

# Receiving & Storing Pfizer Vaccines

## California COVID-19 Vaccination Program



Upon delivery, sites assume responsibility for storing vaccines in temperature-controlled environments. This job aid compiles guidance from CDC, Pfizer-BioNTech, and Controlant and is updated for California providers.

## General Points

- Vaccines ship in ultra-cold thermal shipper with dry ice; ensure staff are trained on [dry ice safety](#)
- Vaccine products have a different formulation with different packaging, product configurations, dosages, National Drug Codes (NDC), and storage requirements
- See CDC [COVID-19 Vaccine Product Guide](#) (details about vaccine, kits, dimensions, PPE & needles; to be updated for gray cap) or [product comparison guide](#) ([CDPH chart](#) includes NDCs)
- Other clinical resources can be found on [CDC's website](#)
- Ancillary kit ships within 24-48 hours of vaccine and includes PPE

## Pfizer Tris-Sucrose 12Y+ (Gray Cap) Formulation | [Fact Sheet](#)

- Comirnaty® is FDA-approved for ages 16+; authorized under EUA for ages 5 through 15
- NDC 59267-1025-4 available in smaller 300-dose configurations (5 cartons)
- Vial will not be labeled Comirnaty initially; look for Pfizer Tris-Sucrose Formulation
- Vaccine ships in a smaller, lighter, single-use shipper; [this video](#) shows how to receive the shipper and return the data logger; do not return shipper
- Sites should ideally carry only one Pfizer 12Y+ formulation at a time; use up Pfizer purple cap before ordering gray cap
- Does not require diluent; to avoid dilution errors, CDC doesn't recommend administering purple and gray cap products in a single clinic at the same time
- May be stored in ULT units (-90 to -60°C) until expiration, or routine refrigerators at 2-8°C (36-46°F) for up to 10 weeks; **do not store in routine freezers**
- **Do not use thermal shipper for on-site vaccine storage**; sites that previously used Pfizer thermal shipping containers for temporary storage must prepare for use of an ULT freezer or refrigerator
- Apply [storage and handling labels](#) to cartons to prevent administration and handling errors
- Apply [beyond-use tracking labels](#) to cartons when storing vaccine in the refrigerator

## Pfizer Tris-Sucrose 5-11Y (Orange Cap) Formulation | [Fact Sheet](#)

- May be stored in ULT units (-90 to -60°C) until expiration, or routine refrigerators at 2-8°C (36-46°F) for up to 10 weeks; **do not store in routine freezers**
- **Do not use thermal shipper for on-site vaccine storage**
- NDC 59267-1055-4 available in 100-dose carton
- Vaccine ships in a smaller, lighter, single-use shipper; [this video](#) shows how to receive shipper
- [Storage and Handling Summary](#) details receiving and storing the product

- Apply [storage and handling labels](#) to cartons to prevent administration and handling errors
- Apply [beyond-use tracking labels](#) to cartons when storing vaccine in the refrigerator

## Pfizer Tris-Sucrose 6M-4Y (Maroon Cap) Formulation | Fact Sheet TBD

- Product would be available after FDA authorization and ACIP/CDC recommendation
- Do not store in routine freezers; do not use thermal shipper for on-site vaccine storage
- NDC 59267-0078-4 available in 100-dose carton
- Label may state age indication of 2Y to < 5Y; product is OK to use in children 6M-4Y
- Label may state vials should be discarded after 6 hours; recent stability studies supersede original labels and support discarding after 12 hours

Applicable to the following cap colors: **MAROON** (ages 6 months to 4 years)

### Label Characteristics

#### Maroon Cap Ages 6 months through 4 years

If authorized by the FDA, Maroon Cap vaccine vials and cartons you receive will be labeled as Pfizer-BioNTech COVID-19 Vaccine

Initial shipments of Maroon Cap vials and cartons will have the following label characteristics:

**Maroon Cap vaccine requires dilution prior to use**

\*Maroon Cap vial labels and cartons may state that a vial should be discarded 6 hours after the first dilution. Results from recent stability studies will supersede the current vial label and support discarding the vaccine after 12 hours from the time of dilution

**IMPORTANT INFORMATION**

- The vial and carton labels may state **2 years to <5 years of age** or **6 months through 4 years of age**.
- Vials with labels that state for use in individuals **2 years to <5 years of age** can be used for individuals **6 months through 4 years of age**.

**\*Note:** Prior to preparation of the vaccine, please review the EUA Fact Sheet (if authorized by the FDA) as the timeframe for use post-dilution has been extended to **12 hours**

Pfizer Medical FOR TRAINING PURPOSES ONLY – THE VACCINE HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS YOUNGER THAN 5 YEARS OF AGE

- Vaccine ships in a smaller, lighter, single-use shipper; [this video](#) shows how to receive shipper
- Storage and Handling Summary (TBD) details receiving and storing the product
- Use [storage and handling](#) and [Pfizer 5-11Y beyond-use tracking](#) labels until CDC releases new labels

## Original Pfizer 12Y+ (Purple Cap) | Fact Sheet

- This product has been retired and is not available for ordering; current national inventory will expire in September 2022 unless extended; always check for extended expiration dates
- **Pfizer 1170:** (1) tray of 195 vials (1,170 doses); **Pfizer 450:** (3) cartons of 25 vials each (450 doses)
- Store unpunctured vials in ULT unit (-90 to -60°C) until expiration or freezer at -25°C to -15°C (-13°F to 5°F) for up to **14 days** or refrigerator at 2-8°C (35-46°F) for up to **31 days** or at room temperature for no more than **2 hours**
- If storing vaccine in a freezer with routine vaccines, adjust freezer temperature to the temperature range for this vaccine
- Vials stored at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F); total cumulative time should be tracked and should not exceed 2 weeks
- Organize storage units to reduce administration errors; group products by age and label cartons, baskets, or shelf space in large letters

- See [Storage and Handling Summary](#) for receiving and storing the product and a [delivery checklist](#)
- Apply [storage and handling labels](#) to cartons to prevent administration and handling errors
- Apply [beyond-use tracking labels](#) to cartons when storing vaccine in the refrigerator or freezer
- [Thermal Shipper Return Instructions \(Pfizer 1170 & 450\)](#) | [Dry Ice Replenishment Instructions](#)

## Critical Notifications

Coordinators receive emails regarding order confirmations, advance shipment notices of vaccine and kits, and temperature monitoring alerts. Add [critical senders](#) to your contact list, or work with IT staff to have these senders added to your organization’s email whitelist, to ensure emails are not filtered to Spam or Junk folders.

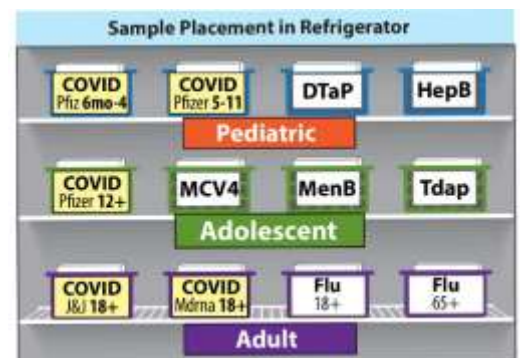
## Organizing Storage Units to Reduce Errors

Set up storage units so staff can locate the correct vaccine to reduce errors caused by inadvertent administration of products similar in packaging or close in age indicators.

Sites should ideally carry only one Pfizer 12Y+ formulation at a time to avoid administration errors, or store purple and gray cap formulations on separate shelves.

Ensure vaccinators can easily locate correct product:

- Group vaccines by age (pediatric, adolescent, adult).
- Label cartons, baskets, or shelf space in large letters.
- Store vaccines and diluents together if storage requirements are the same. Never freeze diluent.
- Store other medicines and biologics on separate shelves.



## Vaccine Expiration Dates

Check [Pfizer EUA Fact Sheets](#) or CDC’s [COVID-19 Vaccine Lot Number and Expiration Date Report](#) for updated expiry dates.

**Pfizer Tri-sucrose 12Y+ (gray cap), 5-11Y (orange cap), and 6M-4Y (maroon cap):** Regardless of storage condition, the vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons. Always discard vaccine at the earlier of the beyond-use or expiration date.

**Pfizer 12Y+ (purple cap):** Expiration date is printed on the vial. (Retired 12/23/21)

## Controlant Monitor Overview

Pfizer products ship with Controlant data logger that monitors temperatures during shipment.

### Start Shipment

- Do not press. Activated before shipment.

### Stop Shipment

- Press Stop Shipment to accept delivery.
- LED indicator will change to a solid color; status report emailed to the order's Point of Contact
- Green: Unpack the vaccine.
- No color or red: Wait for the status report.



## Maximizing Shelf Life for Pfizer 12+ Purple Cap (Retired 12/23/21)

Pfizer recommends storing original purple cap vaccine in ULT freezers. Alternately, transfer trays to the coldest environment you can support then transfer progressively to the next temperature range as indicated below. Carefully track cumulative time vials are stored under these alternate conditions.

Freezer	Refrigerator
<p>Store between -25°C and -15°C (-13°F to 5°F) for <b>up to 2 weeks</b> (<a href="#">label with BUD</a> of 14 days) then <b>transfer remaining doses to the refrigerator</b></p> <p>Carefully adjust thermostat to this narrow range if storing with routine vaccines</p> <p>Vials may be returned one time to the recommended ultra-cold temperature and used by the expiration date</p> <p>Monitor temperatures twice daily and <a href="#">report temperature excursions</a></p>	<p>Store between 2°C to 8°C (35°F to 46°F) for up to <b>1 month</b> (<a href="#">label with BUD</a> of 31 days max)</p> <p><b>Combined freezer &amp; refrigerator storage not to exceed 45 days</b></p> <p>Place vaccine vials removed from frozen storage at the same time in a resealable plastic bag or similar container</p> <p>Monitor temperatures twice daily and <a href="#">report temperature excursions</a></p> <p>After 1 month, <a href="#">report remaining doses as waste and discard</a></p>

If proper storage and handling protocols are followed, plan for the following vaccine shelf life.

Storage Units	Max Shelf Life
Freezer to refrigerator	14 + 31 = <b>45 days</b>
Standalone freezer only	<b>14 days</b>
Standalone refrigerator only	<b>31 days</b>

*For punctured vials:* Store at 2°C to 25°C (35°F to 77°F) and use **within 6 hours** from time vaccine was mixed with diluent then discard.

## Instructions

Follow these instructions to receive and store Pfizer COVID-19 vaccine products.

Step	Description
1.	Examine the shipping container for signs of physical damage.
2.	Open the thermal shipper on the floor in a well-ventilated room. <ul style="list-style-type: none"> <li>a) Use caution when lifting; thermal shipper for Pfizer 12+ Years (purple cap) may weigh up to 80 lb.</li> </ul>
3.	Press STOP button on Controlant Monitor for <b>5 seconds</b> to accept delivery. <ul style="list-style-type: none"> <li>a) The order's Point of Contact will receive an email from the manufacturer on the temperature status of the container during transit. The LED indicator on the TMD will change from blinking to a solid light.</li> </ul>
4.	Proceed based on the color of the LED indicator light. <ul style="list-style-type: none"> <li>a) <b>Green:</b> Unpack the vaccine.</li> <li>b) <b>No color or red:</b> STOP: Wait for status report (emailed to Point of Contact for the order) to confirm vaccine viability; <a href="#">report shipment incident</a> if a temperature excursion occurred.</li> </ul>
5.	Unpack the shipping container following the included unpacking instructions. <ul style="list-style-type: none"> <li>a) Review <a href="#">Dry Ice Safety Job Aid</a> before handling dry ice components.</li> <li>b) Wear safety goggles (or glasses with side shields) and waterproof, insulated gloves.</li> </ul>
6.	Inspect vaccine outer carton for damage and confirm order quantities. <ul style="list-style-type: none"> <li>a) Remove dry ice bag or pod. (<b>Pfizer 12+ Years:</b> Vial trays are visible without opening inner box.)</li> </ul>
7.	Store vaccine under recommended storage conditions, vials upright and in original packaging.

	<p><b>For Pfizer Tris-Sucrose (12Y+ Gray Cap) Formulation</b></p>
	<p>Label carton with expiry date printed on the shipper label before storing. (Vial date is the manufacture date.)</p> <p>Apply <a href="#">storage and handling labels</a> to cartons to prevent administration and handling errors.</p> <p><b>This product CANNOT be stored in a routine freezer.</b></p> <p><b>If transferring to ULT freezer:</b> Store between -90°C to -60°C (-130°F to -76°F) <b>within 5 minutes</b>; do not open tray(s) or touch vials. Store and use up to expiration.</p> <p><b>If transferring to refrigerator:</b> Store between 2°C and 8°C (36°F and 46°F) for up to <b>10 weeks</b>; <a href="#">label with BUD</a> of <b>10 weeks</b> max.</p>
	<p><b>For Pfizer Tris-Sucrose 5-11Y (Orange Cap) Formulation</b></p>
	<p>Label carton with expiry date printed on the shipper label before storing. (Vial date is the manufacture date.)</p> <p>Apply <a href="#">storage and handling labels</a> to cartons to prevent administration and handling errors.</p> <p><b>This product CANNOT be stored in a routine freezer.</b></p> <p><b>If transferring to ULT freezer:</b> Store between -90°C to -60°C (-130°F to -76°F) <b>within 5 minutes</b>; do not open tray(s) or touch vials. Store and use up to expiration.</p> <p><b>If transferring to refrigerator:</b> Store between 2°C and 8°C (36°F and 46°F) for up to <b>10 weeks</b>; <a href="#">label with BUD</a> of <b>10 weeks</b> max.</p>
	<p><b>For Pfizer Tris-Sucrose 6M-4Y (Maroon Cap) Formulation</b></p>
	<p>Label carton with expiry date printed on the shipper label before storing. (Vial date is the manufacture date.)</p> <p>Apply <a href="#">storage and handling labels</a> to cartons to prevent administration and handling errors.</p> <p><b>This product CANNOT be stored in a routine freezer.</b></p> <p><b>If transferring to ULT freezer:</b> Store between -90°C to -60°C (-130°F to -76°F) <b>within 5 minutes</b>; do not open tray(s) or touch vials. Store and use up to expiration.</p> <p><b>If transferring to refrigerator:</b> Store between 2°C and 8°C (36°F and 46°F) for up to <b>10 weeks</b>; <a href="#">label with BUD</a> of <b>10 weeks</b> max. <b>(Use Pfizer 5-11Y BUD until CDC releases new labels.)</b></p>
	<p><b>For Pfizer 12Y+ (Purple Cap) – Retired 12/23/21</b></p>
	<p>Apply <a href="#">storage and handling labels</a> to cartons to prevent administration and handling errors.</p>

	<p><b>If transferring ULT freezer:</b> Store between -90°C and -60°C (-130°F and -76°F) <b>within 5 minutes</b>; do not open tray(s) or touch vials. Store and use up to expiration.</p> <p><b>If transferring to freezer:</b> Store between -25°C and -15°C (-13°F to 5°F) for up to <b>2 weeks</b>; <a href="#">label with Beyond Use Date (BUD)</a> of 14 days.</p> <p><b>If transferring to refrigerator:</b> Store between 2°C and 8°C (36°F and 46°F) for up to <b>31 days</b>; <a href="#">label with BUD</a> of 31 days max.</p>
8.	<p><a href="#">Report shipment incidents</a> immediately for resolution.</p>

## Report Shipment Incidents

Report all shipment incidents in myCAvax for vaccine product or kits (including product viability, damage or packing slip discrepancies) the same day the shipment arrived. (See [Reporting Shipment Incidents](#).)

## Thermal Shipper Return Policy

***Pfizer Tris-sucrose 12Y+ (Gray Cap), 5-11Y (Orange Cap) and 6M-4Y (Maroon Cap) Formulations:***

**Return data logger to Pfizer and dispose of shipper locally.** Single-use shippers will include a Logger Return Kit embedded in the lid of the shipper. Remove logger from the shipper and [return the logger](#) to Pfizer.

***Original Pfizer 12Y+ (Purple Cap) Formulation (1170- and 450-dose shippers, Retiring 12/23/21):***

**Return shipper, data logger, and other components to Pfizer. Do not return vaccine in shippers!**

*Pfizer 1170:* Return within 30 days; *Pfizer 450:* Return within 4 days (shippers are available in limited supply).

Use these [return instructions](#). Controlant will arrange with carrier for collection.