

COVID-19 Provider Packet

Facility Name:	PIN:
Vaccine Coordinator:	Phone Number:
Backup Vaccine Coordinator:	Health Health Human Resources

In this packet you will find documents you may need for the COVID-19 Vaccination Program.

These documents should be maintained on the unit accessible to all staff handling vaccines or close to the vaccine storage unit.

Last update 5/11/2022



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The Vaccine Management Plan **MUST** be reviewed and/or updated annually or as changes occur.

Date Updated	Signature of Person Responsible for Plan Content



Vaccine Coordinator Responsibilities

The Vaccine Coordinator and the Backup Vaccine Coordinator will be responsible for management of the VFC vaccines. Both are responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended ranges and documenting the temperature on the temperature logs for each storage unit twice a day with pin number on every page. The primary person in charge of vaccines should review and complete this document annually. **Any changes in key staff must be reported to the Immunization Services as soon as the change becomes known in your office.**

- Ordering all ACIP recommended vaccines for the patient population served
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday
- Ensuring staff are correctly checking and recording vaccine storage unit temperatures per temperature monitoring
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring all staff are properly trained and training certificates are maintained
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport and overseeing temperature excursions (TE)
- Ensuring appropriate handling of vaccines during a disaster or power outage

Vaccine Coordinator responsibilities may be completed by the Coordinator or delegated to appropriate staff. Ensure the Coordinator has trained the delegate(s) and documented competency for the specific task(s) assigned.

Education and Training

A. The Vaccine Coordinator, the Backup Vaccine Coordinator, and all staff members who handle or administer vaccines, including recording temperatures of vaccine storage units are **required** to complete the online CDC Trainings "You Call the Shots" and "Storage and Handling Training" annually, found at:

https://www.cdc.gov/vaccines/ed/youcalltheshots.html

- You Call the Shots
- Vaccine Storage and Handling

https://www2.cdc.gov/vaccines/ed/covid19/index.asp

• COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers



- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Providers Need to Know
- Moderna COVID-19 Vaccine: What Healthcare Providers Need to Know
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Providers Need to Know

To obtain Continuing Education credit, use this website to register:

- <u>https://tceols.cdc.gov/Home/Steps</u>
- B. Training should occur annually and:
 - a. During new staff orientation;
 - b. Annual for all staff involved in immunization and vaccine storage and handling.
 - c. When program recommendations and requirements are updated; and
 - d. When new vaccines are added to your facility's inventory.
 - Record names of trainings, dates and participants
- C. Competency checks should be in place to ensure staff members are skilled and proficient.
- D. **Train staff on routine vaccine storage and handling, and temperature excursions.** Keep the VFC Vaccine Management Plan near or on vaccine storage units and make sure staff knows where to find them. Document training with dates and participant names.

Maintaining Records

COVID-19 documentation must **maintain all records** related to the VFC program for a minimum of **three years** and make these records available to public health officials, including the state or U.S. Department of Health and Human Services (DHHS), upon request.

Examples of COVID-19 program records include:

- Temperature logs
- Vaccine management training records
- Routine and emergency vaccine management plans with standard operating procedures
- Provider Agreements
- Provider Profiles
- Billing Records
- Vaccine ordering records
- Vaccine purchase and accountability records

Emergency Use Authorization Fact Sheet or Vaccine Information Statements (EUA or VIS)

Federal law requires that EUA or VIS be provided before certain vaccinations are given. CDC encourages the use of ALL EUA or VIS. EUA or VIS are increasingly available in electronic formats that patients can read and take away on smart phones and other electronic devices.

All available EUA or VIS, including versions in 30 different languages, can be downloaded from the Immunization Action Coalition website at http://www.immunize.org/vis/ or from CDC's website at http://www.immunize.org/vis/ or VIS are updated periodically, and it is the provider's responsibility to ensure that the EUA or VIS with the most current publication date is used.



VAERS/National Childhood Vaccine Injury Compensation Act (NCVIA)

The NCVIA requires healthcare providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) <u>https://vaers.hhs.gov/</u>. Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. VAERS data are monitored continually to detect unknown adverse events or increases in known side effects.

VAERS form Information

Information to include:

- The type of vaccine received
- The timing of vaccination
- The onset of the adverse event
- Current illnesses or medications
- History of adverse events following vaccination
- Demographic information about the recipient (age, gender, etc.)

VAERS reports can be submitted online (<u>http://vaers.hhs.gov/index</u>) or on a paper VAERS report form.

Vaccine Management Plan

Each COVID-19 provider must have written vaccine storage and handling plans, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. The routine vaccine storage and handling plan should include guidance on routine vaccine management processes and practices.

Emergency vaccine storage and handling plans must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, or other emergencies that might compromise appropriate vaccine storage conditions. Emergency plans should be reviewed, tested, and revised annually as needed to ensure the emergency system in place will result in the proper cold chain of the vaccines.

At a minimum, the vaccine management plans must be reviewed and updated annually. Plans must also be updated when vaccine management practices change or when there is a change in staff that has responsibilities specified in the plan.



Your plan should include:

- Current Vaccine Coordinator and Backup Vaccine Coordinator
- Proper Vaccine Storage and Handling Procedures
- Vaccine Receiving Procedures
- Vaccine Wastage Procedures
 Current Health Alert
- Emergency Plan Procedure
- □ Vaccine Ordering Procedure
- □ Inventory Control
- Review date with signature of reviewer
- □ Standing Orders for ALL COVID-19 vaccines in your facility

- □ All Staff Training and Documentation on COVID-19:
 - Storage and Handling
 - You Call the Shots
 - COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
 - Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Providers Need to Know
 - Moderna COVID-19 Vaccine: What Healthcare Providers Need to Know
 - Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Providers Need to Know

Vaccine Finder

The COVID-19 Vaccination Program Provider Agreement requires providers to report vaccine supply information directly to the CDC. Organizations or providers locations receiving COVID-19 vaccine should report supply information daily to the Vaccines.gov using the online COVID Locating Health Provider Portal.

The Vacciines.gov website will show patients the locations of providers carrying the COVID-19 vaccines. For provider locations displayed on Vaccines.gov, patients will see:

- Types of COVID-19 vaccines available.
- Vaccine site location information.
- Hours of operation.

Instructions to complete your Vaccines.gov profile are located in the Printables & Instructions section of this manual.



A COVID-19 Compliance Site Visit is an opportunity for state or local staff to educate and support COVID-19 providers. The purpose of these visits, as well as other visits performed, is to educate providers about COVID-19 program requirements, including patient screening and documentation of eligibility and proper storage and handling of vaccine.

Each enrolled and active COVID-19 provider will receive a Compliance Site Visit at least every other year.

What happens during a COVID-19 Compliance Site Visit?

The program staff will contact the COVID-19 provider to schedule a Compliance Site Visit. The visit involves assessment of provider knowledge regarding program requirements and vaccine storage and handling techniques utilized in the practice. It also provides an opportunity for providers to ask questions while allowing VFC program staff to offer resources to support providers' efforts in COVID-19 vaccinations.

Corrective Actions and COVID-19 Compliance Site Visit follow-up

Overall, Compliance Site Visit results confirm that COVID-19 providers understand and implement the program in their practices successfully. However, on occasion, some issues and educational needs are identified and require additional follow-up and communication by the state or local program staff to ensure the provider's success with the program.

Some issues can be corrected during the visit, while other issues may warrant further follow-up and communication by the state or local VFC staff. The program staff will work with provider staff to develop a corrective action plan, including follow-up steps and a timeframe, to address any non-compliant practices identified.

COVID- 19 Vaccine Storage and Handling

COVID-19 vaccine storage unit requirements and set-up:

Use one of the following types of storage units or COVID-19 vaccine:

- Pharmaceutical grade
- Freezer-less refrigerators
- Standalone freezers
- Either the refrigerator or freezer portion of a combination household style storage unit. Make sure a combination household-style storage unit has separate exterior doors that seal tightly and properly.
- Ensure that the storage unit is able to maintain the required temperature range throughout the year.
- Ensure that the storage unit has enough room to store the year's largest inventory without crowding (i.e. community clinics).
- Ensure that the storage unit has enough room to store water bottles (in the refrigerator) and frozen coolant packs/water bottles (in the freezer) to stabilize the temperatures. Does not apply to pharmaceutical storage units.



- Dedicate the storage unit to the storage of vaccines.
- Never store food or beverages in a vaccine storage unit.
- NEVER use a dorm-style unit to store COVID-19 vaccines, even temporarily.
- Refer to your manufacturer information for complete guidance on your storage unit type.

COVID-19 Temperature monitoring device (TMD) aka Digital Data Logger (DDL):

- DDLs are considered the "gold standard" for monitoring storage temperatures for <u>all</u> vaccines.
- Ensure temperature excursions are detected, including the **length of time** a temperature is out of range, thus making them one of the most advanced devices to ensure vaccines are stored correctly and protected from unnecessary waste.
- Provides valuable data that can save vaccine, prevent ineffective vaccine from being administered, and prevent the need to revaccinate affected patients.
- A DDL, with a detachable probe, should be placed in a bottle containing a thermal-buffered material, such as glycol, and placed in the COVID-19 storage unit/s.
- Ensure the DDL is approved for the use in the storage unit type (refrigerated temperatures, frozen temperatures, and ultra-cold temperatures)
- In non-pharmaceutical storage units, place the bottle of thermal-buffered material upright in the center of the vaccine storage unit.
- In pharmaceutical storage units, place the bottle of thermal-buffered material in the area of the storage unit designated for the thermometer equipment. The temperature probe does not need to be in the center of the unit unless there is no manufacturer-designated area.
- Certify and calibrate the DDL every 2-3 years. Replace the DDL as necessary.
- A certified and calibrated back-up thermometer should be available at all times.
- Document COVID-19 vaccine storage unit temperatures at least twice a day (beginning and end of day).
- Review and document COVID-19 vaccine storage unit minimum and maximum temperatures at least once a day.
- If online or remote vaccine monitoring system is available, review the storage unit temperatures on the website and document the storage unit temperatures electronically by "logging in."
- When unable to monitor storage unit temperatures via online or remote vaccine monitoring system for any reason, monitor storage unit temperatures using a back-up digital data logger (preferred) or a min/max thermometer and document the storage unit temperatures on the COVID-19 Vaccine Temperature Log for Refrigerator Vaccine Storage.
- Refer to Pfizer guidance on daily temperature monitoring of the Pfizer ultracold vaccine shipper when using the temperature monitor provided with the vaccine shipper.
- Maintain copies of all Refrigerator/Freezer Temperature Recording Forms for 3 years.

Check the Appendix for instructions on how to use the DDL

COVID-19 Vaccine Storage Unit Set-up

- The storage unit should be level and placed at least 4 inches from the wall.
- Plug the storage unit directly into an outlet dedicated to only that unit and, preferably, connected to a generator.



- Never plug a COVID-19 vaccine storage unit into an outlet that can be activated by a wall switch, a multioutlet power strip, or an outlet with a built-in circuit switch/reset button (GFCI outlet). If built-in circuit 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.
- Place a "Do Not Unplug" sign by the storage unit plug outlet and, if possible, a plug guard or cover over the plug.
- Place a "Do Not Adjust Temperature" sign on the storage unit.
- Label all storage unit circuit breakers to alert people not to turn off power to the storage units.
- Set back-up generators to self-test weekly.
- Manually test the generator quarterly and schedule routine generator maintenance at least annually.

COVID-19 Vaccine Storage and Practice

- Refrigerator temperature should be between 36°F and 46°F (2°C and 8°C), with an ideal average temperature of 40°F (5°C).
- Freezer temperature should be between -58°F and +5°F (- 50°C and -15°C).
- Ultra-low temperature freezer should be between -130°F to-76°F (-90°C to -60°C).
 - Pfizer does not need an ultra-cold storage unit
- The ultra-cold vaccines may be stored in the ultra-cold thermal shipping container for up to 30 days.
- Stabilize temperatures in household storage units, by placing cold bottles of water labeled "Do Not Drink":
 - On the floor
 - In the shelves of the door
 - On the top shelf under the cooling vent
- Do not block the air vent(s). Place frozen coolant packs or frozen water bottles labeled "Do Not Drink" in the freezer along the back, beside the walls and in the door.
- Water bottles will be cold and coolant packs will be frozen prior to putting them in the refrigerator/freezer with vaccine so they don't alter the temperatures of the storage unit.
- Do not overfill the storage unit doors.
 - Note: Place frozen coolant packs or water bottles in the door of the unit securely so they cannot dislodge and prevent the unit door from closing.
- Once storage unit temperatures stabilize, review the temperatures, and check twice a day at the beginning and end of the clinic day.
- The storage unit temperatures will be within recommended range at least 5 days prior to vaccine storage.
- Do not store the Pfizer ultra-cold vaccine shipments in a small space.
- Do not place COVID-19 vaccines against the walls, on the floor of the unit, or under the vent on the top shelf of the storage unit. Store refrigerated COVID-19 vaccines far enough away from the air vent to avoid freezing the vaccine.
- NEVER store COVID-19 vaccines in the door of the storage unit.



- Do not pack storage units too tightly. Allow space between rows of COVID-19 vaccines to promote cold air circulation.
- Store COVID-19 vaccines with similar names or similar packaging separately in the unit to lessen the risk of administration errors.
- Store COVID-19 vaccines in well vented bins or trays.
- Do not store COVID-19 vaccines in vegetable bins or drawers.
- Place COVID-19 vaccines with the soonest (earliest) expiration dates in front of other vaccines of the same type that have later expiration dates.
- Do not keep blood, enteric, or other lab specimens in the COVID-19 vaccine refrigerator or freezer.
- Store COVID-19 vaccines in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light.
- Pfizer diluent is not packaged with the Pfizer vaccine. The diluent used with Pfizer vaccine is provided in the ancillary kits.
- Pfizer diluent stored at room temperature 68°F to 77°F or (20°C to 25°C) is transported at room temperature.
 - Note: Placing room temperature diluent in the transport container can raise the temperature of the container.
- Never freeze diluents, not even during transport.
- Store diluent 0.9% Sodium Chloride injection per manufacturers' recommendations.
- Store all other routinely administered vaccines in appropriate storage units required to maintain recommended temperatures.
- Refrigerator:
 - \Box Clean the storage units once a month.
 - \Box Check the door seals for gaps.
 - □ Clean the coils and if the unit needs to be unplugged or moved for any reason, relocate the vaccines with the backup data logger thermometer to the backup unit **prior** to doing so.
 - □ Temperatures **MUST** be kept between 36°F and 46°F (2°C and 8°C), with an ideal average temperature of 40°F (5°C).
- Freezer:
 - □ If frozen vaccines are stored in a manual defrost freezer it will be defrosted regularly and as needed to avoid having frost build up in the unit.
 - □ Remove excessive ice buildup.
 - □ During defrost, move the vaccines to the backup storage unit until the unit has been completely defrosted and the unit's temperature is in acceptable range.
 - \Box Temperatures **MUST** be kept between -58°F and +5°F (-50°C and -15°C).
- Ultra-low temperature:
 - Ultra-low temperature freezers **MUST** be kept between -112°F to-76°F (-80°C to -60°C).
- Room temperature:
 - □ Maintain the room temperature where the COVID-19 vaccine storage unit is located between 68°F and 77°F.



COVID-19 Vaccines

	Johnson & Johnson	Moderna	Pfizer
Doses	1	2	2
		28 days between doses	21 days between doses
Storage	 Store vaccine in a refrigerator. Store vaccine between 2°C and 8°C (36°F and 46°F). Do not freeze. Protect from light. 	 Frozen vaccine must be thawed before using. Thaw vaccine in the refrigerator or at room temperature: Refrigerator: Between 2°C and 8°C (36°F and 46°F). Room temperature: Between 8°C and 25°C (46°F and 77°F). Amount of time needed to thaw vaccine varies based 	 21 days between doses Frozen vaccine must be thawed before using. Thaw vaccine in the refrigerator or at room temperature: Refrigerator: Between 2°C and 8°C (36°F and 46°F). Room temperature (for immediate use): Up to 25°C (77°F). Do NOT refreeze thawed vaccine. Use vials in the refrigerator before removing vials from ultracold temperature or freezer storage.
		freezer.	
General Information	 Each carton contains 10 multidose vials (50 doses). Each multidose vial contains 5 doses. 	 Two multidose vial presentations: Maximum of 11 doses per vial. Maximum of 15 doses per vial. Dosage: 0.5 mL. Do NOT mix with a diluent. 	 Use a new vial every time. Multidose vial: 6 doses per vial. Dosage: 0.3 mL. Vaccine MUST be mixed with diluent before administration. 5-12 years of age and



Temperature Excursions (TE)

Temperature excursions (TE) are inappropriate storage conditions for any vaccine and require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts is considered a temperature excursion. The Vaccine Coordinator needs to call all the manufacturers of the vaccines that are stored and get an email confirmation for administration of the vaccine that have been exposed to a temperature excursion.

CDC recommends the following steps in the event of a temperature excursion:

- Any staff who hears an alarm or notices a temperature excursion on the digital data loggers (DDL) should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
- 2. Label exposed vaccines, "DO NOT USE," place in a separate container (do not discard)

Temperature Excursion Response Checklist

Separate COVID-19 vaccines exposed to inappropriate temperatures from other vaccines, label the vaccines "Do Not Use", and store at recommended temperatures until vaccine viability is determined.
Place any COVID-19 vaccine shipments exposed to out-of-range temperatures and/or delayed shipments in the vaccine storage unit at appropriate temperatures and mark "Do Not Use".
Move COVID-19 vaccines from a storage unit that will not maintain appropriate temperatures to another storage unit with stable temperatures.
Report any temperature excursion immediately to the primary or alternate Vaccine Coordinator.
Call manufacturers to report the temperatures and time out of range.
Do not discard, use, or transport the vaccine until instructed to do so by the Vaccine Manufacturer or Immunization Program.
Document all temperature excursions and actions taken.
Maintain all copies of COVID-19 Vaccination Program-related documentation for three years.
For a temperature excursion resulting in a Digital Data Logger alert, document the temperature excursion and actions taken in online vaccine monitoring system.



Power Outage

In the event of refrigerator/freezer malfunction, power failure, natural disaster, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location. Your clinic should establish the below protocol before an emergency occurs. The Emergency Plan must be reviewed and/or updated at least annually or more frequently if changes occur and all information must always be up to date. A "review date" is required with an accompanying signature of the person responsible for the plans content. All staff are required to understand the Vaccine Emergency Plan for vaccine relocation and know where it is located.

- Notify the Division of Immunization Services immediately if a vaccine storage unit temperature goes outside of the recommended range during a power outage.
- Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location.
- If you are unsure how long a power outage will last, or you determine power will not be restored in time to maintain proper temperatures inside a vaccine storage unit, implement the Vaccine Emergency Storage, Handling, and Transport Plan.
- Temperatures and duration of power outage must be monitored.
- Vaccine should not be discarded or administered until the situation has been discussed with public health authorities.
- Do Not Use the vaccine until the COVID-19 manufacturer has determined vaccine viability or instructed to do so by the Immunization Program.
- Once power has been restored to a storage unit, document the following:
 - a) The room temperature where the storage unit is located.
 - b) The length of time the power was off.
 - c) The minimum and maximum temperatures reached during the power outage.
 - d) If prior vaccine temperature excursion has occurred, vaccine lot number, expiration date and prior temperature excursion information is needed when notifying vaccine manufacturer.



COVID-19 Vaccine Inventory Management

Vaccine Inventory and Reconciliation

- Count COVID-19 vaccine doses daily to ensure the number of physical doses on hand matches the number of doses indicated in EIMS.
- Complete an Inventory Reconciliation with EIMS at least once a month and no more than 14 days prior to ordering vaccine.
- COVID-19 vaccine inventory will be reported to Vaccine Finder by the Vaccine Management Team (VMT) daily.

Beyond the Use Date Labels

- Note the date and time the vaccine was first punctured or mixed on the vial.
- Discard the vial if vaccine is not used within these times.
- Use the Beyond-Use Date (BUD) Tracking Labels for Vaccine During Freezer or Refrigerator Storage.

Vaccine Stock Rotation and Removal

- Rotate COVID-19 vaccine stock at least once a week and with each vaccine shipment to ensure that shorter-dated vaccines are placed in front and used first.
- Check expiration dates weekly and immediately remove any expired vaccines and diluents. Mark expired vaccines "Do Not Use" and remove from the vaccine storage unit.
- Check the manufacturer's expiration dates on all COVID-19 vaccines before disposing of or removing any COVID-19 vaccine. Expiration dates may have been extended by the manufacturer.

Vaccine Ordering

• Starting January 18, 2022, COVID-19 vaccines should be ordered using the West Virginia Immunization Information System (WVSIIS).

Receiving Vaccine

When receiving vaccine shipments, providers must:

- Upon arrival, examine the shipping container for signs of physical damage.
- Verify the vaccine shipment was shipped to the correct address/facility.
- Unpack and examine vaccine deliveries immediately.
- Ensure the Pfizer vaccine diluent was received with the ancillary kit.
- Place the vaccine received into the appropriate storage unit.
- Never place an unopened vaccine shipment box in a vaccine storage unit.
- Ensure the packing slip matches the vaccines received.
- Check the expiration dates of received vaccines and diluents to ensure that no expired or shortdated vaccines are received.
- Verify that the cold chain monitor included with the vaccine shipment indicates that the vaccine temperature did not go out of range during shipment. Note: Some vaccine manufacturers do not include a cold chain monitor with vaccine shipments.



- Check all inserts included with vaccine shipments. Some manufacturers include important information on vaccine shipments, such as the allowed shipment timeframe, in the shipment container with the vaccine.
- Physically separate COVID-19 vaccine types in appropriate storage unit.
- Notify the Department of Immunization Services or COVID-19 vaccine manufacturer if vaccine viability is questionable when vaccine is received.
- Enter the COVID-19 vaccine in WVSIIS.
- The funding source for COVID-19 vaccine is PAN.
- Maintain all vaccine packing slips for 3 years.

If the provider believes that a vaccine shipment is compromised, temperature monitors are out-of-range, or a warm indicator is activated, they should contact the Division of Immunization Services immediately.

Vaccine Waste

Notify Division of Immunization Services of a vaccine cold chain failure/wastage incidents after discovery of the incident. Immediately upon the Division of Immunization Services finalizing a cold chain investigation where vaccine is deemed non-viable, remove it from the storage unit, place it in a bag or box marked DO NOT USE. Expired vaccines must be removed from the unit and marked DO NOT USE as soon as they expire. All returnable vaccine must be returned in its original packaging, vial, or manufacturer pre-filled syringe.

- Vaccine expiration dates including only a month and year expire at midnight on the last day of the indicated month.
- Vaccine expiration dates including a month, day and year may be used through the day included in the expiration date.
- Check the manufacturer's expiration dates on all COVID-19 vaccines before disposing of or removing any COVID-19 vaccine. Expiration dates may have been extended by manufacturer.
- Returning expired or wasted vaccines to the distributor must be reported by a Vaccine Return Form. This form is located at: https://oeps.wv.gov/immunizations/documents/vfc/manual/7/vaccine_return_form.pdf
- Non-returnable vaccine will be reconciled out of the West Virginia Statewide Immunization Information System (WVSIIS) inventory and disposed of properly.
- The COVID-19 Vaccination Provider Agreement states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste.
- Expired and spoiled COVID-19 vaccines should not be returned to manufacturer or the Division of Immunization Services.
- Short-dated vaccines (vaccines closest to expiration) will be placed in front of longer dated vaccines and used first.
- If short-dated vaccines are discovered that are not able to be used prior to the expiration date and you would like to transfer them to another provider, please contact Vaccine Manager/ VFC Coordinator <u>Jeffrey.J.Neccuzi@WV.org</u> for guidance.



Proper vaccine storage and handling practices play an important role in protecting our communities. Vaccine viability is the shared responsibility of everyone involved, from the time vaccine is manufactured until it is administered. When administering away from a monitored storage unit, the vaccine is more likely to experience temperature fluctuations, putting efficacy and safety at risk. Vaccines taken out of the vaccine storage unit for an offsite clinic should always be stored at temperatures between 2°C and 8°C, until ready to draw up doses for administration.

Following recommended guidelines and best practices for packing vaccines during the offsite clinic will help prevent reduced vaccine potency or vaccine failure. For the safe transport and storage of vaccines, proper supplies are essential. Do not transport the vaccine unless all conditions are met.

Transporting Vaccines

When transporting vaccines from the office to an off-site clinic, temperatures must be monitored using a calibrated digital data logger thermometer. These digital data logger files must be emailed to the Division of Immunization Services with the monthly temperature logs at the end of the month. Any out of range temperatures must be reported to the Division of Immunization Services immediately.

- All vaccine transfers must be pre-approved by the Division of Immunization Services.
- CDC discourages regular transport of vaccines. Proper management of vaccine inventory plays a major role in preventing the need to transport vaccines.
- Shipping vaccines is strictly prohibited.
- It is critical that vaccine viability is protected by maintaining proper vaccine storage temperatures during any vaccine transport.
- Only transport the appropriate estimated number of doses of COVID-19 vaccine to an offsite clinic.
- Use properly insulated containers to transport vaccines. These containers should be validated to ensure they can maintain the vaccine at the correct temperatures. Alternatively, hard-sided, plastic, insulated containers/coolers or styrofoam coolers with at least 2-inch thick walls may be used, as well as portable refrigerator/freezer units.
- "Condition" frozen water bottles prior to use in hard-sided and styrofoam coolers. To condition water bottles, place them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming on the inside near the surface of the bottle. The water bottle is properly conditioned if the ice block inside spins freely when the bottle is rotated. Frozen water bottles that are not conditioned can freeze vaccine.
- Always place a calibrated, certified min/max thermometer or digital data logger (preferred, if available) with the probe in buffered material in each transport container and secure the digital display to the outside of the container.
- Transport and store refrigerated vaccines at 36°F to 46°F at all times.
- Transport and store freezer vaccines at -13°F to 5°F at all times.



- Transport and store ultra-cold vaccines at -117°F to -76°F at all times in thermal shipping container or ultra-cold freezer. Only full trays of Pfizer vaccine may be transported at ultra-cold temperatures.
- Record the date, time, and temperature in the transport container on the COVID-19 Temperature Log upon arrival to an off-site clinic and after returning the vaccine to the local health unit.
- The temperature should always be checked prior to opening the transport cooler.
- Mark any vaccines exposed to out-of-range temperatures "Do Not Use" and store at appropriate temperatures until a determination can be made on the vaccine viability.
- Contact the Division of Immunization to assess vaccine viability before using the vaccine.
- Pack hard-sided coolers and thick styrofoam shipping containers as follows:
 - 1. Place a layer of "conditioned" water bottles in the bottom of the transport container.
 - 2. Place a piece of corrugated cardboard (cut to fit the interior dimensions of the cooler) over the water bottles.
 - 3. Place at least a 1-inch layer of insulating cushioning material over the cardboard (bubble wrap, packing foam, or styrofoam). Do not use packing peanuts, paper towels or any thin material as insulation material.
 - 4. Place the vaccine on the insulating material. Refrigerated vaccines should never be placed directly on frozen water bottles.
 - 5. Place the buffered temperature probe from a calibrated, certified thermometer in the middle of the vaccine.
 - 6. Place at least a 1-inch layer of insulating cushioning material over the vaccine.
 - 7. Place a piece of corrugated cardboard over the insulating material.
 - 8. Place a layer of conditioned water bottles on top of the piece of cardboard.
 - 9. Secure the temperature monitoring device display to the outside of the container to decrease the number of times the container door is opened.
- Pack specialized vaccine transport coolers (e.g., AcuTemp vaccine courier system) as instructed by the manufacturer.
- Never transport COVID-19 vaccines in a vehicle trunk.

Storage and Handling at Off-Site Locations

- Keep the COVID-19 vaccine storage container(s) closed as much as possible.
- Do not prepare more than one multi-dose vial (withdraw the allowed full doses of COVID-19 vaccine) at a time during an off-site clinic.
- Monitor COVID-19 vaccine temperatures in all storage containers every hour and document the temperatures on the Off-Site Refrigerator/Freezer Device Temperature Log.



- Mark any COVID-19 vaccines exposed to out-of-range temperatures "Do Not Use" and contact Department of Immunization. Store any affected vaccine at appropriate temperatures until manufacturer determines vaccine viability.
- Store all temperature logs for 3 years.
- Have additional "conditioned" water bottles available for use at any off-site clinic that lasts longer than 6 hours.

Vaccine Emergency Plan

In the event of refrigerator/freezer malfunction, power failure, natural disaster, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location. Your clinic should establish the below protocol before an emergency occurs. The Vaccine Emergency Plan must be reviewed and/or updated at least annually or more frequently if changes occur and all information must always be up to date. A "review date" is required with an accompanying signature of the person responsible for the plans content. All staff are required to understand the Vaccine Emergency Plan for vaccine relocation and know where it is located.

Follow the process below:

- Designate personnel who have 24-hour access to location where the vaccines are stored.
- Set up a system to notify designated personnel during power outages.
- Identify steps to assure proper storage and handling of vaccines during an emergency.
- Identify an alternate power source (generator) if your clinic does not have one or alternate storage units or facilities (nearby hospital, pharmacy, other provider's office.) Identify procedures that allow access to alternate facilities.
- Keep a cooler in the office; place a copy of the Vaccine Emergency Plan Worksheet in the cooler.
- Follow and complete the Vaccine Emergency Plan and Worksheet.
- **DO NOT** automatically discard the vaccine that has been compromised.
- Mark exposed vaccine and store separately from undamaged vaccines, storing appropriately in a refrigerator/freezer.
- Do not open the storage unit door during a power outage unless vaccine is being moved to an alternate storage facility or site. Open doors only after completing all preparations for packing and moving vaccines.
- If unsure of how long a power outage will last, or it is determined that power will not be restored in time to maintain proper temperature inside the vaccine storage unit, contact the alternate vaccine storage site.
- Verify with the alternate storage facility that their electricity is on or that the generator is working, and they can accept the vaccines for storage.
- Once the alternate storage facility is contacted and transport supplies are gathered, pack the vaccines in the transport container following CDC guidelines.
- Always use a digital data logger to monitor temperatures during vaccine transport.
- Transport frozen COVID-19 vaccines in approved freezer transport cooler.
- Transport frozen vaccines in a portable freezer unit that maintains the temperature between 58°F and +5°F, if at all possible.



- If a portable freezer unit is not available, transport frozen vaccines using a qualified container and pack-out.
- Transport ultra-low frozen COVID-19 vaccine in thermal shipping container using dry ice per manufacturer packing instructions. Refer to Pfizer guidance on packing Pfizer vaccines for transport.
- Pfizer ultra-cold vaccines may be transported in the Pfizer shipping container, but caution should be taken to secure the container during transport, so vaccine vials are not broken.
- Pfizer ultra-cold vaccine if local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F).
- Any hours used for storage or transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F).
- Frozen vials 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)
- Pfizer ultra-cold vaccine may be shipped at refrigerated temperatures 36°F and 46°F (2°C and8°C); however, the vaccine may not be refrozen once thawed. The vaccine must remain at refrigerated temperatures and be used within 5 days.
- Pfizer diluent stored at room temperature 68°F to 77°F or (20°C to 25°C) is transported at room temperature.
 - Note: Placing room temperature diluent in the transport container can raise the temperature of the container.
- Never freeze diluents, not even during transport.
- Place a copy of the COVID-19 vaccine inventory being transported in the transport container with the vaccines.
- Move transport containers directly to a preheated or precooled vehicle.
- Only transport vaccines inside the passenger compartment of a vehicle, not in the trunk.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Upon arrival at the alternate storage facility, confirm their vaccine storage unit temperatures are within recommended ranges.
- Store vaccines immediately upon arrival at the alternate storage facility.
- Once power is restored and the storage unit temperatures are stabilized, transport the vaccine back and place in the vaccine storage unit.
- Call all the vaccine manufacturers and/or *Division of Immunization Services* for further instructions



PRINTABLES & INSTRUCTIONS



Important Contacts

Resource	Contact	Phone Number	Email Address and/or
	Person Name		Website
VFC Program	Jeff Neccuzi	304-352-6258	Jeffrey.J.Neccuzi@wv.gov
Manager and			
Vaccine Ordering			
VFC Assist. Cord.	Christopher Young	304-352-6265	christopher.d.young@wv.gov
and Return labels-			
temp logs			
Division of		304-558-2188	
Immunization		1-800-642-3634	
Services		304-558-6335 (f)	
VFC Quality	Tiffany Kotalic	304-352-6284 (o)	<u>Tiffany.a.kotalic@wv.gov</u>
Assurance Manager		304-541-4162 (c)	
	Cindy Chapman	304-352-6259 (o)	Cindy.a.chapman@wv.gov
		304-546-2068 (c)	
	Matt Hill	304-545-3243	<u>Matthew.p.hill@wv.gov</u>
	Dana Schrack	304-221-2175 (o)	Dana.L.Schrack@wv.gov
VFC, COVID, & IQIP		304-541-1094 (c)	
Field Visits	Malissa Teter	304-538-2391 ext. 12018	<u>malissa.d.teter@wv.gov</u>
		304-546-1896 (c)	
	Noah Davis		<u>noah.j.davis@wv.gov</u>
	Jennifer Wentz	304-419-1994	jennifer.l.wentz@wv.gov
	Allison Toler		<u>allison.d.toler@wv.gov</u>
	Christina Spickler		christina.m.spickler@wv.gov
WV Statewide	Carolyn Smith	304-352-6262	Carolyn.j.smith@wv.gov
Immunization	Deal Diaman	204 252 6264	Paula la transitiona de
Information Services (WVSIIS)	Becky Pierson	304-352-6261	Becky.l.pierson@wv.gov
Refrigerator Repair			
Company			
Freezer Repair			
Company			
Thermometer			
Company Dowor Company			
Power Company			
Temperature Alarm			
System Company			
Generator Company			
(if applicable)			
Other			
	l		

COVID-19 Provider Checklist



For Site Visit Preparation

Yes	Can we answer 'Yes' to all of the questions? If so, we are ready for out site visit?
	Our Vaccine Management Plan has been reviewed, updated, and signed by each administrator of vaccines.
	The COVID-19 Provider and back-up have participated in the annual training and the training has been
	properly documented. ("You Call the Shots" and "Storage and Handling")
	All Emergency Use Authorization Fact Sheets (EUA) or Vaccine Information Statements (VIS) are up to date.
	Only the most current VIS is provided to parents. VIS are provided to parents at each immunization visit.
	Each immunization record has the following documented: date given, parent's consent (signature), type of
	vaccine, manufacturer name, lot number, publication date of the VIS, date VIS provided to parent; and he
	name and title of the person administering the vaccine.
	Our thermometers are properly placed in the central area of each vaccine storage unit.
	We have the thermometer calibration certificates for all our vaccine storage units, and they are available for
	review.
	Staff knows where our back-up thermometer located is. Is it readily available to use, if necessary.
	We have replaced expired thermometers and calibration certificates.
	All temperature logs for each refrigerator and freezer unit used to store COVID-19 vaccine are available for
	review.
	Our digital data loggers are properly placed on the middle shelves of each vaccine storage unit that stores
	COVID-19 vaccines.
	Check calibration certificate dates.
	Fridge calibration date:
	Freezer calibration date:
	Back-up thermometer calibration date:
	All temperature logs are completed twice a day with exact time (i.e. 8:04 am) temperatures are taken,
	temperatures to the tenths place (i.e. 40.2°F), Fahrenheit or Celsius are circled and the initials of the person
	taking the temperatures. The minimum temperatures and maximum temperatures of the units storing
	vaccines are recorded on the temperature log once a day in the morning for the previous 24 hours.
	If we had any out of range temperatures reported on our temperature logs, we document the actions taken,
	and that documentation is available for review.
	Our vaccines with the shortest expiration dates are placed in front of those with the longer expiration dates.
	Our vaccines are stored in the center of the unit, away from the cold air vent, away from the walls; not
	stored in refrigerator or freezer doors, not on the floor, and not stored in the crisper drawers.
	The Division of Immunization Services was notified of any temperature excursions/incidents. Please ensure
	any documentation regarding temperature excursions/incidents is available for review.
	There are water bottles located near the air vents and on the bottom of the storage unit, to prevent
	vaccines from being stored there. There are ice packs in the freezer unit, leaving adequate space for vaccine
	storage.
	We are able to locate the breaker box to view the "do not disconnect" sign with the site reviewer.
	We are aware that failure to be ready will not postpone the site visit.



COVID-19 Vaccine Administration Training Courses

Certificate	DATE	TITLE OF	NAME AND TITLE OF
Included		TRAINING	EMPLOYEE



Vaccine Storage Units

Refrigerator:

Type of Unit	Brand	Model Number	Serial Number	Date of Purchase/Put in Use	Location at Facility

Freezer:

Type of Unit	Brand	Model Number	Serial Number	Date of Purchase/Put in Use	Location at Facility



Emergency Response Plan

The following section includes space for information and necessary actions to take in the event of an emergency such as unit malfunction, power outage, human error, etc.

POST THIS PLAN ON THE VACCINE UNIT OR OTHER PROMINENT LOCATION

Emergency Contacts and Backup Location

	Name	Phone
Primary Emergency Contact		
Backup Emergency Contact		
Contact with 24-hour Access		
to Backup Location		
LHD COVID-19 Contact		

All COVID-19 Providers must identify an appropriate backup unit/location even if a generator is on-site. This is to ensure there is a location for vaccine storage if the actual unit fails and vaccine must be relocated. Reminder: Test your emergency plan to ensure it works when needed!

Backup Location	Address	Phone



In Case of an Emergency

Follow the below protocol in the event of an emergency.

- 1. Power Outage:
 - a. Contact the Power Company. Name and phone number:
 - b. Determine the anticipated length of outage:
 - c. If over _____ hours, relocate the vaccine to: (facility address, contact, and phone number)
- 2. If there is not an area wide power outage:
 - a. Check all power sources: (breaker box, outlet...)
 - b. Make necessary corrections.
 - c. Implement new signs (Do Not Unplug...)
- 3. Check all Data Loggers (DDLs)
 - a. If DDLs are damaged or not accurate, replace them and monitor for correct temperatures.
 - i. Document your actions in the temperature log.
 - b. If DDLs are accurate, move to the next step.
- 4. Remove vaccine and place in appropriate storage.
 - a. Adjust refrigerator or freezer temperature.
 - b. Recheck every 30 minutes until temperature returns to the correct range.
- 5. If unable to adjust temperature, connect with the emergency contact person
 - a. Emergency Contact Person _
 - b. Or call the Division of Immunization Services 1-800-642-3634



Emergency Response Worksheet

Utilize this worksheet to track transported vaccines or vaccines exposed to out-of-range temperatures. Document temperature information and decision on viability when calling manufacturers.

Excursion	Time at Discovery:	Temp at Discovery:
Discovered		
Review	Total time out-of-range:	Max or mon temp reached:
Details		
	Time at start of transport:	Temp at start of transport:
If Transport		
occurs	Time at end of transport:	Temp at end of transport:

Excursion Follow-up: Utilize this for vaccine transported or exposed to out-of-range temperatures.

Vaccine	COVID-19 or Private	Lot	# of Doses	Manufacturer Decision

Contact Division of Immunization Services 1-800-642-3634 to report TE (Temperature Excursion)

Contact each vaccine manufacturer to determine viability. You will need: lot numbers, expiration dates, temperature log, and occurrence information.

Complete Return Vaccine Form (RVF) for each vaccine affected. Fax it to Division of Immunization Services 1-304-957-7591



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Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



- or alternate vaccine coordinator immediately or report the problem to a supervisor.
- » Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.
- Document details of the temperature excursion:
- Date and time
 Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
- Room temperature, if available
 Name of the person
- completing the report General description
- of the event (i.e., what happened) • If using a digital data
- logger (DDL), determine the length of time vaccine may have been affected
- Inventory of affected vaccines
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

- Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- » Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:		
Dynavax	1-844-375-4728	
GlaxoSmithKline	1-888-825-5249	
Massachusetts Biological Labs	1-888-825-5249	
MedImmune	1-877-633-4411	
Merck	1-800-672-6372	
Pfizer	1-800-438-1985	
Sanofi Pasteur	1-800-822-2463	
Segirus	1-855- 358-8966	

- » If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- » Check the basics, including:
 - · Power supply
 - Unit door(s)
- Thermostat settings
- » If the excursion was the result of a temperature fluctuation, refer to the section, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's Vaccine Storage and Handling Toolkit for detailed guidance on adjusting storage unit temperature to the appropriate range.
- » If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Refrigerator and Freezer Temperature Logs can be found at: <u>https://www.immunize.org/</u> Refrigerator: <u>https://www.immunize.org/catg.d/p3037f.pdf</u> Freezer: <u>https://www.immunize.org/catg.d/p3038f.pdf</u>

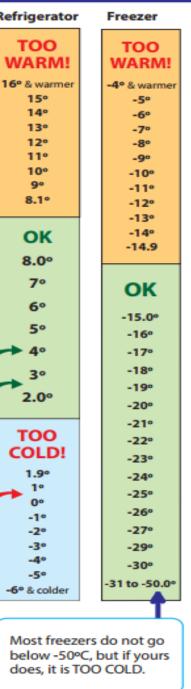


Temperature Excursion

A temperature excursion is any temperature outside the recommended temperature range for a vaccine. The total amount of time a vaccine is stored at an outside temperature range affects the viability of the vaccine.

OUT-	OF-RANGE TEMPURATURE:	Refrigerator	Freeze
	t-of-range refrigerator temperature is below 0°C or above 9°C us) [Below 32ºF or above 47ºF (Fahrenheit)]	TOO WARM!	TOC
	t-of-range freezer temperature is above -15°C (Celsius) [Above 5ºF enheit)] but equal or less than 14ºF (-10ºC	16° & warmer 15°	-4° & wa -5°
Corre	ctive Action:	14° 13° 12°	-6° -7° -8°
1.	Notify the VFC Coordinator, Backup Vaccine Coordinator, or office	11° 10° 9°	-9° -10° -11°
2.	manager. Quarantine exposed vaccine and label as "DO NOT USE." Store vaccines under proper conditions, as quickly as possible.	8.1°	-12° -13°
3.	Download the report from the digital data logger. Print out and review for when the excursion started and for how long.	OK 8.0°	-149
4.	Document detail of the temperature excursion occurrence: date and time, data logger last temperature recorded and temperature when	7° 6°	OK
	discovered, room temperature, how long were vaccine exposed according to the data logger report, what vaccines are involved, and a	5°	-15.0 -16°
5.	detailed report of the event. Report Immediately to the Division of Immunization at 1-800-642- 3634 or at 304-558-2188 . Do not leave voicemails/after hours	4° 3°	-17° -18° -19°
6.	(including weekends, holidays), next business day Contact Vaccine Manufactures and give details of occurrences and	2.0°	-20°
	wait for guidance on vaccine use. Wait for advice and further instructions from the Department of	TOO COLD!	-22° -23°
	Immunization regarding the excursion. Do not use or administer any vaccines until instructed by Department of Immunization.	1.9° 1° 0°	-24° -25°
		-1° -2°	-26° -27°

Merck	877-829-6372
Sanofi Pasteur	800-822-2463
Pfizer/Wyeth	800-505-4426





Vaccine Handling Guidelines

- 1. Vaccines should be ordered monthly by the 5th day of the month.
- 2. Keep no more than two months of vaccine on hand at any time, keep shortest dated vaccines in front and rotate stock on a monthly basis.
- 3. Report any wasted or expired vaccine to the Department of Immunization. Any vaccines that will be expiring within 3 months that will not be used should also be reported.
- 4. Stack vaccines so that air can circulate around them, do not place vaccines in the door or the crisper, do not store food or drink in refrigerator, place water bottles in refrigerator and ice packs in freezer to stabilize temperature.
- 5. Always maintain the cold chain with vaccines even when moving or transporting.

Vaccine Transport			
Coolers/Packing Materials	Location at our Facility	Ordering Information (Company)	Phone Number
Portable refrigerator/freezer units			
Insulated Coolers/Containers			
Insulating Barrier (bubble wrap, Styrofoam, peanuts, exam table paper, etc.)			
Cold Packs			
Freezer Packs			
Calibrated Data Logger Thermometer(s)			
Flashlights			
Plastic Storage Bags (baggies)			
Plastic Storage Containers			
Sharpies			



How to Use a Digital Data Logger

- 1. Place the small temperature bottle in the refrigerator or freezer one hour before you connect the Digital Data logger to it, so it cools off.
- 2. Plug the Digital Data logger into the gel bottle sensor.
- 3. Press the green button for about 5 to 7 seconds (press hard) till the "START" signal goes off and you see a temperature number display on the screen, it's now ready to record.
- 4. Without unplugging the device, you can check temps. You can check temps by pressing the green button for one second and it will give you, **high temp max**. Press it again and it will give you the **low temp max**. Press it again and it will give you the **average temp**.

Checking and recording temps on the computer:

- 1. Before unplugging the device, **press the red stop button until it stops flashing "STOP"** (around 5 to 7 seconds). Now you can unplug the device and insert it into the computer.
- 2. You can then look for the "Flashlink" on one of your ports. Here you can download the information in ADOBE (PDF) or excel file. (make sure you save the information).
- 3. Once this is done you only need to send in the 1st page where the information is condensed as your monthly temperature log submission.

Reinstalling the device:

- 1. Unplug the device from the computer
- 2. Without plugging the device back into the bottle sensor on the refrigerator, press both the green and red button at the same time (around 5 to 7 seconds hard) until the odd-looking plus sign stops flashing. You will then see a moon icon indicating it's ready for re-installment.
- 3. Plug the device into the sensor cord to start recording again.

NOTE: You can always restart the device by pressing both the red and green buttons if you need to start over.

Changing the parameters of the Digital data logger

- 1. Once you have downloaded the Software that came with the DDL, go to the "hidden icons" at the bottom of the page (the one you use when you are removing your thumb drive that says it is now safe to remove).
- 2. Here you should see a "FlashPDF" icon. RIGHT CLICK THIS.
- 3. Go to "Setup" this will bring up Current Configuration, go to NEXT.
- 4. Here are Logging Options this will let you change the minutes between DDL checks (Middle row Logging interval).
- 5. Go to NEXT again. This lets you change the temps and cut off or on alarms. When done go to NEXT ignore **data tags** go to NEXT again, this gives you the parameters you have set. NEXT again. Logger will be configured press OK.

You are finished unless you want to configure another DDL (press no or yes). If you want to configure wit the same parameters, unplug current DDL and plug in a new one. It will set it automatically.



The below guide provides steps to create an account and setup Vaccine Finder.

- 1. Ensure your email address is listed in the Section A part of the Vaccination Program Application (VPAS).
 - 1. If your email address is not correct in VPAS, you will need to update the form.
 - To update the form, locate the VPAS registration email and follow the steps to update your information.
 - If you cannot update the form, contact Christopher Young at (304)356-4082 or <u>christopher.d.young@wv.gov.</u>
- 2. Once your information is correct in VPAS, you will receive an email from VaccineFinder@auth.castlighthealth.com with instructions for enrolling in VaccineFinder.
 - 1. Check your spam folder to locate the email.
 - 2. The link will expire after 7 days.
 - 3. Use Edge, Safari, and Google Chrome web browsers.
- 3. The account username is the email address listed on the VPAS application.
- 4. Create a password.
 - 1. Password criteria:
 - Use upper- and lower-case letters (e.g. Aa)
 - User 8 or more characters
 - Use a number (e.g. 1234)
 - Use a symbol (e.g. !@#?)
 - No guessable password (e.g. Password123!)
 - No password containing part of username
 - No password containing first or last name
- 5. You will be taken to the vaccine selection page. COVID-19 vaccines that have been approved at the time of your registration will pre-populate in the dropdown menu.
- 6. Select the vaccines you will be administering.
 - 1. Once selected, the vaccine(s) will appear in the box labeled Vaccines Added.
 - 2. Vaccines can be removed from this box if they were added in error.
 - 3. This step is optional for locations. If providers do not yet know which vaccines, they will be administering at the time of sign up, they may add vaccines at a later step.
 - 4. Vaccines may be added at any time within the portal.
- 7. Once the vaccines are selected, you are taken to the Inventory Reporting Designation screen.
- 8. You may choose to:
 - 1. Report centrally for all locations in their organization, or
 - 2. Designate reporting to each location individually.
 - This choice cannot be changed for the duration of the COVID-19 vaccination program.
- 9. The **Your Locations** box will show location(s) currently listed in VaccineFinder for your organization.



1. Your inventory reporting designation will automatically be applied to any new locations added to your organization.

- 10. If you choose to report centrally, **only the organization email listed in Section A** will be invited to create a VaccineFinder account.
- 11. To enable the primary and backup contacts to create accounts you must select to have locations report their inventory.
- 12. If you choose to allow each of your locations to report inventory, registration emails will be sent to the email addresses listed for primary and backup location contact.
- 13. The organization contact will continue to have access to VaccineFinder as a reporting redundancy.

1.At this time, VaccineFinder does not have the ability to add additional users who do not come directly from the Provider Agreement. If you would like more than one contact to register inventory, you must delegate reporting to the provider level.

- 14. Select the Save button.
- 15. You are returned to the log in page.
- 16. You created and registered your organization with VaccineFinder.
- 17. This link, <u>https://covid.locating.health/login</u> can be used to update your inventory daily.
- 18. Additional assistance:

- 1. Training documents for VaccineFinder can be found at:
 - https://vaccinefinder.org/covid-provider-resources
- 2. Vaccine finder Help Desk:
 - vaccinefinder@castlighthealth.com



A best practice to avoid handling and storage errors is to designate only one person, or at the most two, to be responsible for storage and handling of vaccines.

Do Not:

- Store food and/or drinks in the vaccine refrigerator/freezer
- Store vaccine in a manner that could jeopardize its quality
- Leave the refrigerator or freezer door open
- Have inadequate door seals
- Store vaccines in a dorm-style refrigerator
- Record only refrigerator or freezer.
- Use an uncalibrated thermometer
- Discard vials if they are expired
- Plug the refrigerator or freezer into a surge protector

Do:

- Record temperatures multiple times a day
- Record both refrigerator and freezer temperatures
- Use a calibrated thermometer
- Report all out of range temperatures
- Keep temperature logs for 3 years
- Have an emergency plan for power outages or natural disasters
- Contact Division of Immunization Services for any problem



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Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temp, see instructions to the right. 5.
- 6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year	PIN or other I)#
------------	----------------	----

Facility Name

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- 1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the 2. bottom of the log.
- 3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
- 7 Day of Month 5 6 8 9 10 11 12 13 14 15 1 2 3 4 Staff Initials AM PM Exact Time Min/Max Temp (since previous reading) Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately! -15°C -16°C -17°C -18°C -19°C -20°C -21°C -22°C -50°C to -23°C Write any out-of-range temps (above -15°C or below -50°C) here. Room Temperature
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record."



Temperature Log for Freezer – Celsius

Days 16-31

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year____ PIN or other ID #

Facility Name_

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.

Da	y of Month	1	6	1	7	·	18	1	9	2	0	21		22		2	3	24		2	5	2	6	2	7	2	8	2	9	30	3	51
Sta	aff Initials																															
Exa	act Time	АМ	РМ	АМ	PM	AM	PM	АМ	PM	AM	РМ	AM F	M	АМ	PM	АМ	РМ	AM	PM	AM	РМ	AM	PM	AM	PM	AM	PM	AM	PM	AM PM	AM	РМ
	n/Max Temp nce previous reading)																						*****									
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4. Document the action taken on the "Vaccine Storage Troubleshooting Record."





Month/Year____ PIN or other ID #

Temperature Log for Freezer – Fahrenheit

Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temp, see instructions to the right. 5.
- 6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Facility	v Name

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. 1. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator or call the immunization program at your state or local health 3. department for guidance.
- Day of Month 1 2 4 7 8 9 11 12 3 5 6 10 13 14 15 Staff Initials AM PM Exact Time Min/Max Temp (since previous reading) Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately! s 5°F ш ~ 4°F F 3°F RA 2°F ш ₽. 1°F Σ ш 0°F F ш -1°F -8 -2°F 4 F -3°F ш -4° F U U -58° F to -5° F × Write any out-of-range z temps (above 5°F 0 or below -58°F) here. Room Temperature
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record."





Month/Year PIN or other ID #

Facility Name_____

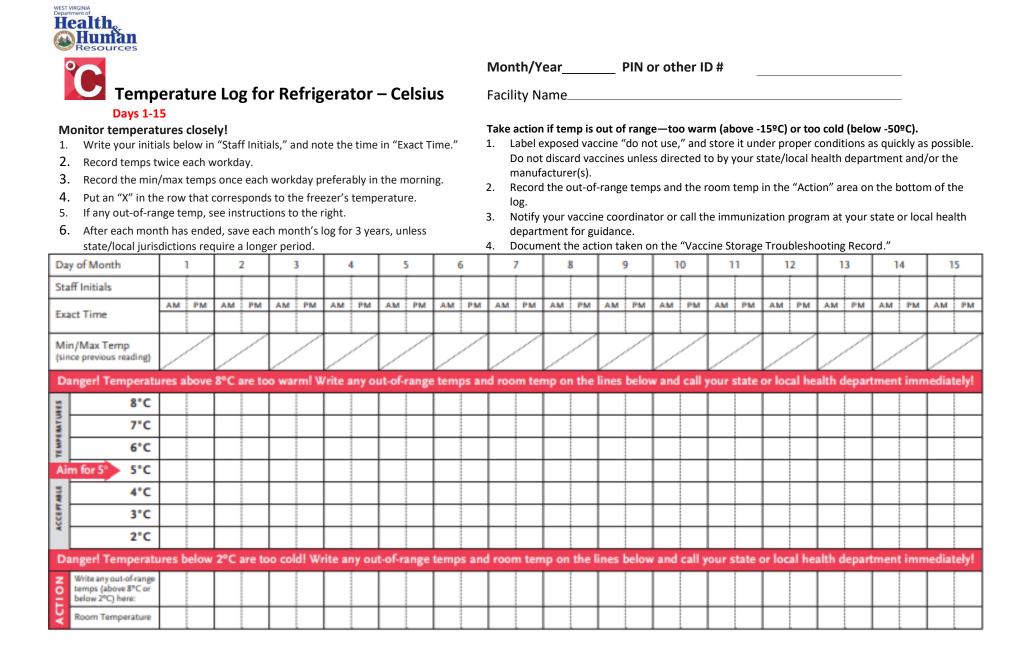
Temperature Log for Freezer – Fahrenheit Days 16-31

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temp, see instructions to the right. 5.
- 6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if tem	p is out of range—	too warm (above	-15ºC) or too cold	l (below -50ºC)
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- Label exposed vaccine "do not use," and store it under proper conditions as quickly as 1. possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- 2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- 3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
- Day of Month 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 Staff Initials AM PM Exact Time Min/Max Temp (since previous reading) Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately! s 5°F ш œ 4°F RAT 3°F 2°F ы 1°F Σ ш 0°F F -1°F ш 8 -2°F ΡTΑ -3°F ш -4° F U U 4 -58°F to -5°F Write any out-of-range temps (above 5°F 0 or below -58°F) here. Room Temperature
- Document the action taken on the "Vaccine Storage Troubleshooting Record." 4.



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Month/Year PIN or other ID #

Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Facility Name_

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- 1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of 2. the log.
- Notify your vaccine coordinator or call the immunization program at your state or local 3. health department for guidance.
- 4. Document the action taken on the "Vaccine Storage Troubleshooting Record."

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Vaccine Storage Troubleshooting Record

Use this page to record details of any vaccine storage incident, including the date and time of the last known temperature within appropriate vaccine storage range.

	Date	Time	Current Storage Unit Temp	Min/Max	Incident	Action Taken	Results	Initials
Example	1/13/22	7:30am	5C	6C/1C	Refrigerator too cold	Put do not use sign on the fridge. Called the WV Immunization department and explained excursion. At 8am, I changed the thermostat to change the temp. Notified other staff of incident and temp change.	Closely monitored refrigerator temps. Temp stabilized at 5C	AB

In the event of a temperature excursion, call the WV Division of Immunizations at 1-800-642-3634.





- » Keep your storage units and vaccines within the appropriate temperature ranges.
- » Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.



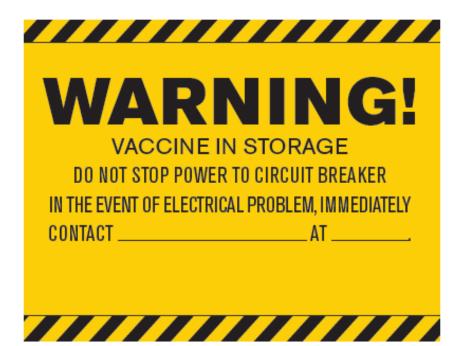
- » Take immediate action if temperatures are out of range.
- » Keep vaccines in their original packages.
- » Many vaccines should be protected from light (consult manufacturer's product information).
- » Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.



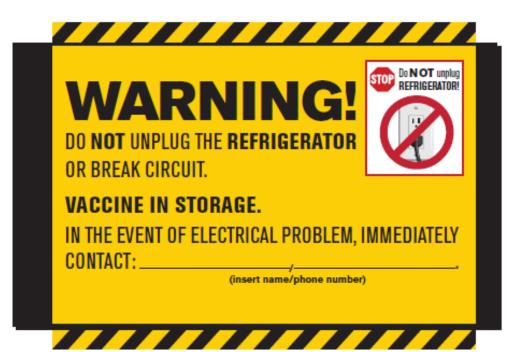






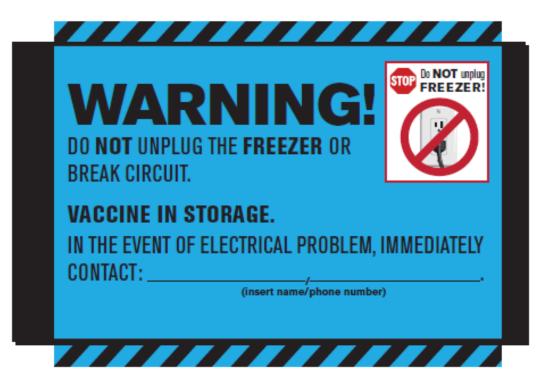






































WARNING! EXPENSIVE VACCINE IN STORAGE! ¡AVISO! Contiene vacunas caras.

DO NOT TURN OFF CIRCUIT BREAKER #____ No apague el interruptor de circuito #____

In the event of an electrical problem, immediately contact Si hay un problema con la electircidad, comuniquese immediatamente con



Pfizer-BioNTech COVID-19 Vaccine	Pfizer-BioNTech COVID-19 Vaccine
Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.	Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
Lot number(s):	
Today's date:// USE BY* Date://	Lot number(s):
*As the 21 day dead line approach as, contract the manufacturer for guidance if you will not be able to use the vacches.	Today's date:// Time:
	USE BY*
Vaccine may be transported for 12 cumulative hours.	
Transition	Date:/ Time:
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Pfizer-BioNTech COVID-19 Vaccine	Pfizer-BioNTech COVID-19 Vaccine
Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.	Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
Lot number(s):	
Today's date:// USE BY* Date://	Lot number(s):
*As the 21 day dead line approach as, contact the manufacturer for guidance if you will not be able to use the vaccine.	Today's date:/ Time:
	USE BY*
Vaccine may be transported for 12 cumulative hours.	
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Lot number(s):	Lot number(s):
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Name:	Name:



C	OVID-19 Vaccine	c	OVID-19 Vaccine
Ages:	18 years of age and older	Ages:	18 years of age and older
Use for:	Any dose in the 2-dose series. COVID-19 vaccines are NOT Interchangeable. Both doses should be COVID-19 vaccine (Moderna).	Use for:	Any dose in the 2-dose series. COVID-19 vaccines are NOT Interchangeable. Both doses should be COVID-19 vaccine (Moderna).
Route:	Intramuscular (IM) Injection	Route:	Intramuscular (IM) injection
Beyond Use Time:	Use within 12 hours after the vial is first punctured.	Beyond Use Time:	Use within 12 hours after the vial is first punctured.
M	oderna OVID-19 Vaccine		oderna OVID-19 Vaccine
Ages:	18 years of age and older	Ages:	18 years of age and older
Use for:	Any dose in the 2-dose series. COVID-19 vaccines are NOT interchangeable. Both doses should be COVID-19 vaccine (Moderna).	Use for:	Any dose in the 2-dose series. COVID-19 vaccines are NOT Interchangeable. Both doses should be COVID-19 vaccine (Moderna).
Route:	Intramuscular (M) Injection	Route:	Intramuscular (IM) Injection
Beyond Use Time:	Use within 12 hours after the vial is first punctured.	Beyond Use Time:	Use within 12 hours after the vial is first punctured.
	oderna OVID-19 Vaccine		oderna OVID-19 Vaccine
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Route:	Intramuscular (IM) injection	Route:	Intramuscular (IM) injection
Beyond Use Time:	Use within 12 hours	Beyond Use Time:	Use within 12 hours after the vial is







Additional Resources

- Immunization Action Coalition
 - Immunization.org
- Immunizations CDC
 - cdc.gov/vaccines
 - https://www.cdc.gov/coronavirus/2019nCoV/index.html?ACSTrackingID=USCDC_450-DM76609&ACSTrackingLabel=3%20COVID-19%20Learning%20Opportunities&deliveryName=USCDC_450-DM76609
 - <u>https://www.cdc.gov/training/learning/index.html?ACSTrackingID=USC</u>
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 <u>19%20Learning%20Opportunities&deliveryName=USCDC 450-</u>
 <u>DM76609</u>
- Office of Epidemiology and Prevention Services
 - o <u>https://oeps.wv.gov/Pages/default.aspx</u>



