

Pfizer-BioNTech COVID-19 Vaccine Transporting Checklist

NOTE: Every line should be marked YES. If any of the following are missing or are answered NO – STOP IMMEDIATELY. Contact Bureau of Immunization at 573-751-6124 for further instruction.

Step	Instructions	Yes	No/ STOP
1	Have an approved portable vaccine freezer, refrigerator, hard-sided or soft-sided cooler	<input type="checkbox"/>	<input type="checkbox"/>
2	Have freezer packs, cooling packs, or conditioned water bottles if using cooler (See attached document regarding conditioned water bottles)	<input type="checkbox"/>	<input type="checkbox"/>
3	Have bubble wrap and corrugated cardboard for insulation and protection (if using freezer packs, cooling packs, or conditioned water bottles)	<input type="checkbox"/>	<input type="checkbox"/>
4	Have Digital Data Logger (DDL) for temperature monitoring (1 per vaccine storage container plus 1 extra for back-up)	<input type="checkbox"/>	<input type="checkbox"/>
5	Have temperature log sheet	<input type="checkbox"/>	<input type="checkbox"/>
6	Notify the Vaccine Coordinator at the pick-up facility location of your ETA	<input type="checkbox"/>	<input type="checkbox"/>
7	Record vaccine temperature (& time) in facility storage device	<input type="checkbox"/>	<input type="checkbox"/>
8	Perform unopened vial count (do not accept open/used vials) & document doses received	<input type="checkbox"/>	<input type="checkbox"/>
9	Transfer vaccine quickly and carefully into transfer freezer, refrigerator, or cooler	<input type="checkbox"/>	<input type="checkbox"/>
10	Place DDL temp probe as close to vaccine as possible and the monitor outside container	<input type="checkbox"/>	<input type="checkbox"/>
11	Document diluent vials received	<input type="checkbox"/>	<input type="checkbox"/>
12	Document number of ancillary kits received (see info sheets for detail list of contents)	<input type="checkbox"/>	<input type="checkbox"/>
13	Place vaccine storage container inside vehicle and out of direct sunlight (do not place in trunk or truck bed)	<input type="checkbox"/>	<input type="checkbox"/>
14	Keep vaccine storage container sealed during transport	<input type="checkbox"/>	<input type="checkbox"/>
15	Document temperature every 30 minutes during transport	<input type="checkbox"/>	<input type="checkbox"/>
16	Notify the Vaccine Coordinator at the receiving facility of your ETA	<input type="checkbox"/>	<input type="checkbox"/>
17	Document temperature and time the vaccines are removed from transport container	<input type="checkbox"/>	<input type="checkbox"/>
18	Ensure copy of vaccine transfer documentation is sent to Bureau of Immunizations	<input type="checkbox"/>	<input type="checkbox"/>

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



» Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, freezer, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer's instructions for returning the thermal shipping container.
- Each thermal shipping container holds up to 5 trays of vaccine.
 - » Each tray contains 195 multidose vials (1,170 doses).
 - » A vaccine tray is approximately 9 in x 9 in x 1.5 in.
- Check and record storage unit temperatures each workday. See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

» Deliveries

Vaccine

Use CDC's Delivery Checklist for Pfizer-BioNTech Vaccine when accepting a delivery and unpacking vaccine.

When vaccine is delivered:

1. Open the thermal shipping container. Press the stop shipment button on the temperature monitoring device for 5 seconds.
2. The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
3. Proceed based on the color of the LED indicator light:
No color or red: Wait for the status report.
Green: Unpack the vaccine.
4. Follow the manufacturer's guidance for unpacking the vaccine. Inspect the trays.
 - » Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
 - » If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.

Dry Ice Safety

1. Dry ice is needed to maintain proper temperatures in the thermal shipping container.
2. Ensure staff has proper PPE and is trained to handle dry ice safely.
3. Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause a depletion of oxygen in the atmosphere, which may lead to asphyxiation.

Ancillary Supply Kit

An ancillary supply kit will be delivered separately from the vaccine and includes:

- **Mixing supplies:** Diluent, needles, syringes, and sterile alcohol prep pads
 - » Mixing supplies are packaged separately with a green identification label.
 - » Do NOT use mixing supplies to administer vaccine.
- **Administration supplies:** Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.

Each ancillary supply kit contains enough supplies to mix and administer 1 tray of vaccine.

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



» Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for **temporary storage** only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance.

Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature.

- Review contact information.
 - » If the contact for your order (inVTrckS) is not valid, you will NOT be notified in the event of a temperature excursion. Contact your jurisdiction's immunization program for assistance.
 - » If your contact is valid and you are not receiving e-mails or cannot load email hyperlinks, refer to Controlant for troubleshooting (<https://in.controlant.com/onsitemonitoring>).
 - » Identify up to 4 contacts to receive e-mails and text alerts on the container's temperature status.
- Review **DAILY** e-mails on the status of the container.
- Click the link in daily e-mails to access and download all temperature data. Save the Excel file summarizing all temperature data for at least 3 years.
- Save the return shipping label provided in your shipping container at delivery. Use the shipping label to return the thermal shipping container with Controlant TMD after 30 days.

- Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter. Follow manufacturer's guidance for adding dry ice.
- Dry ice will be sent for the first re-icing unless you opt out when placing the vaccine order.
- Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.
- Store vaccine vials upright in the tray and protect from light.

» Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

- Store vaccine vials upright in the tray.
- Protect from light.
- Vaccine may be stored until the expiration date.
 - » As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.

» Freezer

Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks.

- These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.
- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Use CDC's freezer storage temperature log for COVID-19 vaccine to document storage unit temperatures.
- Monitor how long the vaccine has been in the freezer using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
 - » Vaccine stored in the freezer can be transferred to refrigerator storage for an additional 120 hours (5 days).
- Store the vaccine in the tray.
- Protect from light.
- Do not use dry ice for freezer storage.
- Vials stored in the freezer may be returned one time to ultra-cold temperature storage (-80°C to -60°C [-112°F to -76°F]).
- Once returned to ultra-cold storage, the 2-week time frame is suspended.

Pfizer-BioNTech COVID-19 Vaccine

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): 123456A

Today's date: 12/14/2020 Time: 2:30 pm

USE BY*

Date: 12/28/2020 Time: 2:30 pm

*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 120 hours (5 days). Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.

Name: Amy Nurse RN

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



» Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal.

- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Store the vaccine in the tray.
- Protect from light.
- Do NOT refreeze thawed vaccine.

» Temperature Monitoring

Ultra-cold freezer, freezer, refrigerator: Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Frozen and refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

- **Option 1 (preferred): Minimum/Maximum (Min/Max) Temperature**
Most DDLs display min/max temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: Current Temperature**
If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

Thermal Shipping Container: Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature. See thermal shipping container information above.

» Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

» Mixed Vaccine

- Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.
- Discard any remaining vaccine after 6 hours.
- Mixed vaccine should NOT be returned to freezer storage.
- Mixed vaccine does not need to be protected from light.

CDC's Pfizer-BioNTech COVID-19 Vaccine materials <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

CDC's Vaccine Storage and Handling Toolkit <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

CDC's Pfizer Beyond-Use Date (BUD) labels <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf>

CDC's Delivery Checklist <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/delivery-checklist.pdf>

CDC's Freezer and Refrigerator Temperature Logs <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters – these and other emergency situations can compromise vaccine storage conditions and damage our vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1. Gather the Supplies

a. Hard-sided coolers or Styrofoam™ vaccine shipping containers

- i. Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- ii. Can use original shipping boxes from manufacturers if available.
- iii. Do NOT use soft-sided collapsible coolers.

b. Conditioned frozen water bottles

- i. Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- ii. Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- iii. Freeze water bottles (can help regulate the temperature in your freezer).
- iv. Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

c. Insulating material — You will need two of each layer

- i. Insulating cushioning material – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- ii. Corrugated cardboard – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

d. Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/- 0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines. Cardboard

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

This information has been taken from the CDC's guide located here:

<https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>

2. Pack for Transport

- a. **Conditioned frozen water bottles** – Line bottom of the cooler with a single layer of conditioned water bottles.
- b. **Insulating material** – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.
- c. **Insulating material** – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).
- d. **Vaccines** – Stack boxes of vaccines and diluents on top of insulating material.
- e. **Temperature monitoring device** – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
- f. **Vaccines** – Add remaining vaccines and diluents to cooler, covering DDL probe.
- g. **Insulating material** – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™
- h. **Insulating material** – Another sheet of cardboard may be needed to support top layer of water bottles.
- i. **Conditioned frozen water bottles** – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.
- j. **Close lid** – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.

3. Arrive at Destination

- a. **Before opening cooler** – Record date, time, temperature, and your initials on vaccine temperature log.
- b. **Storage** – Transfer boxes of vaccines quickly to storage refrigerator
- c. **Troubleshooting** – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.