COVID-19 Vaccine Management Standard Operating Procedure (SOP) Template

# Purpose: To ensure the vaccine cold chain is maintained for optimum potency.

Instructions:

* Review and update document annually, when vaccine management policies change, and when staff with designated vaccine management responsibilities change.
	+ Review your site’s MIIS enrollment page on a regular basis to ensure that all contact personnel and storage units are accurate in your MIIS profile. If any changes need to be made to your site’s enrollment profile, please contact the Vaccine Unit at 617-983-6828 for assistance with obtaining an updated MCVP Agreement.
* Post on or near vaccine storage unit(s).
* All staff handling vaccines must read, sign, and adhere to the protocols described in this document.

|  |  |
| --- | --- |
| **Office/Practice Name** | **Pin Number** |
|  |  |

**Contact Information**

|  |  |  |
| --- | --- | --- |
|  | MA COVID-19 Vaccine Program  | State Vaccine Program (if applicable) |
|  | Primary Vaccine Coordinator | Back-Up Vaccine Coordinator | Primary Vaccine Coordinator | Back-Up Vaccine Coordinator |
| Name  |  |  |  |  |
| Phone Number |  |  |  |  |
| Email Address |  |  |  |  |

*Notify the Vaccine Management Unit within 10 days if a new Primary Vaccine Coordinator or Backup is identified.*

**Vaccine Storage & Handling**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Main Storage Location | Back-Up Storage Location | Centralized Storage Location (if applicable) |
| Location Name |  |  |  |
| Location Address |  |  |  |
| Contact Name |  |  |  |
| Contact Phone # |  |  |  |
| Storage Unit Availability |  [ ]  Refrigerator (2°C to 8°C) [ ]  Freezer (-50°C to -15°C) [ ]  Ultra-Cold (-90°C to -60°C) |  [ ]  Refrigerator (2°C to 8°C) [ ]  Freezer (-50°C to -15°C) [ ]  Ultra-Cold (-90°C to -60°C) |  [ ]  Refrigerator (2°C to 8°C) [ ]  Freezer (-50°C to -15°C) [ ]  Ultra-Cold (-90°C to -60°C) |

|  |  |
| --- | --- |
| **Name and Title** | **Contact Information (phone/email) *Vaccines Coordinators***  |
|  |  |
|  |  |

|  |  |  |
| --- | --- | --- |
|  | **Pfizer**<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/storage.html>  | **Moderna**<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>  |
| **Storage and Handling** | Ultra-cold: -90°C to -60°C until expiryRefrigerate: 2°C to 8°C up to 10 weeks without puncturing **No regular freezer storage** | Freezer: -50°C and -15°C until expiryRefrigerate: 2°C and 8°C for up to 30 days. Do NOT refreeze **Do not store with dry ice or below -50°C**  |
| **Manufacturer Contact Information** | **Website:** [www.cvdvaccine.com](http://www.cvdvaccine.com) **Medical Information:** 800-438-1985**Customer Service:** 800-879-3477 | **Website:** <https://www.modernatx.com/covid19vaccine-eua/> **Medical Information:** 866-663-3762 |

|  |  |  |
| --- | --- | --- |
|  | **Janssen/J&J**<https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>  | **Novavax**<https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/index.html>  |
| **Storage and Handling** | Refrigerate: 2°C and 8°C**Do not freeze** | Refrigerate: 2°C and 8°C**Do not freeze** |
| **Manufacturer Contact Information** | **Website:** [www.vaxcheck.jnj](http://www.vaxcheck.jnj/)**Medical information:** 1-800-565-4008 | **Website:** <https://us.novavaxcovidvaccine.com/hcp> **Medical information:** <https://www.novavaxmedinfo.com/> |

**Receiving COVID-19 Vaccine**

* Staff receiving shipments (front office, loading dock, reception, etc.) must notify thevaccine coordinatorsas soon as a vaccine shipment arrives.
* Contact the Vaccine Management Unit immediately for guidance if there are any concerns or inaccuracies with the vaccine order.
* Ancillary supply kits (needles, syringes, masks, vaccine cards, etc.) will also be shipped to site.
* Examine the shipment for damages.
* Count vaccines in shipment and compare with packing list and original order to make sure the order and delivery is correct. Check to ensure that expiration dates and lot numbers match. Make sure diluent is also accounted for.
* Place vaccine in the ultra-cold/refrigerator/freezer designated for vaccine storage immediately after an inventory of the shipment is completed. If vaccines are being placed in a unit that requires a BUD, please write the BUD on the box immediately. See Beyond Use Date section below for more information.
* If cold-chain monitors indicate that the vaccine has experienced out of range temperatures:
	+ Store vaccines at proper temperatures
	+ Take a picture of indicators
	+ Contact the Vaccine Management

**Storing COVID-19 Vaccine**

* **Store vaccine in original packages to protect vaccine from light.**
* **DO NOT REFREEZE THAWED VACCINE.**
* Use Dates:
	+ The Beyond Use Date refers to the date that vaccines will become non-viable after being stored in storage conditions that are not conducive to long-term (expiration date) storage. The count from the Beyond Use Date starts on the day that the vaccines are moved out of their long-term storage conditions. **Vaccines become non-viable after reaching the Beyond Use Date and should not be administered to patients.** Once the Beyond Use Date is reached, please submit a storage and handling issue in MIIS for any unused doses remaining. **If the expiration date is reached before the Beyond Use Date, please mark the vaccines as spoiled and remove from your storage unit.**

|  |  |  |
| --- | --- | --- |
| **Vaccine Manufacturer** | **Expiration Date Storage** | **Beyond Use Date Storage** |
| **Pfizer COVID Vaccines** | Viable in ultra-cold freezer until expiration date listed for Lot # | Viable in refrigerator for **10 weeks** once placed in unit |
| **Moderna COVID Vaccines** | Viable in regular freezer until expiration date listed for Lot # | Viable in refrigerator for **30 days** once placed in unit |
| **J&J COVID Vaccines** | Viable in refrigerator until expiration date listed for Lot # | N/A |
| **Novavax COVID Vaccines** | Viable in refrigerator until expiration date listed for Lot # | N/A |

**Storage Units and Monitoring for COVID-19 Vaccine**

* **The use of any a dormitory-style, bar-style, or household combination refrigerator/freezer unit for storage of any COVID vaccines, including temporary storage, is strictly prohibited.**
* Refrigerator unit used for COVID-19 storage must be purpose-built (for vaccine) or pharmaceutical-grade units designed to either refrigerate or freeze.
	+ *Pharmaceutical grade units are designed specifically for storage of biologics, including vaccines. These units will often have a (1) microprocessor-based temperature control with a digital temperature sensor and (2) fan-forced air circulation with powerful fans and multiple cool air vents to promote uniform temperature in the unit.*
* Freezer unit used for COVID-19 storage must be a standalone unit.
	+ *A standalone freezer unit must have its own power cord to connect to your wall outlet and cannot be a dual unit that contains refrigerator and freezer utilizing the same power cord.*
* **Please contact the Vaccine Unit when purchasing a new storage unit so that the unit can be approved before your purchase and added to your site’s MIIS account once acquired.**
* The use of a Digital Data Logger (DDL) is **REQUIRED** in all units storing state-supplied COVID-19 vaccines.  A DDL provides the most accurate storage unit temperature information, including details of how long a unit has been operating outside the recommended temperature range.  Unlike a simple minimum/ maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at present intervals. To be in compliance a DDL must have the following features:
	+ Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)†
	+ Alarm for out-of-range temperatures
	+ Low-battery indicator†
	+ Current, minimum, and maximum temperature display‡
	+ Recommended uncertainty of +/-0.5° C (+/-1° F)
	+ Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
	+ DDLs with a current and valid Certificate of Calibration Testing.
* Sites are required to review and acknowledge DDL temperature data every day the practice is open, at least once at the beginning of the day and once at the end of the day; this is critical for vaccine viability.
	+ The temperature readings on the storage unit itself cannot be used in place of a digital temperature monitoring device.
* Providers are required to acknowledge the temperature on the digital data logger twice daily. This must be document in the digital temperature log report. The digital data logger report must show:
	+ Date
	+ Time
	+ Minimum/maximum temperature during the day
	+ Average temperature during the day
	+ Indicate Alarms/Out of Range temperature
	+ Time of acknowledgement
* Digital temperature report must be in a PDF format, so it can be uploaded to the MIIS.
	+ *If using state supplied-DDL you can just press the “read” bottom twice a day, once on the am, once at the pm to record your temperature acknowledgement.*
* Handwritten temperature logs are not acceptable.
* Temperature logs from the digital temperature monitoring device **must be uploaded into your site’s MIIS profile at the time of a site visit or upon request**. **You must download and save your digital temperature logs reports at least once monthly, they must be kept for at least 3 years.** **If the storage unit experienced any out-of-range temperatures, please refer to the “Temperature Out of Range” section of this document below.**
* **A DDL must be in use at all times including during transport of vaccines and temporary storage of vaccines on other units.** Provider sites are responsible for having as many DDLs as needed based on the nature of their practice to have all state supplied vaccine always accompanied by a DDL when storing, transporting and/or administering in a mobile clinic.

**Transporting COVID-19 Vaccine**

* Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) needed to pack vaccines for safe transport.
* Place a digital data logger and associated glycol bottle in each packing container near the vaccine to monitor the temperatures.
* Do not store the vaccines in the packing container until the packing container is reding in-range temperatures (2°C to 8°C) on the digital data logger attached.
* Record the time and temperature when vaccine was removed from the storage units and placed in the containers at the beginning and end of the transport on the *Temperature Troubleshooting log*.
* Vaccine should not be transferred more than one time.
* **For transporting vaccines between site locations,** **please refer to the linked Vaccine Transport Guide from CDC** at <https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

**Transportation when thawed**

* Care must be taken to ensure vaccine does not re-freeze during transport.
* Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
* Vaccine should be transported in the carton whenever possible.
* If transport must be conducted at the vial level, the vial should be placed with padding material (ex. bubble wrap) to minimize movement during transport.
* Transport in insulated containers qualified to maintain 2°C to 8°C for the duration of transport.
* Secure transport containers to prevent unnecessary movement.
* Allowable timelines for transport of thawed vaccine are shown below.  Total transport time should not exceed 12 hours in total.
	+ Transport while walking or using hand cart: not to exceed 1 hour
	+ Vehicle transport: not to exceed 12 hours

**Temperatures Out of Range**

**If there are out of range temperatures, suspend vaccine administration, quarantine the vaccine, upload digital temperature logs to the MIIS, and immediately contact the manufacturer. Once the manufacturer determines viability immediately call and notify the Vaccine Management Unit of the incident and final determination (617-983-6828,** **dph-vaccine-management@mass.gov****).**

* **Quarantine vaccines by keeping the vaccines in the proper temperatures and marking them as ‘Do Not Use’**.
* Upload temperature logs into the MIIS and select ‘Urgent Temperature Log Issue’.
* Immediately call the Manufacturer for viability results on your vaccines. Once the manufacturer provides the viability results, please call the Vaccine Management Unit and report your out-of-range temperature.
* **In the event of an out-of-range temperature, please complete the Temperature Troubleshooting Guide located as a downloadable file from the link below**. When contacting the Vaccine Management Unit to provide the viability results determined by the manufacturer, please also attach a copy of the completed Temperature Troubleshooting Guide for documentation.
* Temperature Troubleshooting Guide: <https://www.mass.gov/resource/vaccine-management>
* Please note that out of range temperatures of **any** duration must be reported, even if they do not trigger an alarm.

# Power Failure/Refrigerator Failure

* Immediately call the Vaccine Management Unit to report the power failure/refrigerator failure.
* If instructed by the Vaccine Management Unit to move your vaccines, pack vaccines according to the Vaccine Transportation Procedures and transport to Emergency Storage location.
* If power failure/refrigerator failure occurs outside of regular business hours, pack vaccines according to the Vaccine Transportation Procedures and transport to Emergency Storage location. Contact the Vaccine Management Unit by the next business day.

**Staff Training/Provider Education Requirements**

* All staff administering and working with the COVID-19 vaccines should also **complete the** [**Competencies Assessment form**](https://www.cdc.gov/vaccines/covid-19/downloads/competencies-screening-checklist.pdf) **(located at the link below) on a yearly basis**.
* All staff administering the COVID-19 vaccines must also complete the CDC COVID Training Modules located at the link below. Certificates of completion should be kept on file.
	+ Training Module Link: <https://www.mass.gov/info-details/covid-19-vaccine-training-and-education-resources-for-providers>

**Additional Resources**

* Visit [Massachusetts COVID-19 Vaccine Information | Mass.gov](https://www.mass.gov/info-details/massachusetts-covid-19-vaccine-information#guidance-for-covid-19-vaccine-providers-) for additional information, such as COVID-19 vaccine timeline and availability, training materials, vaccine provider FAQ, and <https://www.mass.gov/info-details/covid-19-vaccine-information-for-providers> guidance on COVID-19 vaccine management and administration.

|  |
| --- |
| This SOP was created and completed by: |
| Name |  |
| Title |  |
| Date of Completion |  |
| Signature |  |

**Staff Acknowledgment**

|  |  |  |
| --- | --- | --- |
| **Date** | **Employee Name** | **Employee Signature** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |