

# Storage and Handling of the COVID-19 Vaccine

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The updated (bivalent) COVID-19 boosters are the best protection against COVID-19 variants causing illness right now.

**Goal: Increase COVID-19 Vaccination Among Older Adults in Long-term Care Settings**

# CDC COVID-19 Vaccination Program 90 Day Initiative Using the Sub-Provider Agreement

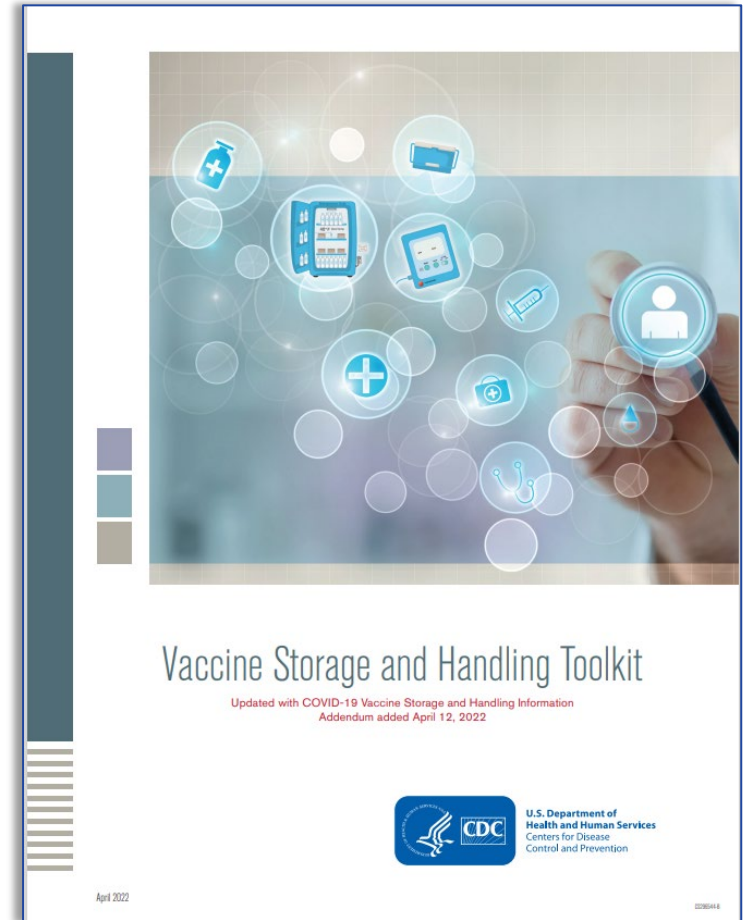
- Only for use by long term care facilities (LTCF) not already enrolled as full providers in the CDC COVID-19 Vaccination Program
  - Organization may order COVID-19 vaccine from the designated enrolled pharmacy for direct administration by Organization to their residents and staff.
- Must store, prepare and administer COVID-19 Vaccine in accordance with all [ACIP applicable requirements and recommendations](#).
- Handling and Storage: The designated enrolled pharmacy is authorized to provide Organization only single dose vials of COVID-19 Vaccine. [Organization must store and handle such single dose COVID-19 Vaccine vials under proper conditions.](#)
- This Agreement is interim and valid through March 15, 2023, unless extended by CDC

# Storage and Handling Basics

- Vaccines are very fragile and sensitive to temperature changes. If not properly stored, the **effectiveness of the vaccine may be diminished.**
- The temperature of vaccines must be continuously monitored, by a Digital Data Logger (DDL).

# COVID-19 Vaccine Storage and Handling

- Providers are required to follow storage and handling guidelines outlined in the [CDC Storage and Handling Toolkit](#).
- See the [Provider Operations Manual](#) for additional information on storage and handling, as well as detailed information about other aspects of the California COVID-19 Vaccination Program.



# Refrigerators

- Must maintain stable temperature range of 2°C to 8°C
  - Purpose-built refrigerators for biologics are most likely to hold stable temperatures, but some household grade refrigerators may work too.
- Do **not** use dorm style refrigerators, they can freeze the vaccine!
  - They have a single exterior door and an evaporator plate/cooling coil which is usually located in an icemaker/freezer compartment.
  - You can use compact, purpose-built units designed for biologics.



Tip:

Are you unsure if you have a dorm-style refrigerator? Email [covidcallcenter@cdph.ca.gov](mailto:covidcallcenter@cdph.ca.gov)

# Storage Unit Organization: Best Practices

**Sample Refrigerator**

The diagram shows a refrigerator with a temperature of 40.4°F. The interior is organized into three main age groups, each with a color-coded label: Pediatric (orange), Adolescent (blue), and Adult (purple). Vaccines are stored in baskets on shelves, with water bottles placed on the top shelf, floor, and back of shelves. Dashed lines indicate usable space for vaccines. Arrows point from callout boxes to specific areas of the refrigerator.

**Best Practices (Checkmarks):**

- ✓ Add water bottles in top shelf, floor and door, and back of shelves.
- ✓ Group vaccines by age (pediatric, adolescent, adult).
- ✓ Label shelf space or baskets to make vaccines easy to find.
- ✓ Position vaccines or baskets 2-3 inches away from walls, floor, and other baskets.
- ✓ Store vaccines in original packaging with earliest expiration date in front.
- ✓ Diluents may be stored next to refrigerated vaccines unless manufacturer states otherwise. Never store diluents in the freezer.
- ✓ If necessary, medications or biologics may be stored below vaccines and on a different shelf.

**Warnings (Red X's):**

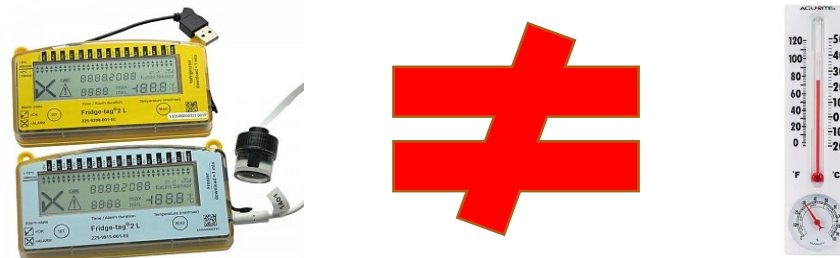
- ✗ Do not block air vents.
- ✗ Do not stack baskets on top of each other.
- ✗ No vaccines in doors.
- ✗ No food or beverages.

**Additional Callouts:**

- Usable space for vaccine is inside dashed lines.

# What is a Digital Data Logger (DDL)?

- Digital Data Loggers are tools that ***continuously read and record*** temperatures to provide an accurate report of vaccine temperatures over time.
- DDLs can be set to alarm if the temperature of a storage unit goes outside of the temperature range that you set it for.
- DDLs should have a probe and a screen that shows the current, min, and max temperatures.
- DDLs read and record temperatures at set time intervals and store data in an internal memory.
  - This data should be downloaded and reviewed at least every 15 days
- **DDLs should be used at *all times!***



***Digital Data Logger does not equal a thermometer!***



# Manual Temperature Log

- In addition to using a DDL, providers should also use a manual temperature log
  - Usually, providers attach the manual log on the outside of the storage unit
- COVID-19 Temperature Log
- How To Record Temperatures For COVID-19 Vaccine Storage Units

**CHECK TEMPERATURES TWICE A DAY.**

- 1 Fill out header.**
- 2 Check the temperature range for the product and storage unit you are using.**
- 3 Record the time and your initials next to the day of the month:**  
a.m. temperatures **before** opening the refrigerator or freezer.  
p.m. temperatures about an hour before the office closes to allow time for corrective actions.
- 4 Record a check mark if you see or hear an alarm.**  
If the alarm did not go off, leave blank.
- 5 Record CURRENT, MIN, and MAX temperatures neatly, accurately, and in the correct columns.**  
Do not record LO/HI alarm settings.

**Temperature Log (COVID-19 Vaccine)**

MONTH & YEAR	VACCINE STORAGE UNIT LOCATION/ID	COVID PIN
January 2018	Injection Room Unit #2	012345

Select temp range by product.

**Pfizer-BioNTech:**


- ULT Freezer: 6 months  
-80°C to -60°C (-112°F to -76°F)
- Refrigerator: 5 days (120 hours)  
2°C–8°C (36°F–46°F)

**Moderna:**

- Freezer: 6 months  
-25°C to -15°C (-13°F to 5°F)
- Refrigerator: 30 days  
2°C–8°C (36°F–46°F)

Remember to write in pen.

Day	Time	Initials	Alarm	CURRENT	MIN	MAX
16	8:00 am	CS	✓	2.4 C	0.6 C	4.1 C
	pm					



# What is a Temperature Excursion?

- A temperature excursion is any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert or Fact Sheet for Healthcare Providers.
  - Example: If storing a refrigerated vaccine at 2°C to 8°C and your refrigerator's temperature raises up to 12°C!
- How do you know if you had a temperature excursion?
  - Your digital data logger will tell you!

# Temperature Excursion? What to Do...

1. Quarantine the vaccines – label "DO NOT USE"
2. Download and save the digital data logger's temperature file.
3. Look at the file for the excursion details.
4. Use the [temperature excursion worksheet](#) to record the details of the excursion.
5. Contact the manufacturer to determine if the vaccines are still viable
6. Maintain records of steps taken
  - ★ This is necessary even if the manufacturer determined your vaccine was still viable!
7. If the vaccine is no longer viable, dispose of it and report it as waste.

# Expiration Dates and Beyond Use Dates

- Expiration dates
  - The dates determined by the manufacturer beyond which the vaccine is no longer acceptable to administer to patients, **regardless of storage condition.**
- Beyond Use Dates/Times (BUD)
  - The last day/time that the COVID-19 vaccine can be safely used after it has been transitioned between storage states (thawed, refrigerated, etc.). The BUD replaces the manufacturer's expiration date but never extends it.
- **Dispose of the vaccine on whichever date/time comes first!**

# Checkpoint 1: Expiration and Beyond Use Date (BUD)

You have a vaccine that has an expiration date of 01/31/2023. When you received the vaccine from your pharmacy it was labeled with a BUD of 02/10/2023.

When should you dispose of this vaccine?

# Checkpoint 1: Expiration and Beyond Use Date (BUD)

You have a vaccine that has an expiration date of 01/31/2023. When you received the vaccine from your pharmacy it was labeled with a BUD of 02/10/2023.

When should you dispose of this vaccine?

**Answer: The vaccine must be discarded on its expiration date, which is by the end of the day on 01/31/2023.**

## Checkpoint 2: Expiration and Beyond Use Date (BUD)

You have a vaccine that has an expiration date of 02/23/2023. When you received the vaccine from your pharmacy it was labeled with a BUD of 02/15/2023.

When should you dispose of this vaccine?

## Checkpoint 2: Expiration and Beyond Use Date (BUD)

You have a vaccine that has an expiration date of 02/23/2023. When you received the vaccine from your pharmacy it was labeled with a BUD of 02/15/2023.

When should you dispose of this vaccine?

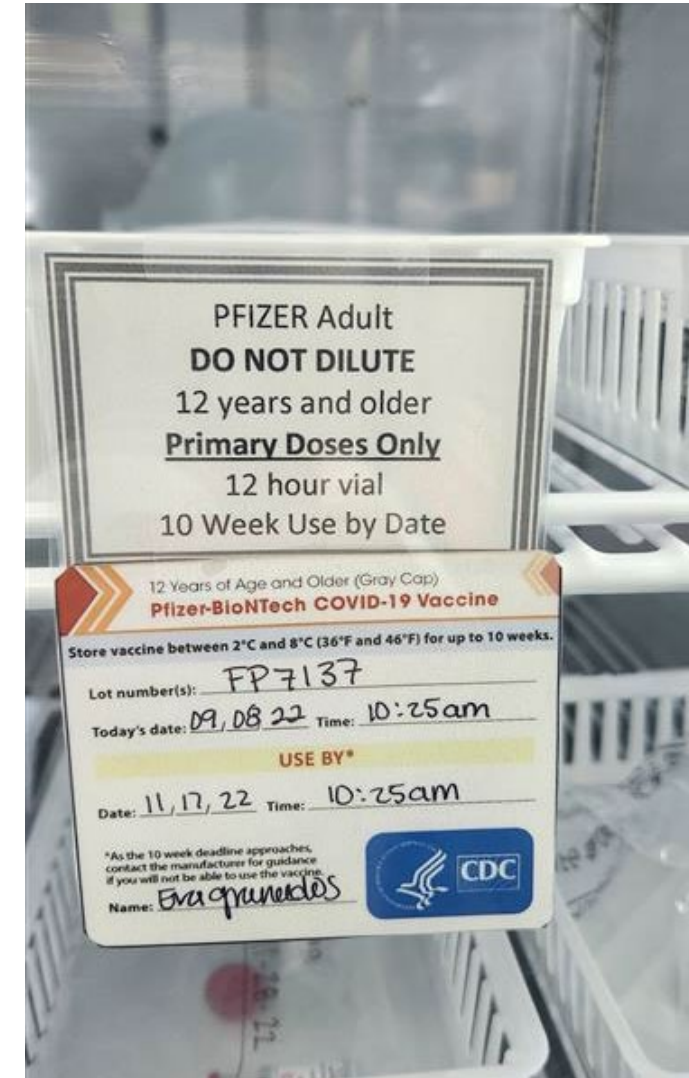
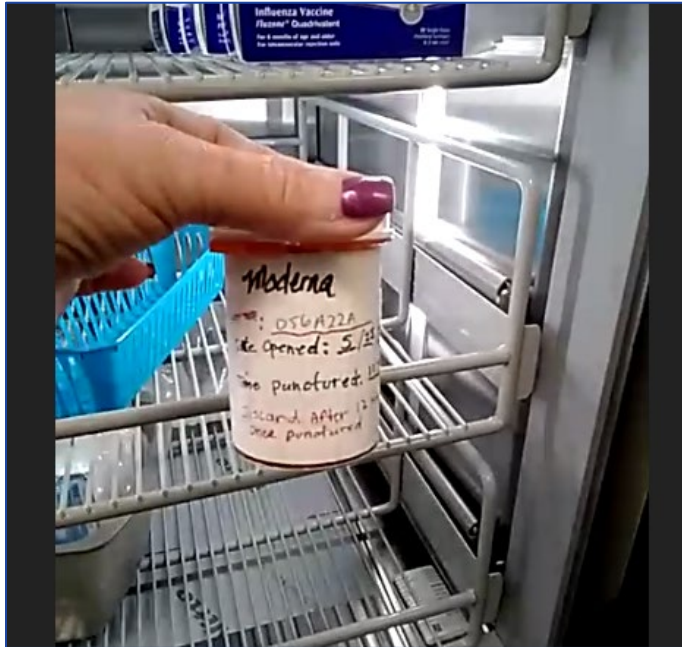
**Answer: The vaccine must be discarded on its beyond use date, 02/15/2023.**



Remember, you should always discard on whichever date/time comes first!



# Beyond Use Date/Time Best Practices



# Pfizer 12+ Bivalent – Single Dose Vial

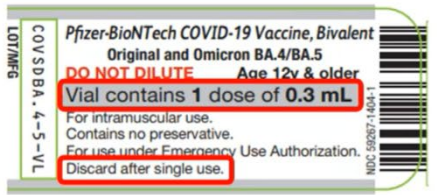
Check vaccine labels and [EUA fact sheets](#) before use to avoid mix-ups. EUA fact sheets supersede info on vials and carton. Refer to [CDC Product Guide](#) for more information.

## Single Dose Vial Overview: DO NOT DILUTE / 12 years and older

Ages 12+



BIVALENT  
Booster Dose  
Single Dose Vial



### Single Dose Vial Dose Preparation:

- ✓ Before use, mix by inverting vaccine vial per EUA Fact Sheet Preparation Instructions.
- ✓ Withdraw a single 0.3 mL dose.
- ✓ Administer immediately.
- ✓ Discard vial and any excess volume.

Single-Dose Vial THAW TIME	
Refrigerator (2°C to 8°C)	Up to 2 hours
Room Temperature (up to 25°C)	30 minutes

For detailed step by step instructions for preparation and administration, please refer to the EUA Fact Sheet for Vaccination Providers which is available at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).



Before administration, please see full Prescribing Information: 12 years of age and older or appropriate EUA Fact Sheet for Vaccination Providers. For the most recent prescribing information and fact sheets, please visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)

35

Source: Pfizer Medical Updates presentation 12/22

	Pfizer	
	Adol/Adult Primary Series 12+ years	Bivalent Booster 12+ years
		Multi-dose  Single "Bivalent" on label
<b>Packaging</b>	Gray Cap	Gray Cap
Doses Per Vial	6 doses	6 / 1 doses
Carton Size	60 doses	60 / 10 doses
Min. Standard Order	180 doses	180 / 50 doses
<a href="#">NDC-Unit of Use (vial)</a>	59267-1025-01	59267-0304-01 59267-1404-01
CVX Code	217	300
<b>Storage Limits Before Puncture:</b> Label vaccine with expiration		
ULT (-90°C to -60°C)	Until expiration	
Thermal Shipper		
Freezer		
Refrigerator (2-8°C)	Up to 10 weeks	
Expiration Date	18 months from manufacture date on vial and carton. Check <a href="#">product website</a> .	
<b>Administration</b>		
Diluent (supplied)	<b>Do not dilute</b>	
Dose Volume-- Primary/Additional	0.3 mL (30 mcg dose)	N/A
Dose Volume-- Booster	<b>Do not use for boosters.</b>	0.3 mL (30 mcg dose)
Refrigerator Thaw Time (2° to 8°C/ 36°F to 46°F) (Do not refreeze)	Up to 6 hours in carton	In carton, Multi-dose: up to 6 hours. Single-dose: up to 2 hours.
Room Temp Thaw Time	Vial: 30 minutes at up to 25°C (77°F)	
Total Time at Room Temp (Do not refreeze)	Up to 12 hours (including thaw time) at 8°C to 25°C (46°F to 77°F)	
<b>Storage Limits After Puncture (Multi-dose vials):</b> Record pu		
Use-By Limit (Discard Time After 1st Puncture)	Discard after 12 hours at 2°C to 25°C (35°F to 77°F)	

# Important Links

- Pfizer EUA: [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA](#)
- [Pfizer Lot Expiry Checker](#)



# Questions?

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Storage and Handling SMEs