP) may be found in [Appendix A](#).

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 (once available) 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

VPDIP requires completion of CDC's COVID-19 Vaccine Training Modules for all primary and back-up coordinators at all sites enrolled in the COVID-19 Vaccination Program.

Pharmacists signing the Storage and Handling portion of the COVID-19 Provider Agreement are also required to complete the training modules. Continuing Education Units (CEUs) are available upon completion of each module and must be provided to VPDIP for review.

Current training modules are listed below and may be found on [CDC's COVID-19 Vaccine Training Modules Homepage](#).

- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know
- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know

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 should never 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, an appropriate 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 -95°C and -60°C.

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-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) Mutual 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 1 cm 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 serviced annually.

Section Four: Pfizer/BioNTech COVID-19 Vaccine Storage

Using the Thermal Shipping Container for Vaccine Storage

Vaccine that is stored in a thermal shipping container should maintain temperatures between -80°C and -60°C (-112°F to -76°F). The thermal shipping container should be stored at 15°C–25°C (59°F –77°F). **Thermal shipping containers may not be used for vaccine storage beyond 30 days.** Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

A Digital Data Logger (DDL) capable of monitoring ultra-cold temperatures must be placed in the location of the vial tray if the thermal shipping container is being used for storage. CDC will provide a temporary DDL with each thermal shipper that may be activated while utilizing the container for vaccine storage. All DDLs purchased separately must have a current, valid Certificate of Calibration.

The thermal shipping container should be re-iced every five days. Re-icing every 5 days helps maintain the level of dry ice and the temperature of the vaccine product. The thermal shipping container should not be opened more than 2 times per day and should not be opened for more than three (3) minutes at a time. Strict adherence to this guideline will ensure the thermal shipping container can maintain ultra-cold storage conditions.

To properly replenish the container, add dry ice to the maximum lines within the payload insert areas and dry ice pod. The thermal shipper and Controlant temperature data logger should be returned to Pfizer within 30 business days of delivery.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered “thawed” and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine that is stored in the thermal shipping container with the temporary DDL provided will be continuously monitored. Providers using this method of vaccine storage will not be required to document minimum and maximum daily temps, as the DDLs provided will not have a temperature display. Instead, providers utilizing this method of vaccine storage should review and print the DDL reports provided by Pfizer and/or Controlant to each Primary and Back-up Vaccine Coordinator listed on the COVID-19 Provider Agreement.

Using an Ultra-cold Freezer for Vaccine Storage

Vaccine that is stored in an ultra-cold freezer should be stored between -80°C and -60°C (-112°F to -76°F). Pfizer/BioNTech COVID-19 vaccine may be stored in ultra-cold freezers for up to six (6) months. Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered “thawed” and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine stored in ultra-cold freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Freezer for Vaccine Storage

Pfizer/BioNTech COVID-19 vaccine that is stored in a freezer should be stored between -25°C and -15°C (-13°F to 5°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a freezer for up to two (2) weeks. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures **must** be stored in a separate, approved standalone freezer. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Frozen vials stored or transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). This includes vials that are held up to two weeks at -25°C to -15°C (-13°F to 5°F), and at risk of not being used in time. Any time that the vials are stored or transported at -25°C to -15°C count against the two-week limit. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed two weeks. CDC is updating Pfizer Beyond-Use Date Labels to track this two-week timeframe.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine

storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage

Pfizer/BioNTech COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a refrigerator for up to 1 month (31 days). Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Five: Moderna COVID-19 Vaccine Storage

Using a Freezer for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a freezer should be stored between -50°C and -15°C (-58°F to 5°F). Moderna COVID-19 vaccine may be stored in a freezer for up to six (6) months. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures **must** be stored in a separate, approved standalone freezer. Unpunctured vials may be stored

between 8° to 25°C (46° to 77°F) for a total of 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Moderna COVID-19 vaccine may be stored in a refrigerator for up to thirty (30) days. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Six: Janssen COVID-19 Vaccine

Using a Refrigerator for Vaccine Storage

Janssen COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Do **not** store Janssen COVID-19 vaccine in a freezer or ultra-cold freezer.

DRAFT: updated 05/20/2021

Janssen COVID-19 vaccine may be stored in a refrigerator for up to three (3) months. Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Seven: 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 colder than 2°C or warmer than 8°C
- Frozen vaccines reach temperatures colder than -25° or warmer than -15°C
- Ultra-cold vaccines reach temperatures colder than -95°C or warmer than -60°C
- 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 Eight: 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 or per manufacturer recommendations.

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 Nine: Vaccine Transport

Vaccine Transport to Offsite PODs or Mobile Clinics

Vaccines should never be transported to an offsite clinic, POD, or mobile clinic without written approval from the VPDIP Program. It is imperative that your facility has the appropriate equipment and processes in place to ensure the vaccine cold chain is maintained before, during, and after transport. Please contact Vaccine.Storage@tn.gov if your facility intends to conduct mobile or offsite clinics. A vaccine storage and handling expert will evaluate your proposed equipment and protocols to ensure vaccine can be

safely transported offsite. Required equipment includes a portable plug-in vaccine refrigerator and/or freezer and approved DDLs with valid Certificates of Calibration. Written protocols for vaccine transport will also be required.

Emergency Vaccine Transport

Vaccines should not be routinely transported. However, **emergencies** such as storage unit failure or power outage 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:

- 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 emergency 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

Emergency 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.
- Prior to transport, take an inventory of vaccines and record actions to protect vaccines during transport.
- Use the COVID-19 vaccine Transport log in Appendix B to 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.
- 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.

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. A DDL report from the DDL used in transport should be printed, reviewed for TEs, and maintained with COVID-19 vaccine records for three (3) years.

Section Ten: 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.

Routine and Emergency Vaccine Management Plan (REVMP)

KEEP YOUR MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) requires COVID-19 Vaccination Program providers to maintain a vaccine management plan for routine and emergency situations. This document is a template for information, such as guidelines, protocols, contact information, and staff training, about your practice. None of the information included in this template may be excluded in the plan.

Review and update your plan at least once a year, when COVID-19 Vaccination Program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever your plan is revised.

CDC Site Visit Reviewers may ask to review your plans during routine and drop-in site visits.

STAFF ROLES AND CONTACT INFORMATION

Facility Name: _____

Facility Address: _____

Facility Phone Number: _____ COVID PIN: _____

Role/Responsibility	Name	Phone Number	Email Address
Chief Medical Officer			
Chief Executive Officer or Chief Fiduciary Officer			
Primary Vaccine Coordinator			
Back-up Vaccine Coordinator			
Pharmacist			
Receives Vaccines			
Stores Shipping			
Handles Vaccines			

Please refer to [Page 3](#) of this document for descriptions of the key duties assigned to designated vaccine management staff.

Staff must sign and date the [Acknowledgement and Signature Log](#) at the end of this document to confirm that they understand and agree to the duties assigned to them.

COVID-19 REQUIRED TRAINING LOG

Please list designated vaccine management personnel and have them sign and acknowledge that they have completed required training.

Primary and Back-up Vaccine Coordinators must complete CDC's COVID-19 Vaccine Training Modules. Additionally, if a pharmacist is listed as the signatory under the Storage and Handling section of the COVID-19 Provider Agreement, this individual must complete the training modules. These modules include a [General Overview of Immunization Best Practices](#), [Moderna COVID-19 Vaccine](#), [Janssen COVID-19 Vaccine](#), and [Pfizer COVID-19 Vaccine](#). Staff at your facility that routinely handle or administer COVID-19 vaccine are recommended to also participate in these trainings, in case of staff turnover.

Name and Title	Signature	Date Training Completed			
		General Overview	Moderna	Pfizer	Janssen
Primary Vaccine Coordinator					
Back-up Vaccine Coordinator					
Pharmacist					

KEY DUTIES FOR DESIGNATED VACCINE MANAGEMENT STAFF

All staff who work with COVID-19 vaccines should be familiar with all requirements outlined in the COVID-19 Vaccination Program Provider Agreement. Below are highlights of key duties for designated vaccine management staff.

CMO/CEO:

- Complies with all federal vaccine management requirements, including key areas outlined in this plan
- Oversees designated vaccine management staff to ensure COVID-19 program requirements are being met
- Designates one employee as Primary Vaccine Coordinator
- Designates one employee as Back-up Vaccine Coordinator
- Authorizes and reports changes to Primary and Back-up Vaccine Coordinators, CEO, or CMO to the COVID-19 Onboarding Team at Vaccine.Onboarding@tn.gov as soon as possible following any changes
- Meets and documents required training for designated vaccine management staff
- Ensures designated vaccine management staff are skilled and knowledgeable regarding VPDIP Program requirements for temperature monitoring and storage equipment
- Ensures practice's vaccine inventory management is consistent with VPDIP Program requirements
- Ensures practice's vaccine storage units and temperature monitoring devices meet VPDIP program requirements
- Updates and revises vaccine management plans at least annually and whenever necessary
- Reviews VPDIP program requirements and management plans with staff at least annually and whenever necessary

Primary Vaccine Coordinator:

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

Back-up Vaccine Coordinator:

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

Pharmacist (only required if a pharmacist signed Storage and Handling section of Provider Agreement):

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

The Primary Vaccine Coordinator should review and acknowledge the following requirements by checking the box next to each item:

VACCINE STORAGE EQUIPMENT

Equipment:

- This facility uses VPDIP-compliant and approved vaccine storage refrigerator(s) and/or freezer(s)
- Vaccine storage units maintain recommended unit temperature ranges:
 - Refrigerator: between 2 and 8 °C
 - Freezer: between -15 °C and -25 °C
 - Ultra-cold Freezer: between -96 °C and -60 °C
- Vaccine storage units have adequate capacity to store vaccine supply at all times
- Vaccine storage units are routinely cleaned inside, kept dust-free outside, and have proper seals on the doors
- This facility keeps maintenance and repair records for vaccine storage units on file and makes them available to review upon request by VPDIP or CDC Site Visit Reviewers

Power Supply:

- Each vaccine storage unit is directly plugged into a wall outlet
- No vaccine storage unit is controlled by a light switch, power strips, or surge protectors with on/off switch
- Extension cords are never used to connect storage units to an outlet
- Plug guards are used to prevent power interruption
- "DO NOT UNPLUG" signs are posted at each outlet and at the circuit breakers

Set-up:

- Vaccine storage units are set up according to requirements outlined in the [CDC Storage and Handling Toolkit](#)
- Vaccine storage units are located away from direct sunlight and away from walls to allow air circulation
- Vaccines are never stored in the doors, drawers, or bins of storage units
- Drawers/deli crispers are removed from vaccine storage units
- Vaccines are stored 2-3 inches away from the walls, air vents, and floors of vaccine storage units to allow space for air circulation
- To stabilize temperatures, frozen cold packs are kept in **standalone** freezers and water bottles are kept on the top shelf, in the door, and on bottom of refrigerators where vaccines cannot be stored.
- The freezer compartment of a combination refrigerator/freezer storage unit is **NEVER** used for vaccine storage
- Dorm-style units are **NEVER** used for vaccine storage
- Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine
- Buffered DDL probes are placed in the center of the vaccine storage units, near the vaccines
- DDL displays are securely attached on the outside of vaccine storage units
- Vaccines are stored in their original packaging until administered
- Food, beverages, and laboratory specimens are never stored in vaccine storage units
- When medication or biologic media (not inoculated) are stored in the same unit as vaccines, they are placed on the shelves below vaccines

TEMPERATURE MONITORING EQUIPMENT

Digital Data Loggers (DDLs):

- Each vaccine storage unit has a continuous temperature monitoring device with the following capabilities:
 - Data that can be routinely downloaded

- Active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door
- Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- Alarm for out-of-range temperatures
- Low battery indicator
- Accuracy of +/- 0.5°C
- Memory storage of at least 4,000 readings
- User-programmable logging interval (or reading rate)
- Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- Each DDL has a current and valid Certificate of Calibration (also known as a Report of Calibration Testing)
- Each DDL has a digital display of current, minimum, and maximum temperatures
- Each DDL displays temperatures in degrees Celsius (°C)
- Each DDL is set to alarm when:
 - Temperature in refrigerator goes **above** 8°C or **below** 2°C
 - Temperature in freezer goes **above** -15°C or **below** -25 °C
- Probes are placed in the center of vaccine storage units and never in the unit doors, near or against the walls, underneath air vents, or on unit floors
- DDL batteries are replaced every six months or as needed
- There is at least one back-up DDL that is readily available on-site to ensure that temperature assessment and recordings can be performed twice a day

DDL Calibration:

- All primary and back-up DDLs are calibrated as recommended by the manufacturer
- DDL calibration is done by either a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating that calibration testing meets ISO/IEC 17025 International standards for calibration testing and traceability
- Certificates of Calibration are maintained in a readily accessible area, until expiration, and presented to VPDIP staff for review upon request
- DDLs are replaced on or before expiration date listed on device
- DDLs are replaced when no longer accurate within +/- 0.5°C

Safeguarding Vaccines, Handling, and Reporting Temperature Excursions:

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage
- Temperature excursions are reported immediately to 800-404-3006 or Temperature.Health@tn.gov
- Vaccines involved in temperature excursions are labelled "Do Not Use Until Further Notice"
- This facility has an Emergency Vaccine Management Plan to follow in case of power outage, appliance malfunction, severe weather conditions, or human error that may affect vaccine viability
- When necessary to transport vaccine to another storage unit or to a predetermined site, facility always follows CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid

Temperature Monitoring and Documentation:

- Vaccine storage unit temperatures are read twice a day, when the clinic opens and before it closes
 - Minimum and maximum temperatures are read and recorded once each day
 - AM temperatures are read and recorded before opening vaccine storage units

- PM temperatures are read and recorded at the end of each day, allowing time for corrective actions in the event of out-of-range unit temperatures
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are posted on storage unit doors or nearby
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are completed daily and DDL reports are printed weekly
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are initialed by person who documents temperatures
- Completed temperature logs are maintained for three years and made available to VPDIP upon request for review

Please refer to the [VPDIP website](#) for guidance on [Temperature Monitoring and Excursions](#)

INVENTORY MANAGEMENT

Inventory Maintenance:

- Physical vaccine inventory is reconciled in TennIIS daily
- Facility has adopted an inventory control system
- Accurate records, including packing slips and inventory management records, are maintained and made available upon request to VPDIP
- Vaccines that are drawn up and not used are disposed of correctly and recorded in TennIIS
- Facility stores diluent for vaccine appropriately
- Facility clearly labels diluents that are not packed with its vaccine so they can be easily identified
- Diluents are not placed in the freezer

Stock Rotation, Returns, and Transfers

- Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first
- If vaccine expires or spoils, it is:
 - Removed from storage unit
 - Reconciled appropriately in TennIIS
 - Returned to the vaccine manufacturer or wasted per VPDIP guidance
- If vaccine is due to expire within two weeks and will not be used, this facility will:
 - Notify VPDIP at VPDIP.Pandemic@tn.gov about vaccine
 - Request a transfer approval from VPDIP
- If facility needs to transfer or transport vaccine, CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid is followed
- This facility does not return the following items:
 - Used syringes with or without needles
 - Syringes with vaccine drawn up and not used
 - Broken or damaged vaccine vials
 - Multi-dose vials that have already been withdrawn
- Spoiled, expired, or wasted vaccine are reported to VPDIP before placing a new vaccine order

Vaccine Ordering:

NOTE: While supplies are limited, TDH will continue to allocate doses directly to providers. Any orders submitted through VOMS will be rejected. VPDIP will communicate to all vaccinating providers when ordering is permitted.

- Orders are submitted in TennIIS and placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and current inventory in stock.
- A physical vaccine inventory is conducted before placing a vaccine order
- This facility places orders with sufficient inventory on hand to allow time for order processing delivery
- This facility confirms operation hours in TennIIS before submitting each order
- This facility reports any changes to the practice's hours to VPDIP to avoid receiving vaccine shipments when the clinic is closed or staff is not available

Receiving and Inspecting Vaccine Shipments:

- Staff is familiar with procedures for accepting vaccine shipments in TennIIS
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip and order confirmation
- This facility assumes responsibility for all COVID-19 vaccine that is shipped to its site
- This facility never rejects a vaccine shipment
- Shipment discrepancies and vaccines exposed to out-of-range temperatures are reported to VPDIP at 800-404-3006 or Temperature.Health@tn.gov immediately
- Vaccines are stored immediately and appropriately upon delivery
- Vaccines are accepted in the TennIIS inventory upon receipt

VACCINE STORAGE UNIT INFORMATION

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Refrigerator (3)				
Refrigerator (4)				
Freezer (1)				
Freezer (2)				
Freezer (3)				
Freezer (4)				

Where are your digital data logger reports and temperature logs located?

If you have a manual defrost freezer, please provide a description of your plan for regular defrosting *:

* A defrost plan is required for providers with a manual defrost freezer. The plan should include 1) where you will transfer vaccines, 2) what equipment will be used to transfer vaccines, and 3) when/how often you will defrost your freezer.

VPDIP must be notified before transporting vaccines, and all temperature excursions that occur during transport must be reported to VPDIP.

DIGITAL DATA LOGGER AND CALIBRATION INFORMATION

Primary Data Loggers (must have one for each unit listed in previous section):

DDL Brand, Model # /Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

Primary Data Loggers (must have at least one readily available on-site):

Data Logger Model/Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

Calibration Company: _____ **Phone Number:** _____

Location of Certificates of Calibration: _____

USEFUL EMERGENCY NUMBERS

Service	Name	Main Phone Number	Alternate Number	Email Address
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair Company				
Point of Contact for Vaccine Transport				

VPDIP Team	Main Phone Number	Alternate Number	Email Address	Fax Number
Temperature Excursions (available Monday – Friday, 8AM – 4:30PM) *	(800) 404-3006	615-741-7247	Temperature.Health@tn.gov	(615) 401-6829
Vaccine Storage and Handling	(800) 404-3006	615-741-7247	Vaccine.Storage@tn.gov	
VOMS (available Monday – Friday, 8AM – 4:30PM) *	(800) 404-3006	615-741-7247	TennIIS.VOMS@tn.gov	
TennIIS Help Desk (available Monday – Friday, 7AM – 6PM) *	(844) 206-9927		TennIIS.Help@tn.gov	

* All times are in Central Time Zone. Unavailable on all [Tennessee State Holidays](#)

Emergency Vaccine Management Plan

The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Role/Responsibility	Name	Phone Number	Email Address

Does the clinic have a generator? If so, where is it located?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it may be necessary to transport vaccine to alternate storage locations.* Please identify two back-up locations:

Alternate Vaccine Storage Location	Address and City	Point of Contact Name	POC Contact Information

*** Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit**

I have confirmed that the point of contact for the alternate storage locations will accept my vaccines during an emergency situation.

Signature: _____ **Date:** _____

Where is the location of your emergency packing supplies?

If you have a generator and no back-up locations, the generator should be tested quarterly and serviced once a year. In the section below, please record the last date that the generator was tested and serviced and sign and date each time this occurs during the year.

The REVMP does not need to be re-submitted each time the generator is tested or serviced, but it will be reviewed during routine and drop-in site visits:

Quarterly Tests

Quarter	Signature	Date
Q1		
Q2		
Q3		
Q4		

Annual Service

Signature: _____ Date: _____

OTHER USEFUL EMERGENCY INFORMATION

Complete the following information for emergency storage units that will be used by your facility for emergencies that do not require an alternate storage location.*

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Freezer (1)				
Freezer (2)				

*** Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit**

Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g. power outages, severe weather, building maintenance/repairs, etc.):

Before an Emergency:

- Maintain emergency contact information for designated vaccine management personnel
- Place water bottles on the top shelf, in the door, and on the bottom of vaccine refrigerators, where vaccines cannot be stored to stabilize temperatures. Place frozen cold packs in standalone freezers for similar purposes.
- Identify alternate vaccine storage locations (e.g. a local hospital, a local health department, or another COVID-19 provider). Ensure the location has adequate space to accommodate vaccines and that their temperature monitoring equipment meets requirements.
- Update necessary contact information for alternate vaccine storage locations, including facility name, address, contact person, and telephone number.
- Stock emergency supplies as indicated in CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- Label and keep accessible any necessary vaccine packing and transport supplies, copies of vaccine transport job aids, facility floor plans when available, and other related information
- Be familiar with back-up power sources for commercial, laboratory, and pharmacy-grade storage units

During an Emergency:

- Assess the situation. Do not open the vaccine storage unit.
- Determine the cause of the power failure and estimate the time it will take to restore power.
- Notify key vaccine management staff listed on the Emergency Plan as appropriate
- If the power outage is expected to be short-term, usually restored within 2 hours:
 - Record the time that the outage started, unit temperatures (current, minimum, and maximum) for each day, and the room temperature
 - Place a "DO NOT OPEN" sign on the storage unit(s) to conserve cold air mass
 - Monitor the temperature until power is restored
- If the outage is expected to be long-term, usually longer than 4 hours, consider moving vaccines to an alternative unit or facility. See details below, under Relocating Vaccine.

NOTE: Temperatures in vaccine storage units tend to increase faster during power outages. As a result, clinics may need to monitor temperature more frequently and/or transport vaccines to an alternate location sooner.

Relocating Vaccine:

If a power outage is expected to be long-term (e.g. not restored by the end of the day) or storage units are not working properly, prepare to relocate vaccines to alternate storage locations. If moving vaccines, **a DDL must remain with the vaccine at all times.**

Before transporting vaccines:

- Review CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- Contact the alternate storage facility to verify that they can accept the vaccines
- If transport or relocation is not feasible (e.g. alternate location is not available or travel conditions are unsafe):
 - Keep units closed and document the current, minimum, and maximum temperatures for each day
- Notify the VPDIP Team at 800-404-3006 or Temperature.Health@tn.gov

Packaging and transporting vaccines:

- Complete the [Refrigerated Vaccine Transport Log](#) and/or the [Freezer Vaccine Transport Log](#)
- Attach DDL to cooler
- Prepare cooler(s) for transport following CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
 - Use frozen cold packs for frozen vaccines. Never use dry ice.
 - Use conditioned (slightly defrosted) frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore, damage vaccine. If clinic does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
- Package and prepare diluent
 - Diluents stored in the refrigerator should be transported with refrigerated vaccines
 - Diluents stored at room temperature should be transported at room temperature
 - Diluents packaged with their vaccine should be transported with their vaccine
- Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the current, minimum, and maximum temperatures in the transport cooler(s), and the current, minimum, and maximum temperatures in the alternate storage unit(s).

After Power is Restored:

- Verify storage units are functioning properly and temperatures are within range before attempting to move any vaccine
- Follow the same transportation procedures and transfer vaccine back to its original storage unit
- Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used
- For any vaccine not stored at proper temperature:
 - Segregate it in the storage unit
 - Mark it "Do Not Use Until Further Notice"
 - Contact the VPDIP Team at 800-404-3006 to report the excursion
- Never return vaccine to the vaccine distributor without authorization from VPDIP

Acknowledgement and Signature Log

Please sign and date this acknowledgement and signature log when you update practice-specific information.

By signing this log, facility staff are acknowledging that they have reviewed, understand, and agree to the key duties assigned to them as vaccine management personnel for this facility.

Updates and comments to changes made in Routine and Emergency Vaccine Management Plans:

CMO:

Name: _____

Signature: _____ Date: _____

PRIMARY Vaccine COORDINATOR:

Name: _____

Signature: _____ Date: _____

BACK-UP Vaccine COORDINATOR:

Name: _____

Signature: _____ Date: _____

CEO/CFO:

Name: _____

Signature: _____ Date: _____

Pharmacist (if applicable):

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____

COVID-19 Vaccine

Refrigerated Vaccine Transport Log



Instructions: Complete this log when transporting vaccines to an alternate or back-up refrigerator.

Date: _____

Provider Name: _____ COVID/VFC PIN: _____

Transferred To: _____ COVID/VFC PIN: _____

Vaccines Transferred Due To: Power Outage Excess Supply Short Dated Unit Malfunction Building Maintenance Other: _____

Vaccine Inventory Information – may also attach most recent reconciliation report from TennIIS.

Vaccine	Lot Number	Number of Doses	Expiration Date	Vaccine Previously Transported? (Yes/No)	Comments

Temperature Monitoring Information

Temperature of vaccine in refrigerator prior to transfer: _____ Celsius/Fahrenheit: _____ Time: _____

Temperature of vaccine in cooler before departure: _____ Celsius/Fahrenheit: _____ Time: _____

Temperature of vaccine in cooler upon arrival: _____ Celsius/Fahrenheit: _____ Time: _____

Temperature of back-up refrigerator: _____ Celsius/Fahrenheit: _____ Time: _____

Contact the VFC Program (800-404-3006) if temperatures during transport exceed recommended ranges.

Total Transport Time: _____ Min/Hr