

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary



» Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, 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 (975 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- Check and record storage unit temperature 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

When vaccine is delivered:

1. Open the thermal shipping container. Press on the stop shipment button on the temperature monitor 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. Dry ice requires special handling.
3. Ensure staff is trained to handle dry ice safely and have proper PPE.
4. 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 an oxygen-deficient atmosphere.

Ancillary Supply Kit

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

- Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads.
 - Do NOT use mixing supplies to administer vaccine.
- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE supplies

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

» Ultra-Cold Freezer

Vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures. Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred)** Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: 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.

Vaccine may be stored until the expiration date. The expiration date could be extended as more stability data become available. Store vaccine vials upright in the tray and protect from light.

» 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 on regular maintenance.

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» Thermal Shipping Container Continued

Use the Controlant Temperature Monitoring Device (TMD), included with the thermal shipping container, to monitor the temperature.

- Up to 4 contacts can be identified to receive e-mails and text alerts on the temperature status of the container.
 - » If the contact for your order (in Vtrcks) is not valid, you will not be notified in the event of an excursion. Contact your jurisdictional immunization program for assistance.
 - » If your contact is valid and you are not receiving emails or cannot load email hyperlinks, refer to Controlant for troubleshooting.
- 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. Return the shipping container with Controlant TMD after 30 days, using the shipping label provided.
- For troubleshooting and support: <https://in.controlant.com/onsitemonitoring>

Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days after. Follow manufacturer's guidance for adding dry ice.

- Dry ice will be sent for the first re-icing.
- 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.

» 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), remove any remaining vials from the refrigerator and discard following the manufacturer's and your jurisdiction's guidance on proper disposal.

Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred)** Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: 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.

Use beyond use date labels to track how long the vaccine has been in the refrigerator.

Monitor the beyond-use-date/time.

- Place vaccine vials removed from frozen storage at the same time together in a resealable plastic bag or similar container.
- Complete the information on the storage label and attach it to the container holding the unmixed vaccine vials.
- Once labeled, store unmixed vaccine vials upright in the refrigerator.

Thawed vaccine cannot be refrozen.

» 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.