

(Revised April 2021)

This Vaccine Storage and Handling SOP is based on the CDC Vaccine Storage and Handling Toolkit and "You Call the Shots" webinars. It provides information for proper management of publicly-funded vaccine. Use of this template assures that vaccine is managed according to VCVF/VAVP and Vermont Immunization Program requirements. Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

[illegible]

# Vaccine Storage and Handling SOP

Practice Name \_\_\_\_\_

PIN# \_\_\_\_\_

Vaccine Coordinators (see page 3)		
Name	Title (e.g. RN, MA)	Home and/or Cell Phone
Vaccine Coordinator:		
Back-up Coordinator:		
2 <sup>nd</sup> Backup Coordinator ( <i>optional</i> ):		

COVID-19 Vaccine Coordinators (if different than above)		
Name	Title (e.g. RN, MA)	Home and/or Cell Phone
Vaccine Coordinator:		
Back-up Coordinator:		
2 <sup>nd</sup> Backup Coordinator ( <i>optional</i> ):		

Alternate vaccine storage location (see page 4)	
Location name	
Location address	
Phone	
Primary contact person off-hours phone #	

Regional Immunization Specialist	
Name	
Phone number	
Email address	

# Vaccine Storage and Handling SOP

Supplies Needed to Transport Vaccine	
Supplies	Location on Site
Hard sided cooler	
Frozen Water Bottles	
Cardboard and bubble wrap	
Back-up Data Logger (see page 10)	

Person Completing This Form	
Date of completion	
Your Name	
Title	
Your Signature	

**Contact the Immunization Program at 802-863-7638 whenever there are changes.**

Additional Information (use as needed)	

## Abbreviations:

ACIP: Advisory Committee on Immunization Practices

MMR: measles, mumps, and rubella vaccine

MMRV: measles, mumps, rubella, and varicella vaccine

VDH: Vermont Department of Health

VCVP: Vermont Child Vaccine Program

VAVP: Vermont Adult Vaccine Program

VIMS: Vaccine Inventory Management System

# Vaccine Storage and Handling SOP

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# Vaccine Storage and Handling SOP

## I. Rationale

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Providers enrolled in the VCVP and state VAVP programs are entrusted with publicly funded vaccine and must ensure viability. Vaccine that is not stored under required conditions may be ineffective at producing an immune response. In 2020, the value of vaccine distributed to VCVP and/or VAVP enrolled practices in Vermont was more than \$16,000,000.

## II. Vaccine Emergency Management

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### A. Temperature excursions

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If you experienced a temperature excursion, contact the Immunization Program during the standard business hours promptly by phone 1-800-640-4374 or email [ahs.vdhimmunizationprogram@vermont.gov](mailto:ahs.vdhimmunizationprogram@vermont.gov)

- **Do not move vaccine without approval.**
- Place all vaccine of questionable quality on hold in storage (*as if* it is still viable), but do not use until guidance is obtained from the Immunization Program. Refrain from making assumptions about vaccine spoilage.
- Correct obvious problems. For example, if the door is ajar – close it; if the unit is unplugged – plug it in.
- Do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator quickly, as this may lead to overcompensation and freezing.
- Once an issue is resolved, acknowledge the alarm in the cloud system and note all actions taken. After an alarm is confirmed, no further documentation is possible, so this should be the last step taken. (see section D for guidance).
- Reconcile your vaccine inventory in VIMS if it has been longer than 3 months.

If it is after hours and you need to use the vaccine before the next business day, or plan to move the vaccine, dial the below number to reach someone on-call. Otherwise, wait until the next business day.

Immunization Program  
**1-800-640-4374**

Failure to seek and follow VDH guidance for vaccine storage & handling or transport may result in vaccine loss.

When a vaccine storage unit will undergo maintenance or repair, contact VDH in advance for instructions regarding vaccine storage during the repair work.

**Never transport vaccine unless authorized by VDH Immunization Program Staff.  
Vaccine stored in the freezer is NOT usually transported.**

# Vaccine Storage and Handling SOP

## **B. Alternate storage location**

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1. Determine a suitable backup location with a generator for vaccine storage in the event of a mechanical or power failure. An extended power outage is defined as a lack of power for more than 2 hours.
2. This location CANNOT be a private home. The unit must accommodate the amount of vaccines currently in storage and meet the requirements outlined in this plan. Consult with the management at the alternate site to assure your vaccine can be appropriately stored if needed.
3. Permission from the Immunization Program is always required before moving state-supplied vaccine, even to your alternate storage location.

## **C. Emergency plan for a power outage**

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NEVER move vaccine to a home, another storage unit, or an approved location without permission from the Immunization Program. In many cases, it is better to leave the vaccine during a power outage rather than move it. If the building has lost electrical power, check with the building maintenance or the power company to learn if a time for the restoration of power can be determined.

### **1. During a short-term power outage (2 hours or less)**

- Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range.
- If the outage occurs during business hours, note the time of the power failure.
- Once power is restored, note the time and monitor temperatures (until it reaches 2° to 8°C for the refrigerator, -50° to -15°C for the freezer).
- Determine if the temperature has been out of range; if yes, contact the Vermont Immunization Program.

### **2. During a long-term power outage (greater than 2 hours)**

- Do not open the refrigerator or freezer door unless approval is requested and received from VDH to transport vaccines to the backup location.
- If instructed to move vaccine to your alternate location:
  - Contact the alternate location to ensure their power is functional and that they can store vaccine. If they do not have power or enough space to store this vaccine, contact VDH for assistance in finding another location.
  - Follow the instructions from the Immunization Program on packing and transporting vaccine.  
<http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>
- NOTE: Varicella (including both varicella and MMR-V) vaccines are highly temperature-sensitive, and moving these is usually not permitted.

# Vaccine Storage and Handling SOP

## D. SensoScientific alarm notifications

Alarm	Meaning	Conditions	Action Required of Practice During Normal Business Hours	Action Required After Standard Business Hours
Data Alarm	Temperature is out of range.	Alarms when temperatures are out of range for 45 minutes.	<ul style="list-style-type: none"><li>• Contact the Immunization Program.</li><li>• After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.</li></ul>	<ul style="list-style-type: none"><li>• Contact the on-call person for guidance if you need to use the vaccine before the next business day or if you need to move the vaccine.</li></ul>
Signal Alarm	Internet connection has been lost.	Alarms when Wi-Fi is off for 2 hours. The downloads once the connection is reestablished unless the data logger is reset.	<ul style="list-style-type: none"><li>• Wait 60 minutes for the connection to reestablish. If it has been longer than 60 minutes, contact the Immunization Program.</li><li>• After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.</li></ul>	<ul style="list-style-type: none"><li>• No action is required outside standard hours of operation.</li><li>• If the network failed to reconnect, contact the Immunization Program the next business day.</li></ul>
Battery Alarm	The batteries are low.	Alarms when batteries need to be replaced.	<ul style="list-style-type: none"><li>• The practice is responsible for purchasing replacement batteries. Data loggers use four 1.5V AA Lithium Batteries.</li><li>• If you need help with replacing the batteries, contact the Immunization Program.</li><li>• Login to the cloud system under the Monitoring tab to confirm an alarm after you replace the batteries.</li></ul>	<ul style="list-style-type: none"><li>• No action is required outside standard hours of operation.</li><li>• Replace the batteries on the next business day.</li></ul>
Audible Alarm	Only if your audible alarm is enabled, then the data logger will sound off for the above noted reasons. Press the middle button to temporarily turn it off or log in to the SensoScientific cloud system to turn it off permanently.			
Do not suspend the alarm notification until the issue is resolved and the Immunization Program provides instructions.				

Confirm the alarm only after the issue is resolved. Once a unit alarms, it will stay red until you confirm the alarm, even if the unit is reconnected to Wi-Fi, goes back into temperature range or the battery is replaced.

# Vaccine Storage and Handling SOP

## III. Roles and Responsibilities

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### A. Vaccine coordinators

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Designate a Primary Vaccine Coordinator and at least one Backup Vaccine Coordinator. This personnel is responsible for managing state-supplied vaccine, as described in this plan. Both should be knowledgeable about vaccine management, and the Backup should be capable of fulfilling all vaccine storage and handling requirements.

When the Primary Vaccine Coordinator or the Backup is replaced, notify VDH so that the required training can be scheduled promptly.

**Training:** The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VCVP/VAVP compliance site visit for the calendar year or if they were not present for the duration of the site visit.

1. You Call the Shots: Module 10, Storage and Handling
2. You Call the Shots: Module 16, Vaccines for Children Program [VFC providers only]

Find the modules at <https://www.cdc.gov/vaccines/ed/youcalltheshots.html>

### B. Other staff

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All staff with vaccine storage and handling responsibility should read and sign (on the cover page) this Vaccine Storage and Handling SOP annually *and* when changes are made to the plan.

## IV. Storage and Handling-Best Practices

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### A. Selecting storage units (refrigerators and freezers)

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1. Stand-alone refrigerators and freezers are strongly recommended over combination units.
2. Combination refrigerator/freezer units must have separate doors and should have separate temperature controls for each section. Use of such units is discouraged due to documented problems managing frozen vaccine and refrigerated vaccine in this style unit.
3. Never Permitted: Dormitory or bar-style refrigerators. These are small combination refrigerator/freezer units outfitted with one exterior door.
4. Freezer
  - The freezer should be auto defrosting or self-defrosting.



# Vaccine Storage and Handling SOP

- Stand-alone freezers are strongly recommended. NIST<sup>1</sup> studies have shown that the freezer in a combination unit is unreliable for keeping frozen vaccines at the proper temperature.
- Freezer temperatures must be maintained between -50°C and -15°C (-58°F and +5°F).

## 5. Refrigerator

- Stand-alone refrigerators are strongly recommended. The refrigerated vaccine may be stored in a combination unit; preferably, the freezer section is not used.
- Refrigerator temperature must be maintained between 2°C and 8°C (36°F and 46°F).

## 6. Consider the following to determine what size unit is required:

- The vaccine should not be stored in the door, crisper, or space created by removing the crisper bins.
- The vaccine should not be placed on the floor of the unit.
- The vaccine should not be stored near a cooling fan or vent.
- Keep vaccine at least 2-3 inches away from the walls, floor, and coils of the storage compartment.
- Place vaccine as centrally as possible in the unit to allow for air circulation.
- Allow air space between each large package, block, tray, or bin of vaccines.
- There should be enough room to accommodate the largest inventory of the year – typically during flu season (or back-to-school) – without over-crowding.
- There should be space for water bottles marked "do not drink." (See B.2 below.)
- If medications and biological materials need to be stored with the vaccine, they should be placed below the vaccine on a separate shelf to prevent possible contamination. They should not impede airflow.
- Keep vaccine away from cooling vents/fans if you use a combination refrigerator/freezer unit. Place water bottles in front of such vents, but don't block air circulation.
- Avoid the use of the top shelf of the combination refrigerator when possible.
- Keep all vaccine vials/syringes in their original closed boxes, including opened multi-dose vials.
- It is best to store each type of vaccine in a separate, labeled basket or tray. Mesh containers are recommended over solid-sided ones because they allow for airflow. If solid-sided containers are used, they cannot have a lid.

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<sup>1</sup> National Institute of Standards and Technology

# Vaccine Storage and Handling SOP

## B. Preparing the unit for vaccine storage

1. Do not store food and beverages in a vaccine unit.
2. Water bottles marked "Do Not Drink" can be placed in the refrigerator in the door, or on the floor as a thermal buffer. If possible, condition water bottles prior to adding them. Place against the back and along the walls if possible.
3. Frozen water bottles can be placed in the freezer as a thermal buffer. Place these in the door and on the floor, or along the back if possible
4. A "Do Not Disconnect" notice must be posted next to every outlet where a vaccine freezer or refrigerator is plugged in. A second "Do Not Disconnect" sticker must be posted on or near the corresponding circuit breaker.<sup>2</sup>

## Unit Approval

Prior to use for storage of vaccine, the unit(s) should be inspected by Immunization Program staff and have at least 3 consecutive days of in-range temperatures, as monitored by a data logger supplied by the Immunization Program.

## C. Vaccine transport (transfers)

**All vaccine transport must be pre-approved by the Vermont Immunization Program**

Transport involves the movement of vaccine over a short time frame and distance between providers. The time needed to transport should be less than 8 hours, and vaccine should be placed in a stable storage unit as quickly as possible. Vaccines should only be transported when necessary (in an emergency or to ensure the use of vaccines that are about to expire). Frozen vaccine should never be transported except in an emergency and with prior approval.

**Supplies each practice must have on-site to transport vaccines safely:**

- Hard-sided container or Styrofoam
- Backup data logger (see section D)
- Frozen water bottles (that need to be conditioned before packing)
- Insulating materials such as corrugated cardboard and bubble wrap (enough for two layers per container)

Follow instructions on packing and transporting refrigerated vaccine at <http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

Instructions on packing frozen vaccines for transport are provided during approval from the Vermont Immunization Program.

**Never place vaccine directly on frozen water bottles or frozen ice packs.**

<sup>2</sup> These are available from VDH.

# Vaccine Storage and Handling SOP

## D. Backup data loggers

Backup data loggers are required to be used if an on-site data logger malfunctions, during vaccine transport, and for off-site vaccination clinics. The Vermont Immunization Program provides backup data loggers to all VCVP/VAVP enrolled practices and the device location should be documented. For additional data loggers, contact the Immunization Program.

### Backup data loggers:

- Need to be stored in a documented location in the white box
- Ensure at least one computer has the current LogTag software installed  
<https://logtagrecorders.com/software/lta3/download/>
- Cradle to download the data logger

### Backup data logger setup prior to use:

1. Condition the glycol bottle to the appropriate temperature by placing it in the fridge/freezer.
2. Once in range, you may package the vaccine according to instruction (see section C).
3. Transport the vaccine.
4. If the data logger stays in range for the entire length of transport, no further communication with the program is needed.
5. If the data logger goes out of range during transport OR it was never able to get into proper range due to time constraints, you **MUST contact the program** and report this as a temperature excursion.

## E. Proper vaccine placement

Vaccine to store in the freezer		Vaccine to store in the freezer <i>or</i> refrigerator	Vaccine to store in the refrigerator
✱ Varicella ✱ MMRV		✱ MMR <i>Freezer is preferred.</i>	✱ All others
Diluent	✱ Diluents that are packaged with their vaccines (e.g. ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed. ✱ Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, <i>not in the freezer</i> . This includes diluents for MMR, MMR-V, and Varicella.		

\*COVID-19 Vaccine Storage Conditions found in Section VI

# Vaccine Storage and Handling SOP

## F. Avoid administration errors

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- Label each basket/tray with the vaccine type. Labels are available for printing at <https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf>
- Separate and label privately-purchased vaccine vs. state-supplied vaccine.
- Separate and label adult vs. pediatric vaccine.
- Mark the date a multi-dose vial is opened. It should be used through manufacturer's expiration date printed on the vial.
- Conduct a weekly inventory to ensure rotation of vaccines. Short-dated vaccine must be used first.
- Report vaccine administration errors to <http://verp.ismp.org/>

## G. Temperature monitoring

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- **Thermometers:** Storage unit temperatures must be continuously monitored using data loggers purchased and installed by the Vermont Immunization Program.
- **Placement:** The probe in glycol bottle must be placed centrally in the storage unit.
- **Calibration:** Vaccine thermometers must have a current certificate of calibration. VDH is responsible for recalibration services.
- **Malfunction:** If a data logger malfunctions call the Immunization Program immediately.

### 2. Each day the clinic is staffed, and for each vaccine storage unit:

- At the **start of each clinic day** document min/max temperatures
  - i. If using Senso: log in to the SensoScientific cloud system, check off each vaccine storage unit and click "Audit Node." This will time stamp the min/max and "sign" with the login account.
  - ii. If using a non-Senso system (third party or a LogTag Data logger): Min/Max, time, and initials must be documented on paper or through another accessible system.
- The **refrigerator** temperature must be between **2°C and 8°C** (36°F - 46°F).
- The **freezer** temperature must be between **-50°C and -15°C** (-58°F to 5°F).

# Vaccine Storage and Handling SOP

## Strive for 5°C

The refrigerator must be between 2°C and 8°C.

*Strive for an average reading of 5°C.*

## Freezer temperature

The freezer must be between -50°C and -15°C.

## ALARM

Take action if the unit is alarming.

## V. Inventory Management and Ordering Vaccine

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### A. Vaccine ordering schedule

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1. Each practice is assigned an ordering frequency with a 2-week window of time.
2. If the practice runs out of vaccine before the next scheduled order, call the Immunization Program to discuss placing an additional order.
3. If there is not enough space in your refrigerator or freezer to store vaccine as described in this document, the unit is too small. Request an increased ordering frequency and consider the purchase of a unit that can store the largest anticipated inventory.

### B. VIMS and Vaccine ordering

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1. VIMS is accessed through the Vermont Immunization Registry (IMR) found here: <http://www.healthvermont.gov/health-statistics-vital-records/registries/immunization>.
  - To reach VIMS, users must have IMR access. Users who do not have or do not know if they have IMR access, should contact IMR support at 888-688-4667.
  - Once logged in, Select "Vaccine Inventory Management System (VIMS)" from the left navigation menu.
2. A step-by-step VIMS User Guide is available on the Immunization Program website: [http://www.healthvermont.gov/sites/default/files/documents/pdf/ID\\_IZ\\_vax\\_ordering\\_User%20Guide.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_vax_ordering_User%20Guide.pdf)
  - **Flu vaccine:** Flu vaccine is ordered by the Immunization Program for all practices, beginning the first week of Sept. Specific guidance will be provided annually in August.
3. All vaccine orders are reviewed by the Immunization Program. Should adjustments be necessary, you will be contacted.

# Vaccine Storage and Handling SOP

4. Status and tracking information for vaccine orders can be checked using the View History link.

## C. Receipt of vaccine shipments

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1. Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines (varicella and MMR-V) are shipped by the manufacturer, Merck.
2. Upon receipt of **refrigerated** vaccines, open the box and check the enclosed temperature monitoring card. If it shows that an out-of-range temperature occurred during shipping, mark the vaccine "do not use," immediately store it in the refrigerator and call McKesson Specialty at 1-877-836-7123 *the same day*, for further instructions.
3. **Frozen** vaccines are NOT packed with temperature indicators. Instead, they come with a shipper insert that identifies the allowable shipping time. Check the packing slip's shipping date to determine how long the vaccines were in transit. If the shipment arrived beyond the allowed time, mark the vaccine "do not use", store it in the freezer, then call the Immunization Program.
  - The lid of the box contains diluent. Remove the diluent from the lid before you discard the box. Diluent can be stored in the refrigerator or at room temperature, but not in the freezer.
4. Verify that the packing slip agrees with the content of the shipment. Date and sign the packing slip and keep it for your records. Do not fax it to VDH.
  - If the shipment contents and the packing slip do not match, call the Immunization Program *the same day* the shipment is delivered.
5. Rotate vaccine stock within storage units to ensure that vaccines with the shortest expiration dates are placed in a position to be used first.

## D. Avoiding wastage due to vaccine expiration

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1. Conduct a weekly inventory to ensure that vaccine with the earliest expiration date is used first.
2. Sixty to 90 days before expiration, if a vaccine is not likely to be used, contact the Immunization Program for assistance redistributing the vaccine to a practice that can use it. Immunization Program permission is required before moving state-supplied vaccine.
3. **Remove** the expired or non-viable vaccine from the storage unit. Mark "Do Not Use".

**Always maintain the integrity of your vaccine stock by never swapping or borrowing doses between state-supplied and private purchase vaccine**

# Vaccine Storage and Handling SOP

## **E. Handling expired, spoiled, and wasted vaccine**

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All spoiled, expired, or wasted vaccines must be accounted for and reported to the Immunization Program in VIMS. These doses are documented via an Adjust Request with an Adjustment Type of Return or Waste.

- 1. RETURN:** Non-viable, unopened and intact state-purchased vaccine vials and syringes should be returned to McKesson for federal excise tax credit.
  - All expired, or spoiled vaccines must be reported in a VIMS Adjust Request. Print the Request to use as a packing slip.
  - The Immunization Program will review the request and, upon approval, UPS will email the user a shipping label.
  - Upon receiving the shipping label, vaccine should be packed to prevent vial breakage and shipped to McKesson within six months of spoilage or expiration. Enclose the Request print out as a packing slip.
- 2. WASTE:** Vaccines are considered wasted if they have been opened or damaged and cannot be administered to patients. These vaccines may not be returned and should be discarded as medical waste.
  - Reasons for waste include: being drawn into a syringe but not administered, opened in error, error in reconstitution, vaccine whose sterility has been compromised by the vial being dropped or broken or open multi-dose vials that have expired.
  - All wasted vaccine must be reported in a VIMS Adjust Request.
  - Dispose of wasted vaccine on site in a sharps container.

The Immunization Program greatly appreciates and values the many significant contributions of Vermont primary care practices in ordering, storing, handling, and administering immunizations to children, adolescents and adults.



# Vaccine Storage and Handling SOP

## VI. COVID-19 Vaccine Storage and Handling

COVID-19 vaccine storage and handling guidance is changing rapidly. Always refer to the specific Emergency Use Authorization for storage and handling information. Find these at the manufacturer websites listed below.

Refer to the below websites frequently to obtain the most up to date information on available COVID-19 Vaccines:

CDC - U.S. COVID-19 Vaccine Product Information  
[www.cdc.gov/vaccines/covid-19/info-by-product/index.html](http://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)

CDC – Vaccine Storage and Handling Toolkit (COVID-19 starts on pg.49)  
[www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

Health Department – Vaccine Information for Health Care Professionals  
[www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals](http://www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals)

Pfizer-BioNTech  
[www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)

Moderna  
[www.modernatx.com/covid19vaccine-eua/](http://www.modernatx.com/covid19vaccine-eua/)

Janssen  
[www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com)



# Vaccine Storage and Handling SOP

## A. Provider agreement

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All providers are required to sign a COVID-19 Vaccination Program Provider Agreement before receipt of this vaccine. As a part of this agreement, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with the guidance.
- Comply with Immunization Program guidance for handling temperature excursions (above).
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

## B. Provider training

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All staff members who receive vaccine deliveries and those who handle or administer vaccines should be trained in vaccine-related practices and procedures. Please refer to the Role and Responsibilities section in this document.

In addition to general vaccine management training, it is the enrolled facility's responsibility to ensure that staff remains trained in the face of rapidly changing guidance. COVID-19 vaccine administration is much more complicated than the standard vaccines, and as more data becomes available, stability storage guidelines may change. Please refer to the below Training Guide for many resources to assist your staff's training.

**Vermont COVID-19 Vaccine Program Training Guide**  
[www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Training-Quick-Guide.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Training-Quick-Guide.pdf)

# Vaccine Storage and Handling SOP

## C. Temperature monitoring

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Please refer to the above document for general information on the Immunization Program's temperature monitoring systems and reporting requirements. For COVID-19 enrolled providers, a third-party monitoring system may be approved.

- 1.) **Refrigerator temperatures** – Between 2°C and 8°C, strive for an average reading of 5°C.
- 2.) **Freezer temperatures** – While most vaccines are viable between -50°C and -15°C, some COVID-19 vaccines have a narrower frozen temperature range of -25°C and -15°C. For this reason, even if your freezer was approved previously, you may need to undergo another approval before being allowed to order and store the COVID-19 vaccine.
- 3.) **Ultra Cold temperatures** – At this time, only Pfizer-BioNTech vaccine has ultra-cold temperature requirements between -80°C and -60°C. These temperatures require special monitoring equipment, and the vaccine must direct ship to a facility from the manufacturer.
- 4.) **During transport** – Even when transported short distances, temperature monitoring of COVID-19 vaccine is required. Please refer to Vaccine Transport (transfers) above.
- 5.) **During clinics** - If working out of a cooler, qualified pack-out, or portable refrigerator during a clinic, continuous monitoring is required, and documentation occurs hourly.

**COVID-19 Vaccine Storage and Handling for Off-site Clinics**  
[www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Off-Site-Clinic-Guidance.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Off-Site-Clinic-Guidance.pdf)

## D. Beyond use date

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The current presentation of COVID-19 vaccines available is that of multi-dose vials with no preservatives. Being preservative-free means that the time a vaccine is thawed, brought to room temperature, reconstituted, punctured, or drawn into a syringe will determine its shelf life and viability. To ensure that you administer an effective vaccine, track and document every change in temperature or presentation in the cold chain before administration. The CDC has developed resources to assist with this here: [www.cdc.gov/vaccines/covid-19/info-by-product/index.html](http://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)

## E. Vaccine deliveries and inventory management

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You will manage the state-supplied COVID-19 vaccine in the VIMS system, similar to other vaccines. However, special circumstances may impact how this system is utilized specifically to the COVID-19 vaccines.

- 1.) The Immunization Program is currently managing all orders and transfers of state-supplied COVID-19 vaccine.

# Vaccine Storage and Handling SOP

- 2.) The CDC has allowed for practices to use “bonus-doses” from the vials of specific vaccines. The number of doses may need to be adjusted into your VIMS inventory.
- 3.) Shipments may be sent as first and second doses, which must be part of your planning and inventory management.
- 4.) Reporting requirements are more frequent for COVID-19 vaccine. Reconciliation of state-supplied COVID-19 vaccine is required after each clinic day, including administered, wasted and on-hand doses.

Resources to assist are available on the Health Department – Vaccine Information for Health Care Professionals: [www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals](https://www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals)

COVID-19 Vaccine Inventory Management System (VIMS) User Guide  
<https://www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-VIMS-Hospital-User-Guide.pdf>

# Vaccine Storage and Handling SOP

## F. Vaccine specific temperature guidance

The below chart is provided for reference and is accurate as of 03/01/2021. The COVID-19 vaccine information is changing rapidly, and you should always reference the above CDC and manufacturer websites for the most current guidance. Always call the Immunization Program if the COVID-19 vaccine experiences any temperatures outside of the below ranges.

Pfizer-BioNTech		Moderna	
Permanent storage- Between -80°C and -60°C		Permanent storage- Between -50°C and -15°C	
Before dilution	<b>In the refrigerator</b> Between 2°C and 8°C for 120 hours	Before puncture	<b>In the refrigerator</b> Between 2°C and 8°C for 30 days
	<b>At room temperature</b> Between 8°C and 25°C. Must mix within 2 hours.		<b>At room temperature</b> Between 8°C and 25°C for 24 hours. Do not refreeze.
	<b>In the Freezer</b> Between -25°C and -15°C For 2 weeks		
After dilution	Between 2°C and 25°C for 6 hours	After puncture	Between 2°C and 25°C for 12 hours

Janssen	
Permanent storage- Between 2°C and 8°C	
Before puncture	<b>In the refrigerator</b> Between 2°C and 8°C Until expiration
	<b>At room temperature</b> Between 9°C and 25°C. For 12 hours
After puncture	Between 2°C and 8°C for 6 hours If at room temperature must use within 2 hours