

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.
- 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.
- Vaccine can be ordered in 2 amounts:
 - 1170 doses per tray
 - 450 doses divided between 3 boxes. Each box contains 25 vials.

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.
5. If not using the thermal shipping container to store vaccine, return the thermal shipping container per the manufacturer's instructions.
 - Ensure ALL the vaccine has been removed before returning the container.

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.
 - Ancillary supply kits have been reconfigured to support the number of doses ordered.

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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 or box.
- 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. This beyond-use date replaces the manufacturer's expiration date. 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.
- Store the vaccine in the tray or box.
- 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.
- Vaccine stored in the freezer can be transferred to refrigerator storage where it can be stored for up to 1 month (31 days).

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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: ____/____/____ Time: _____

USE BY*

Date: ____/____/____ Time: _____

*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.

Name: _____

*Dry ice will not be provided for Pfizer 450 COVID-19 vaccine orders.

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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 1 month (31 days). After 31 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.
- Vaccine can be ordered in 2 amounts:
- Store the vaccine in the tray or box.
- 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.
- Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Disposal

Once vaccine has reached its expiration or beyond-use date, contact the manufacturer for guidance on whether it can still be used. If instructed to dispose of vaccine, dispose of the vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program (<https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html>) for guidance.

- Do NOT return vaccine in the thermal shipping container.

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>

For additional information, refer to the manufacturer's website at www.cvdvaccine.com