

Vaccine Storage and Handling Refresher

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Disclosure Statements

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- Elisha Hall
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Objectives

- Staff Training
- Vaccine Cold Chain
- Storage Equipment
- Vaccine Inventory Management
- Emergency Storage and Handling
- Vaccine Transport
- Clinical Resources
- FAQs and Q&A

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Overview

Question

Why does vaccine storage and handling matter?

Improper storage and handling can:

- A. Affect how well vaccines work.
- B. Erode patient's confidence in vaccines or staff
- C. Increase costs-staff time, replacement products, etc.
- D. All the above



Answer!

Why does vaccine storage and handling matter?

- A. Improper storage and handling can affect how well vaccines work.
- B. Improper storage and handling can erode patient's confidence in a practice or personnel
- C. Improper storage can increase costs-staff time, replacement products, etc.

D. All the above



Storage and Handling SOPs

- Facilities should develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) for three major areas:
 - Routine storage and handling – information for vaccine inventory management.
 - Emergency vaccine storage, handling, and transport – steps to be taken when circumstances might compromise vaccine storage condition.
 - General information – contact information for vaccine manufacturers, equipment service providers, and staff training requirements.

Staff Training

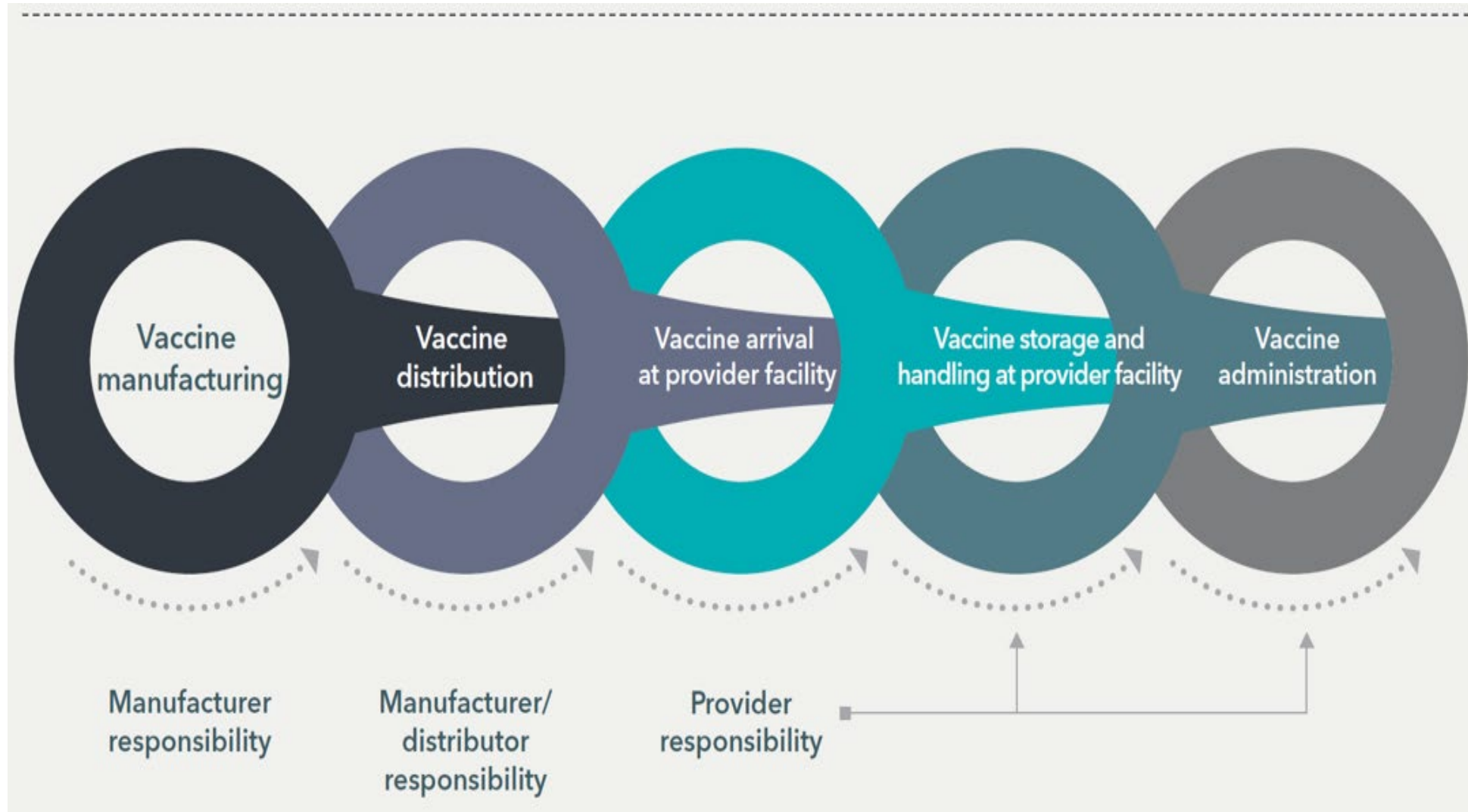
- **Complete training:**
 - As part of employee orientation
 - Annually
 - When recommendations change
 - When new vaccines are added



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**Vaccine
Cold Chain**

Vaccine Cold Chain



Who Maintains the Cold Chain at Your Facility?



Primary and Alternate Vaccine Coordinator Duties

■ Primary coordinator

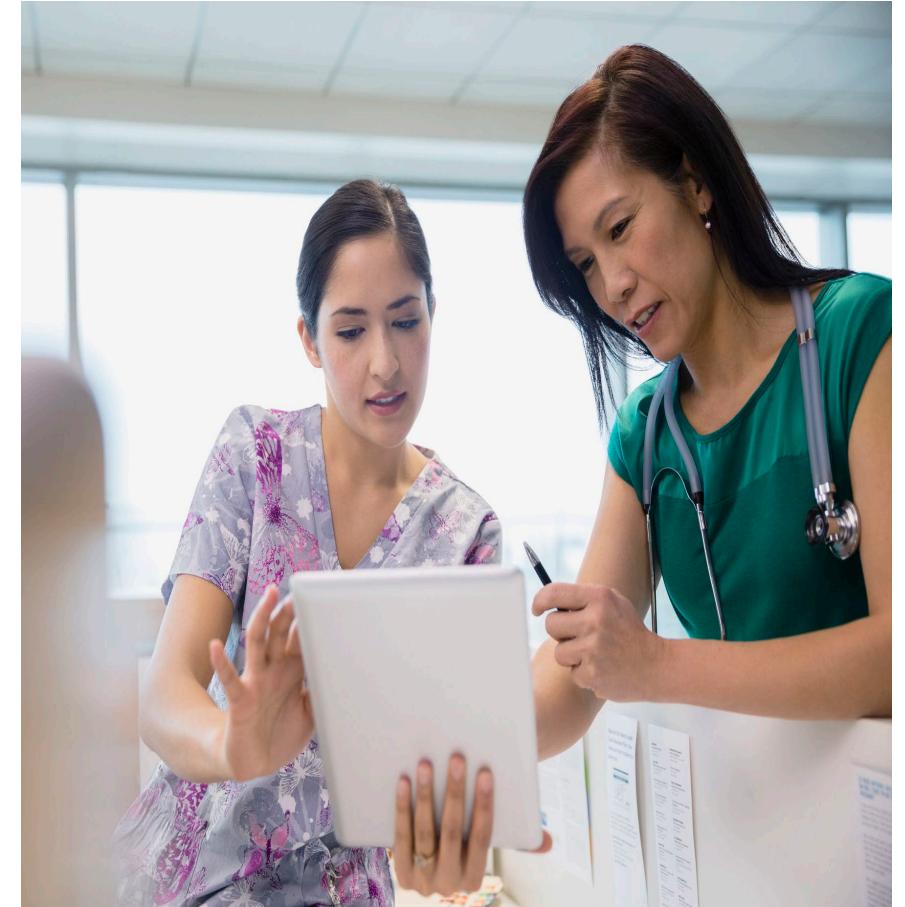
- Responsible for ensuring all vaccines are stored and handled properly
- Expert on routine and emergency SOPs
- Review and update SOPs annually

■ Alternate coordinator

- Expert that can assist primary and fulfill duties in their absence

■ All other staff

- May delegate duties to trained staff



Primary and Alternate Vaccine Coordinator Duties

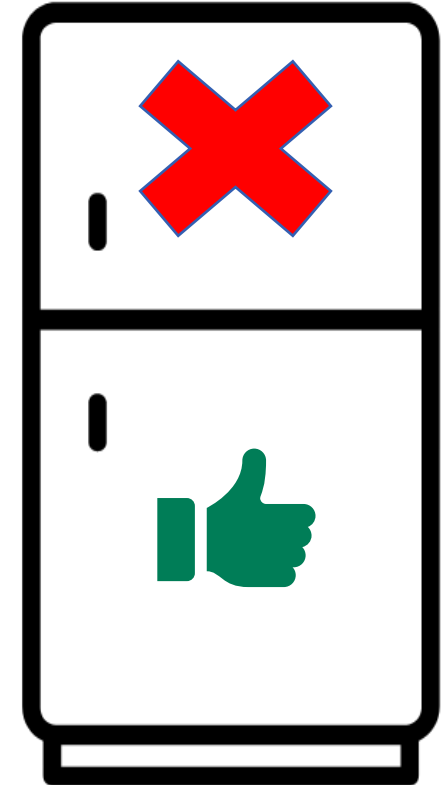
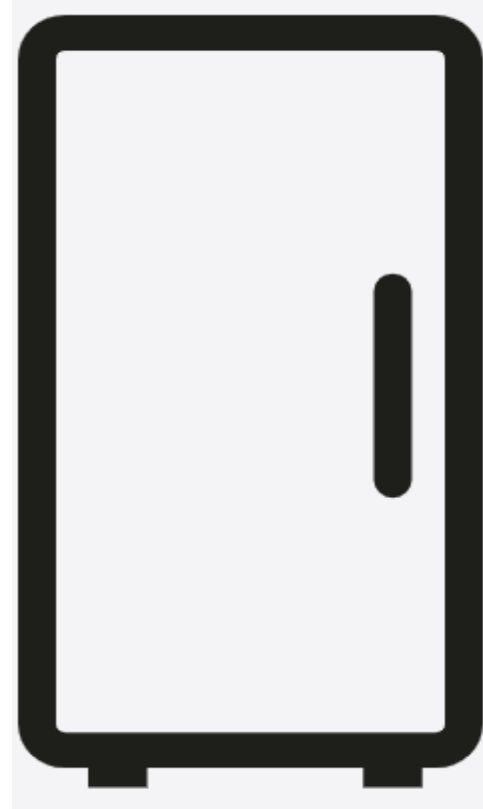
- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- **Removing expired vaccine from storage units**
- **Responding to temperature excursions (out-of-range temperatures)**
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- **Overseeing proper vaccine transport (when necessary) per SOPs**
- Overseeing emergency preparations per SOPs:
- Tracking inclement weather conditions
- Ensuring appropriate handling of vaccines during a disaster or power outage

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**Storage
Equipment**

Equipment: Vaccine Storage Units

- Purpose-built or pharmaceutical-grade (large or compact) is preferred
- Household-grade is acceptable
 - Do not use freezer



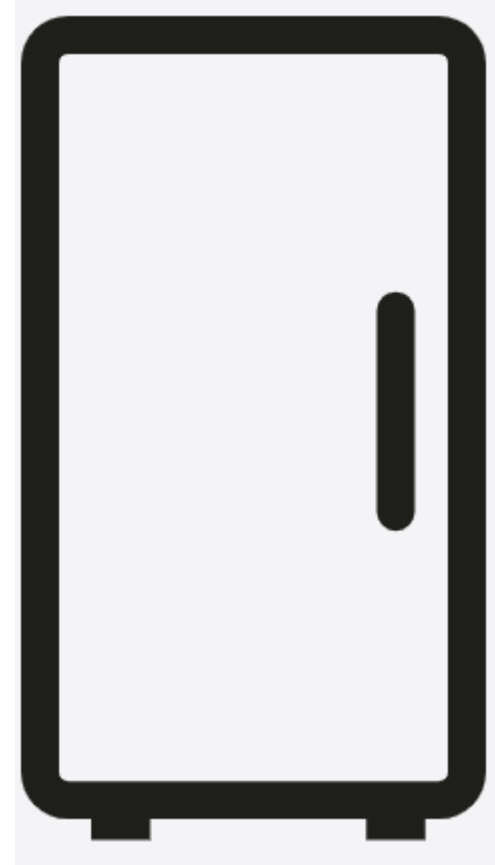
Equipment: Vaccine Storage Units



Ultra-cold freezer
Between
-90°C and -60°C
(-130°F and -76°F)



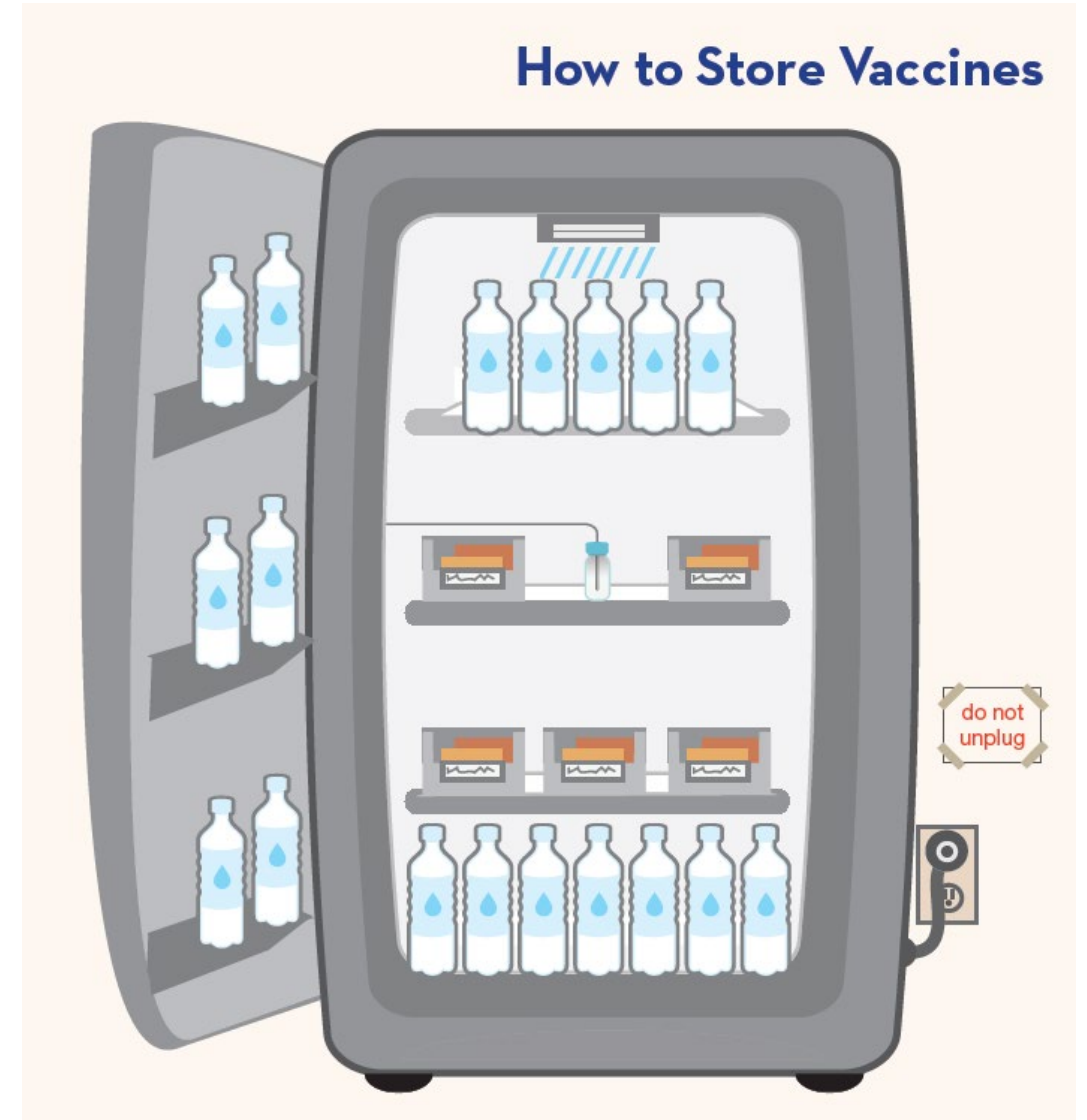
Standard freezer
Between
-50°C and -15°C
(-58°F and +5°F)



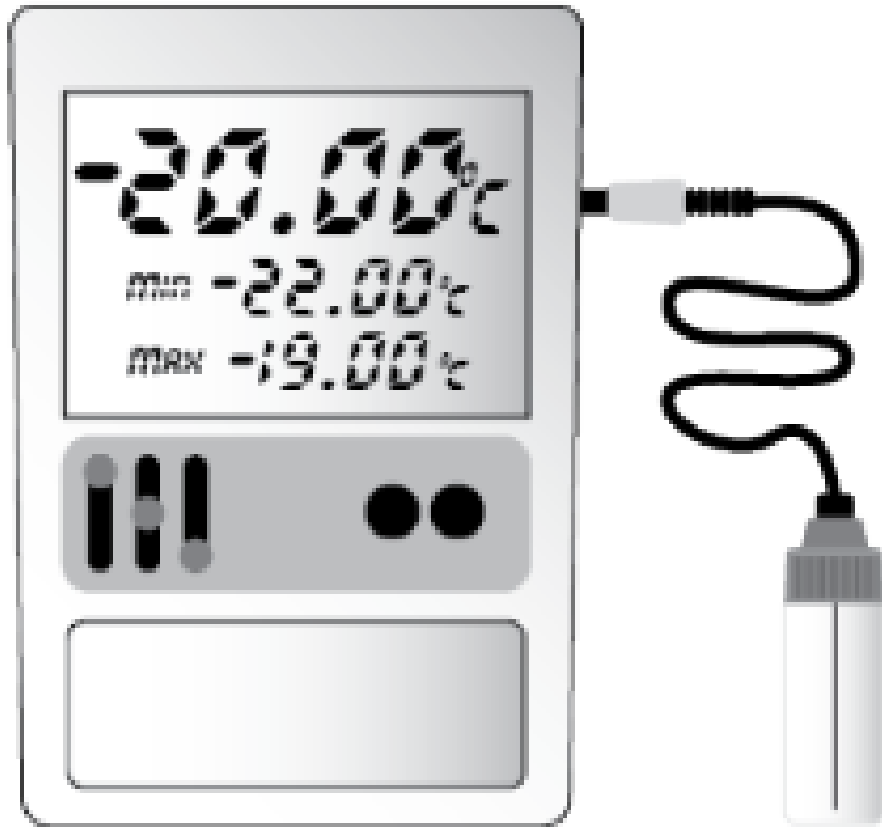
Refrigerator
Between
2°C and 8°C
(36°F and 46°F)

Organization

- Store in the original packaging
- Label vaccine containers
 - [Vaccine Label Examples \(cdc.gov\)](https://www.cdc.gov/vaccines/imz/downloads/2015/05/20150501-Vaccine-Label-Examples.pdf)
- Avoid danger zones
- Use water bottles appropriately



Equipment: Temperature Monitoring Devices (TMDs)



- **Recommended: A digital data logger (DDL) with these features:**
 - A detachable buffered probe
 - Able to measure minimum and maximum temperatures
 - Uncertainty of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$)
- **Other features**
 - Alarm
 - Low battery indicator
 - 30-minute reading rate

Certificate of Calibration

■ Should include:

- Model/device name or number
- Serial number
- Date of calibration
- Confirmation that the instrument passed testing
- Recommended uncertainty of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$) or less



Monitoring Storage Unit Temperatures

- Check and record **minimum/maximum temperatures once each workday**, preferably in the morning

F° Temperature Log for Freezer – Fahrenheit
DAYS 1–15

Monitor temperatures closely!
1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max once each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps twice, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

max temps, document current temps twice, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 2
Facility Name _____

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).
1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp in Unit (since previous reading)															
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES	5°F														
	4°F														
	3°F														
	2°F														
	1°F														
	0°F														
	-1°F														
	-2°F														
	-3°F														
	-4°F														
-58°F to -5°F															
ACTION	Write any out-of-range temps (above 5°F or below -58°F) here. Room Temperature														

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Adapted with appreciation from California Department of Public Health
www.immunize.org/cdc/dph/10101.pdf • Item #P303MF (8/21)

COVID-19 Vaccine
Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 1–15

Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit*, *COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)
1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature
1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

! If the temperature is out of range, TAKE ACTION!
1. Do NOT discard the vaccine.
2. Label the vaccine "Do Not Use."
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____
Facility Name _____

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Time															
Staff Initials															
Min/max temperatures															
Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.															
Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Staff Initials															
2°C															
3°C															
4°C															
5°C															
6°C															
7°C															
8°C															

For additional information, see the vaccine manufacturer's product information.

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

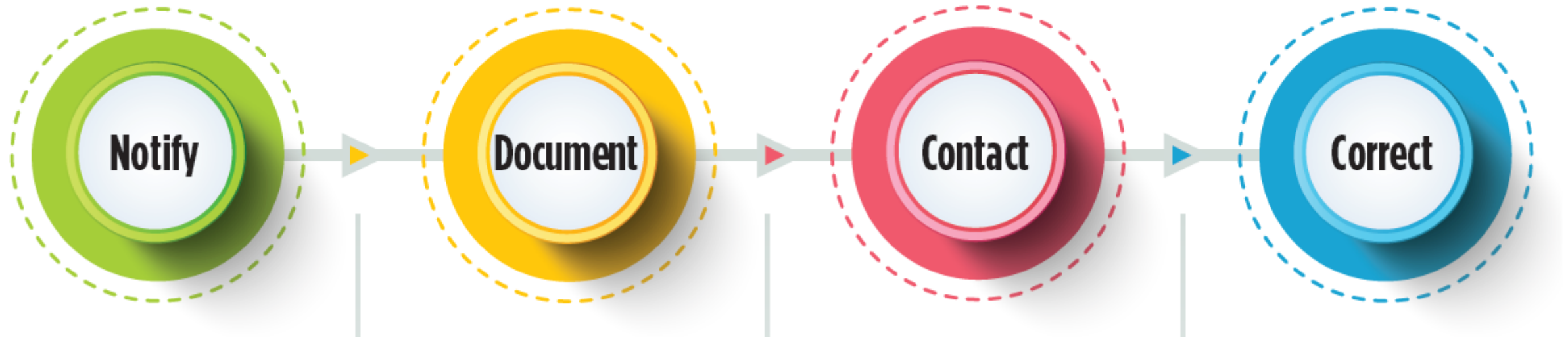
[Temperature Logs - Handouts for Healthcare Professionals \(immunize.org\)](https://www.immunize.org)

[U.S. COVID-19 Vaccine Product Information | CDC](https://www.cdc.gov)

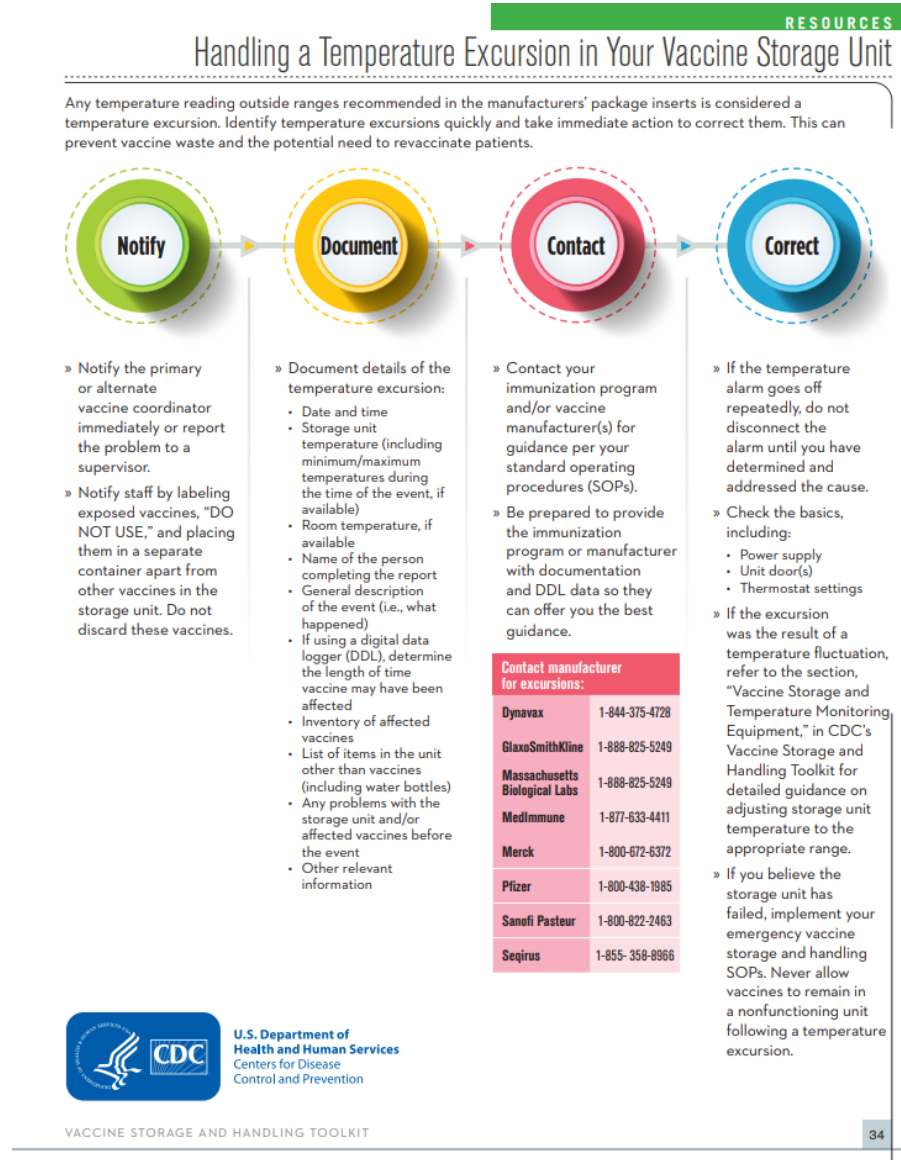
Temperature Excursion

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



CDC Resource: Handling a Temperature Excursion



In the Event of a Temperature Excursion

- Notify the primary/secondary vaccine coordinator or supervisor immediately
- Label exposed vaccines “DO NOT USE” and store at appropriate temperature; **do not discard exposed vaccines**
- Document the event
- Implement your facility SOPs to adjust unit temperature to the appropriate range
- Contact your immunization program and/or vaccine manufacturer(s) for further guidance

Temperature Excursion Documentation

- **Date and time of the temperature excursion**
- **Storage unit temperature and room temperature**
- **Name of the person completing the report and description:**
 - General description of what happened
 - The length of time vaccine may have been affected
 - Inventory of affected vaccines
 - List of items in the unit other than vaccines (including water bottles)
 - Any problems with the storage unit and/or affected vaccines before the event
 - Other relevant information

Vaccine Storage Troubleshooting Record

Vaccine Storage Troubleshooting Record

(check one) ☐ Refrigerator ☐ Freezer ☐ Ultra-Cold Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

A fillable pdf of this form is available at www.immunize.org/catg.d/p3041.pdf

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>	Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:	Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title: Date:
Description of Event <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none">• General description (i.e., what happened?)• Estimated length of time between event and last documented reading of storage temperature in acceptable range (2° to 8°C [36° to 46°F] for refrigerator; -50° to -15°C [-58° to 5°F] for freezer; -80° to -60°C [-112° to -76°F] for ultra-cold freezer (may be used for Pfizer COVID-19 vaccine).• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?• Include any other information you feel might be relevant to understanding the event.				
Action Taken <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none">• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)• IMPORTANT: What did you do to prevent a similar problem from occurring in the future?				
Results <ul style="list-style-type: none">• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)				

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/21)

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Vaccine Inventory Management

Vaccine Delivery

- **Maintain cold chain; immediately check and store vaccines upon arrival:**
 - Unpack
 - Examine and document:
 - Damage
 - Receipt of order
 - Temperature monitoring device or cold chain monitor
 - Expiration dates
 - **Immediately store at recommended temperature**

Vaccine Delivery Temperature Excursion

- Notify the primary/secondary vaccine coordinator or supervisor immediately
- Label exposed vaccines “DO NOT USE” and store at appropriate temperature; **do not discard exposed vaccines**
- Document the event
- ~~■ Implement your facility SOPs to adjust unit temperature to the appropriate range~~
- Contact vaccine manufacturer(s) for further guidance and notify your immunization program

Vaccine Inventory and Stock Records

■ Stock record

- Delivery date
- Name or initials of person who unpacked delivery
- Manufacturer
- Lot number and expiration date
- Number of doses
- Delivery cold chain monitor reading
- Number of doses used and balance

Other Inventory Issues

- **Rotate stock so that vaccines that expire first are used first:**
 - Rotate stock weekly and when there are deliveries.
 - Remove expired stock and handle per policy (return, discard, etc.).
- **Avoid overstocking of vaccine supply:**
 - Check stock and anticipate upcoming patient needs (i.e., flu season, back to school, community event, etc.).

**Vaccine
Inventory
Management**



**Expiration
Date**

Expiration Date

- All products have an **expiration date**
- The expiration date is the **final day** that the vaccine can be administered
- Determined by the **manufacturer**



Where to Find the Expiration Date



Month, day, and
year of expiration



Month and year of
manufacture

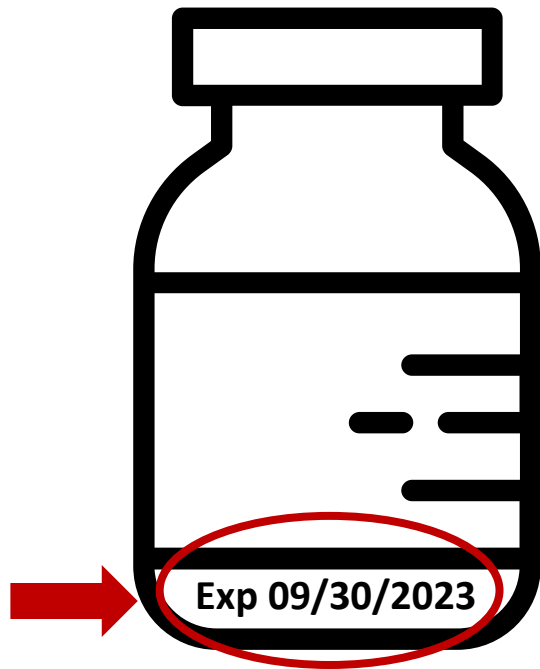


QR Code, website, or
phone number



Month and year
of expiration

Where to Find the Expiration Date



Month, day, and
year of expiration



Month and year
of expiration



QR Code, website, or
phone number



Month and year of
manufacture

Where to Find the Expiration Date



Month, day, and
year of expiration



Month and year of
manufacture



QR Code, website, or
phone number



Month and year
of expiration

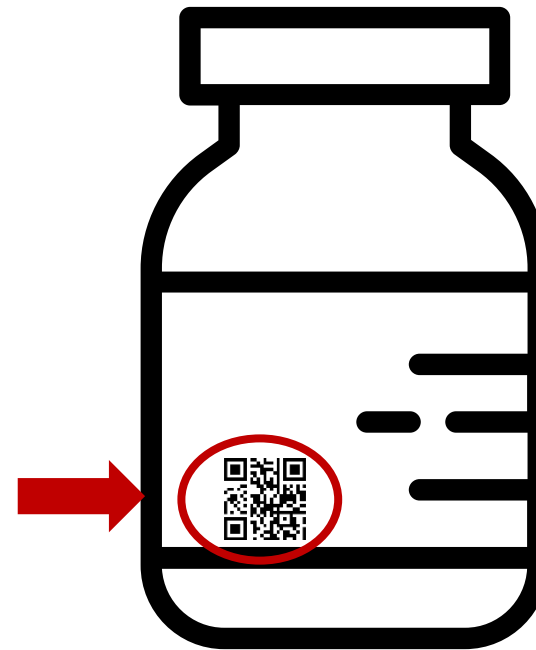
Where to Find the Expiration Date



Month, day, and
year of expiration



Month and year
of expiration



QR Code, website, or
phone number



Month and year of
manufacture

Where to Find the Expiration Date



Month, day, and
year of expiration



Month and year of
manufacture

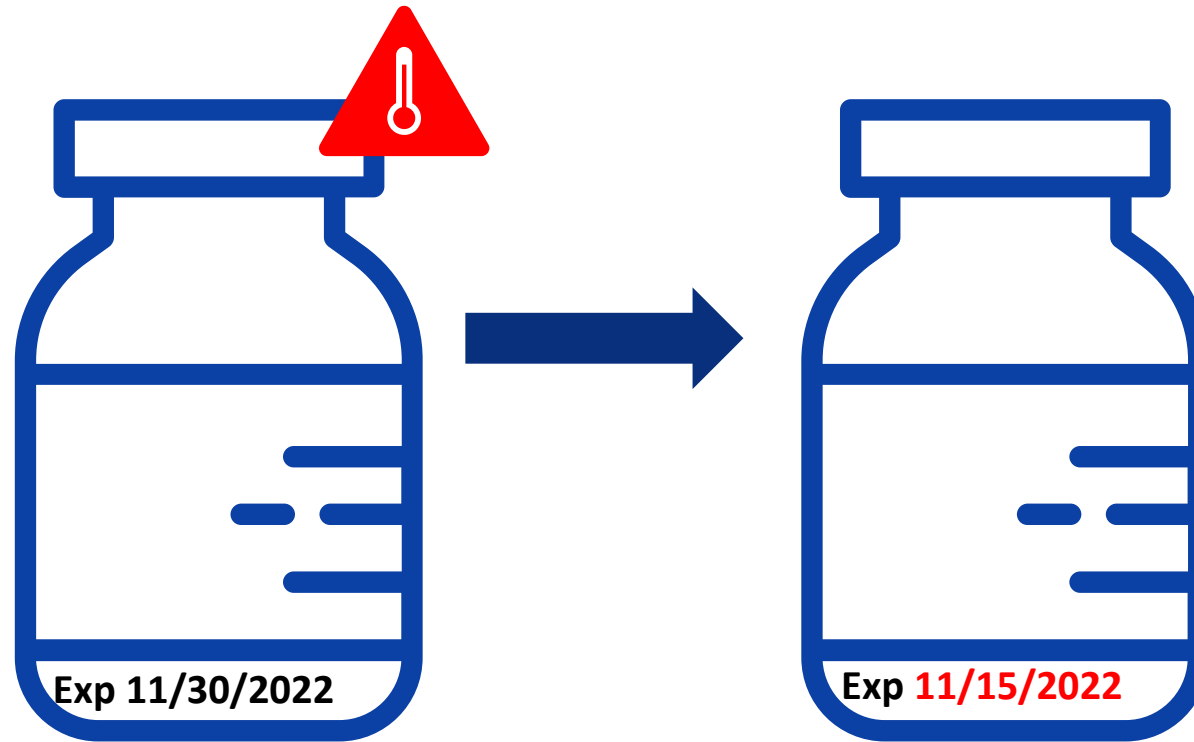


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phone number

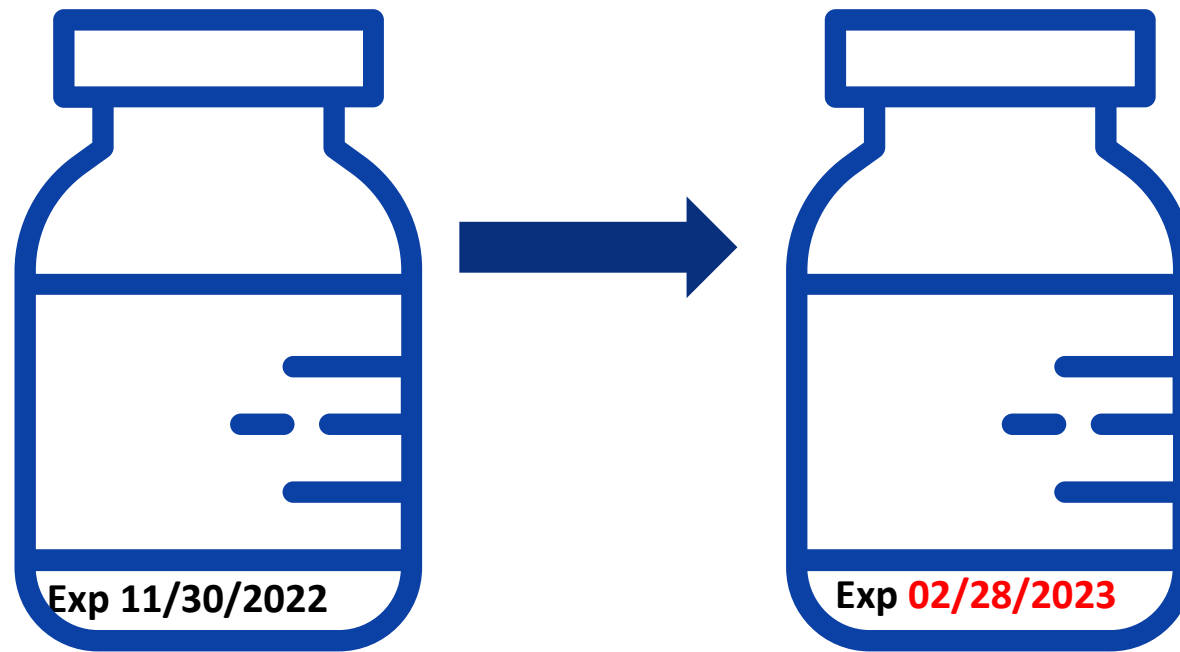


Month and year
of expiration

Expiration Date Changes: Shortened Expiration



Expiration Date Changes: Extended Expiration



**Vaccine
Inventory
Management**

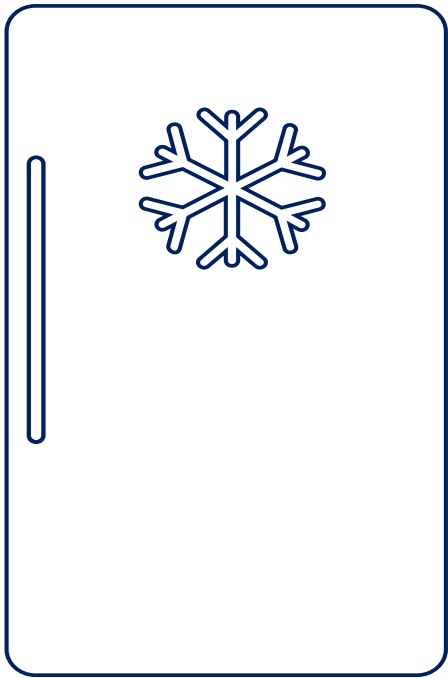


**Beyond-Use
Date/Time**

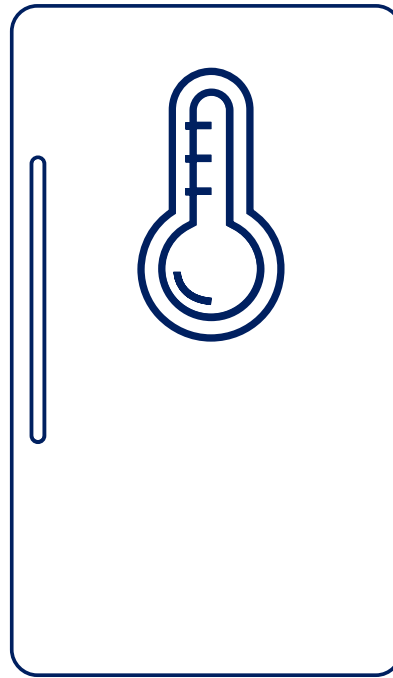
What is a Beyond-Use Date/Time (BUD)?

- Date/time generated when a product is **transitioned between storage states or altered for patient use**
- Set by the **provider**
- Replaces but **does not extend the expiration**; always use the earlier date
- Only some vaccines have a BUD

BUD and Transition Between Storage States



Freezer



Refrigerator

Never use vaccine
after the
beyond-use
date/time!



Expiration Date Extension and Beyond-Use Date

Pfizer-BioNTech COVID-19 Vaccine

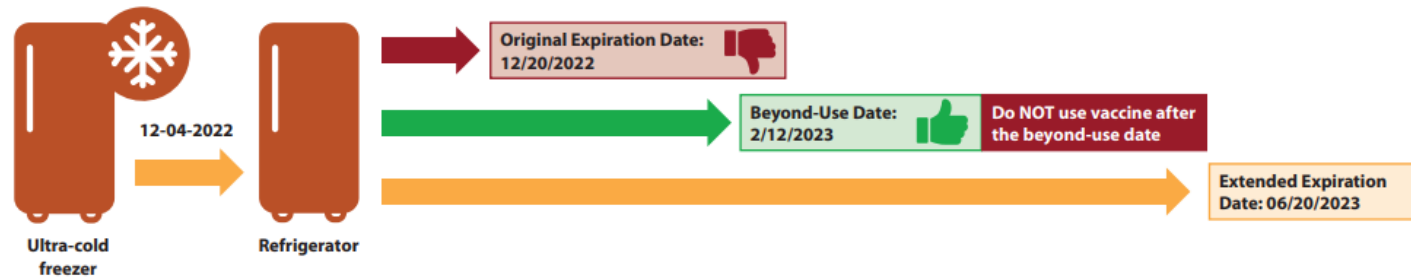
Expiration Date Extension and Beyond-Use Date



Recently the Food and Drug Administration (FDA) extended the expiration date for Pfizer-BioNTech COVID-19 Vaccine (monovalent and bivalent) from 12 to 18 months from manufacturer date. Before discarding any vaccine, providers should check the expiration date using Pfizer-BioNTech's expiration date tool at [Pfizer-BioNTech COVID-19 Lot Expiry \(cvdvaccine.com\)](https://www.pfizer-biontech.com/covid-19/lot-expiry).

NOTE: This expiration date extension applies to both vaccine vials currently stored at ultra-cold temperatures (-90°C and -60°C [-130°F and -76°F]) or refrigerated temperatures (2°C and 8°C [36°F and 46°F])—even if these vials were moved to refrigerated temperatures prior to the extension.

Example



Vaccine (original expiration date = 12/20/2022) was removed from ultra-cold storage and placed in a refrigerator on 12/4/2022. Pfizer-BioNTech COVID-19 Vaccine stored in a refrigerator must be used within 10 weeks (beyond-use date [BUD]). Based on the date the vaccine was placed in the refrigerator, the vaccine's BUD is 2/12/2023. Without the expiration date extension, this vaccine could only be used up to the expiration date (12/20/2022)—not the full 10 weeks. **HOWEVER, with this extension, the expiration date is now AFTER the BUD. The vaccine can be used for the full 10 weeks.**

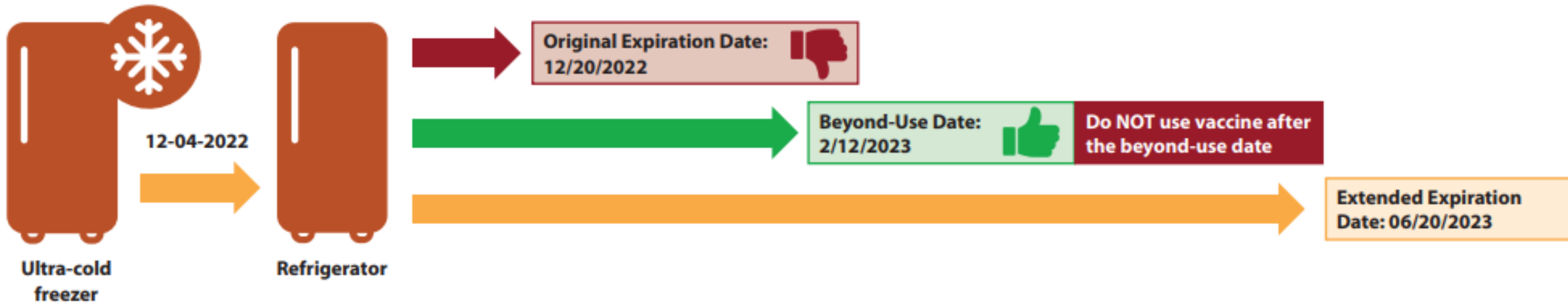
Additional resources

[Storing and Handling Vaccines: Expiration Date, Beyond-Use Date, and Beyond-Use Time](#)

[Vaccines Storage and Handling Toolkit | CDC](#)

[Storage and Handling of Pfizer-BioNTech COVID-19 Vaccines | CDC](#)

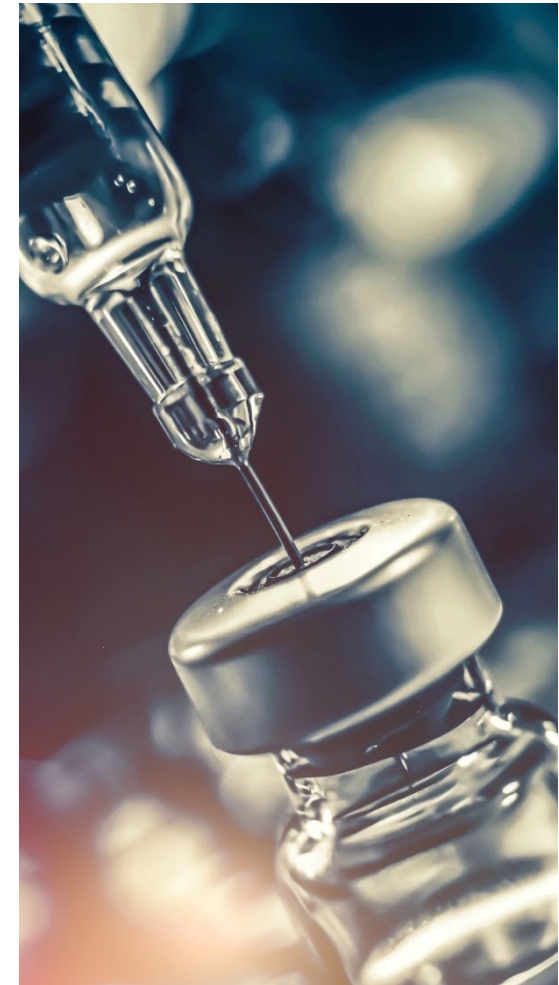
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BUD and Vaccine in a Multidose Vial

- Some multidose vials (MDV) have a specified time frame they should be used after the vial is first punctured.
- The BUD can **vary from hours to days.**
- Some MDV have a specific maximum number of doses that can be withdrawn or punctures to the vial stopper.



BUD and Vaccine in a Multidose Vial

2022– 2023 Influenza Season Vaccine Labels

Afluria Quadrivalent (IIV4)
(Quadrivalent Inactivated Influenza Vaccine)
5 mL Multi-dose Vial

Ages: 6 months or older
Dosage: 0.25 mL for age 6 months through 35 months
0.5 mL for age 3 years or older
Route: Intramuscular (IM) injection

Protect from light

Beyond Use Date: Discard within 28 days after the vial has been opened or punctured.

Number of needle punctures should not exceed 20 per multidose vial.

PharmaJet® Stratis® Needle-Free Injection System: ages 18 years through 64 years only

BUD and Reconstituted Vaccines

- Once mixed with diluent, vaccines have a limited period for use.
- The BUD can vary from minutes to hours.

Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert [†]	Diluent storage environment
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	Sanofi Pasteur	Rabies virus	Sterile water	Immediately [‡]	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menveo (MenACWY)	GlaxoSmithKline	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately [‡]	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{CCCV})	GlaxoSmithKline	Rabies virus	Sterile water	Immediately [‡]	Refrigerator
Rotarix (RV1) [§]	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GlaxoSmithKline	RZV	AS01 adjuvant suspension	6 hrs	Refrigerator
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	Sanofi Pasteur	YF	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (ZVL)	Merck	LZV	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow the steps below.

- For single-dose vaccine products (exception is Rotarix[§]), select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine. For Rotarix, see the package insert.[†]
- Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that:
 - they are the correct two products to mix together,
 - the diluent is the correct volume, and
 - neither the vaccine nor the diluent has expired.
- Reconstitute (i.e., mix) vaccine **just prior to use** by:
 - removing the protective caps and wiping each stop-

- per with an alcohol swab,
 - inserting needle of syringe into diluent vial and withdrawing entire contents, and
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder.
- Check the appearance of the reconstituted vaccine.
 - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
 - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or the

vaccine cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.

- If reconstituted vaccine is not used immediately or comes in a multidose vial, be sure to:
 - clearly mark the vial with the date and time the vaccine was reconstituted,
 - maintain the product at 2°–8°C (36°–46°F); do not freeze, and
 - use only within the time indicated on chart above.









[†]If the reconstituted vaccine is not used within this time period, it must be discarded.

[‡]For purposes of this guidance, IAC defines "immediately" as within 30 minutes or less.

[§]Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

^{||}AS01₁ is composed of 3-O-decyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* and QS-21, a saponin purified from plant extract *Quilaja saponaria Molina*, combined in a liposomal formulation. The liposomes are composed of 1,3-bis(sn)-phosphatidylcholine (BPPC) and cholesterol in phosphate-buffered saline solution containing disodium phosphate anhydrous, potassium dihydrogen phosphate, sodium chloride, and water for injection.

BUDs for Vaccines with Diluents

	Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert*	Diluent storage environment
	ActHIB (Hib)	Sanofi	Hib	Sodium chloride 0.4%	24 hrs	Refrigerator
	Comirnaty (COVID-19, some formulations)	Pfizer-BioNTech	1vCOV-mRNA or 2vCOV-mRNA	Sodium chloride 0.9%, unpreserved	12 hrs [†]	Refrigerator or room temp
	Dengvaxia (DEN4CYD)	Sanofi	Dengue	Sodium chloride 0.4%	30 min	Refrigerator
	Hiberix (Hib)	GSK	Hib	Sodium chloride 0.9%	24 hrs	Refrigerator or room temp
	Imovax (RAB _{HDCV})	Sanofi	Rabies virus	Sterile water	Immediately [‡]	Refrigerator
	M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
	Menveo [§] (MenACWY)	GSK	MenA	MenCWY	8 hrs	Refrigerator
	Pentacel (DTaP-IPV/Hib)	Sanofi	Hib	DTaP-IPV	Immediately [‡]	Refrigerator
	ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
	RabAvert (RAB _{PCECV})	GSK	Rabies virus	Sterile water	Immediately [‡]	Refrigerator
	Rotarix (RV1)	GSK	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
	Shingrix (RZV)	GSK	RZV	AS01B [¶] adjuvant suspension	6 hrs	Refrigerator
	Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
	Vaxchora (CVD 103-HgR)	Emergent	Cholera	Buffer solution plus bottled water	15 min	Refrigerator
	YF-VAX (YF)	Sanofi	YF	Sodium chloride 0.9%	60 min	Refrigerator or room temp

How is the BUD Calculated?

- The designated timeframe is not the same and varies from product to product.
- Specific information regarding the BUD and how it is calculated can be found in the vaccine's package insert or Emergency Use Authorization (EUA) Fact Sheet.

How is the BUD Calculated?

December 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Day 0: First puncture

January 2023						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

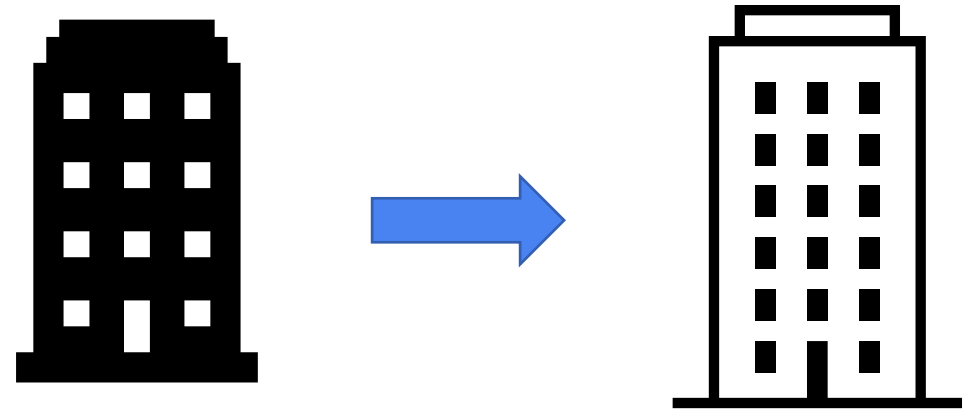
Day 28: From puncture

5

Emergency Vaccine Storage and Handling

Emergency Backup Equipment

- **Backup generator**
 - May prevent need for transport
- **Alternative storage facility**
 - Even if generator is on site
- **Additional storage unit(s)**
 - In use or for emergency use



Power Outage


- **Record room temperature**
- **Record min/max storage unit temperatures:**
 - As soon as the power goes out AND during the outage
- **Avoid temperature excursions:**
 - Shift to transport plan or use alternative containers.
- **If temp reading can only be obtained by opening door and there is no alternative facility, wait until power is restored.**
 - Record room and unit min/max temperatures and length of time power was off.
 - Follow procedures for temperature excursion, if one occurred.

Alternative Facility Inaccessible

- **Keep storage units and containers closed**
- **Use TMDs**
- **Use one of the following:**
 - Portable vaccine unit (if power source available)
 - Qualified containers and pack-outs

Emergency Response Worksheet

- Immunize.org's tool can be used to document inventory affected by power failure or another emergency event
- Use in conjunction with Immunize.org's [Vaccine Storage Troubleshooting Record](#)

Emergency Response Worksheet					
What to do in case of a power failure or other event that results in vaccine storage outside of the recommended temperature range			For information on COVID-19 vaccine storage, see the COVID-19 Vaccine Addendum in CDC's Vaccine Storage and Handling Toolkit at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf .		
Follow these procedures:					
1. Close the door tightly.			4. Notify the state/local health department or call the manufacturer (see manufacturers' phone numbers below).		
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator or freezer is plugged in and working properly, or move the vaccines into proper storage conditions as quickly as possible.			5. Document the inventory of affected vaccines below and document the circumstances of the event and the actions taken on the Vaccine Storage Troubleshooting Record (see www.immunize.org/catg.d/p3041.pdf).		
3. Do NOT discard the affected vaccines unless directed to by your state/local health department and/or the manufacturer(s). Label the vaccines "Do Not Use" so that the potentially compromised vaccines can be easily identified.					
Vaccines Stored in Refrigerator					
Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)	
Vaccines Stored in Freezer					
Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)	
Important Contact Information:					
Vaccine Manufacturers					
AstraZeneca	(877) 633-4411	GlaxoSmithKline	(877) 356-8368	Sanofi Pasteur	(800) 822-2463
Bavarian Nordic ¹	(844) 422-8274	MassBiologics	(617) 474-3220	Seqirus	(855) 358-8966
Dynavax Technologies	(844) 375-4728	Merck & Co., Inc.	(800) 672-6372	Valneva ⁴	(301) 556-4500
Emergent BioSolutions ²	(866) 300-7602	Pfizer Inc. ³	(800) 438-1985		
Manufacturer for less commonly used vaccine:					
1. Bavarian Nordic: Rabavert (rabies), Jynneos (smallpox and monkeypox)					
2. Emergent BioSolutions: Biothrax (anthrax), Vaxchora (cholera), Vivotif (typhoid)					
3. Pfizer: Ticovac (tick-borne encephalitis)					
4. Valneva: Isixaro (Japanese encephalitis)					
Health Departments					
Local Health Department phone _____			State Health Department phone _____		
Adapted by the Immunize.org, courtesy of the Michigan Department of Community Health					
			FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org		
www.immunize.org/catg.d/p3051.pdf • Item #3051 (6/22)					

6

**Vaccine
Transport**

Transport Situations

- Off-site, satellite facilities, or relocation of stock
- Emergencies



Transport Systems

Transport System Recommendations

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System [†]	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

- **Total time for transport alone or transport plus clinic workday should be a maximum of 8 hours, unless manufacturer guidance differs**

Conditioned Water Bottle Transport System

- Use this transport system only if you do not have a portable vaccine refrigerator or qualified pack-out

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 your 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. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

1 Gather the Supplies



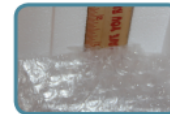
Hard-sided coolers or Styrofoam™ vaccine shipping containers

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



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- 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 (this normally takes less than 5 minutes).



Insulating material — You will need two of each layer

- **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.
- **Corrugated cardboard** - Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



- **Temperature monitoring device** - Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) 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.

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 cushioning 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.



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Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

CS246275-1 August 2015

Transport Planning

■ Protocols

- Identify trained staff
- Vehicles
- Inventory
- Documentation

■ Emergencies

- Contact emergency vaccine storage facility
- Suspend operations prior to emergency

■ Considerations

- Company or personal vehicle
- Use passenger compartment
- Avoid sunlight
- Monitor vaccine temperature
- Move vaccines into storage unit upon arrival

Temperature Monitoring during Transport


■ For any type of transport:

- Use a DDL
- Place buffered probe with vaccines
- Keep display on top
- Record min/max temps at the beginning of transport

YOU CALL THE SHOTS

Temperature Log

when Transporting Vaccine at Refrigerated Temperatures




When transporting refrigerated vaccines, use:

- A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- This temperature log to document temperatures and how long the vaccine is in the portable storage container.

Temperature monitoring and transport time frames

- Most DDLs display minimum/maximum (min/max) temperatures.*
- Record the time and min/max temperatures:
 - At the start of transport
 - Every time the portable storage container is opened
 - When transport is completed
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.†
- Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

**If the temperature is out of range, TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Today's date: _____

Transport start time: _____

Transport end time: _____

Provider name: _____

Facility name: _____

PIN number: _____

Temperatures measured in (circle one): Celsius Fahrenheit

Time																				
Staff initials																				
Min/max temperatures																				

Temperatures lower than 2°C (36°F) and higher than 8°C (46°F) are out of range.† Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

- After packing the vaccine, open the portable storage container only when necessary.
- If using a company or personal vehicle, transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Avoid leaving the portable storage container in direct sunlight or unattended.
- If needed, transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents. Follow the manufacturer's guidance for specific temperature requirements for diluents.

- Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit* for additional guidance.
- Refer to CDC's *Vaccine Storage and Handling Toolkit* for additional guidance when transporting vaccines.

* If the DDL does not measure min/max temperatures, check and record temperatures hourly.

† Follow the manufacturer's guidance if it differs from this time frame.

03/04/2021 CS322033-C

Temperature Monitoring after Transport

- Immediately upon arrival, store vaccines in appropriate on-site storage unit with DDL and continue temperature monitoring as usual
- If on-site storage unit unavailable, keep vaccine in portable vaccine storage unit and
 - Place DDL as close as possible to vaccines and **check and record min/max temperatures when portable unit is opened**
 - Keep the container closed as much as possible
 - Remove only one multidose vial or 10 doses at a time

7

**Clinical
Resources**

Vaccine Storage and Handling Toolkit

- **Primary source for CDC storage and handling recommendations**
 - Most current recommendations
 - Other materials updated based on toolkit contents



Vaccine Storage and Handling Toolkit



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

January 2019

12256418

CDC Resources for Staff Education

- Multiple storage and handling resources available through CDC website, including:
 - Vaccine Storage Temperature Logs
 - Storage and Handling best practice fact sheets
 - [Handling a Temperature Excursion in Your Vaccine Storage Unit](#)
 - [Packing Vaccines for Transport during Emergencies](#)
 - [Storage and Handling Best Practices: Hawaii](#)



CDC Centers for Disease Control and Prevention
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Healthcare Providers / Professionals

Healthcare Professionals / Providers Home Administration Tools Vaccine Storage & Handling


Vaccine Storage and Handling Resources

[Print](#)

Recommendations and Guidelines

At a Glance

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases. Vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered.



Resources on Proper Vaccine Storage and Handling

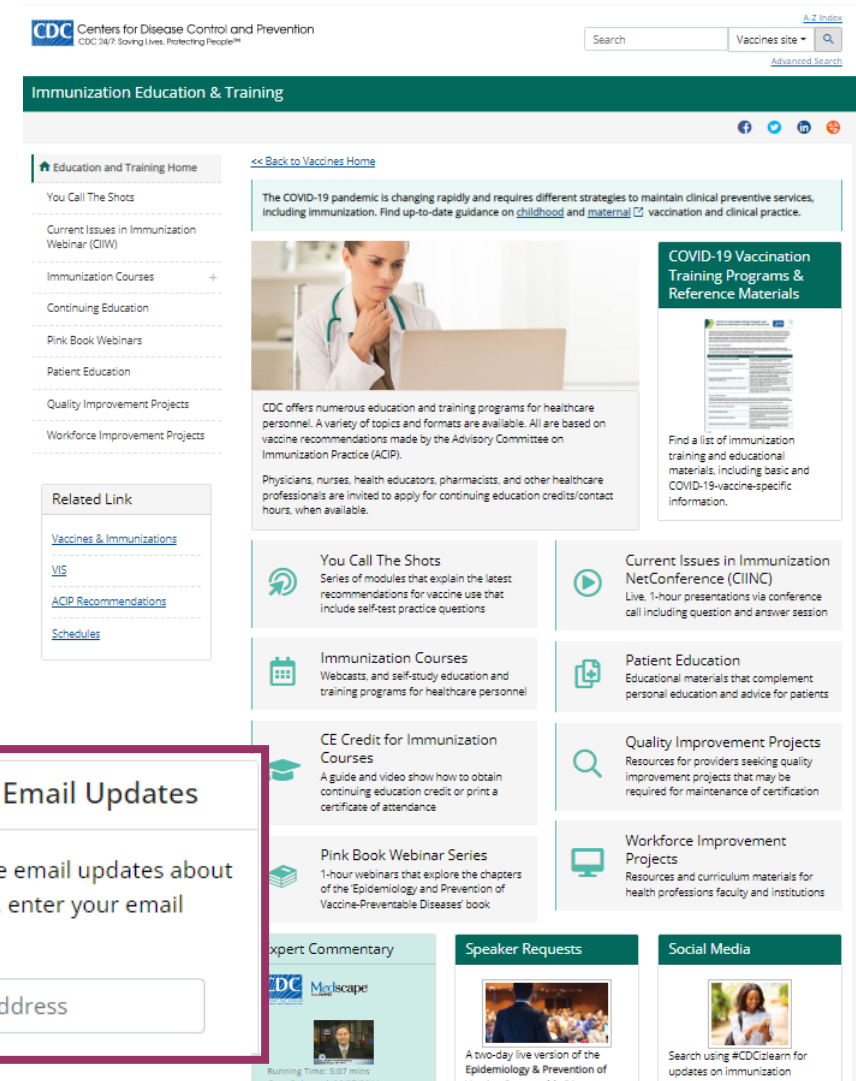
- COVID-19 Vaccine Storage Temperature Logs:
 - [Refrigerator Storage Temperature Log \(Celsius\)](#)
 - [Refrigerator Storage Temperature Log \(Fahrenheit\)](#)
 - [Ultra-Cold Vaccine Storage Temperature Log \(Celsius\)](#)
 - [Ultra-Cold Vaccine Storage Temperature Log \(Fahrenheit\)](#)
- [Safe and Proper Sharps Disposal During the COVID-19 Mass Vaccination Campaign](#)
This fact sheet reinforces how you can protect yourself from needlestick injuries while administering COVID-19 vaccines or while helping at vaccination sites.
- These storage and handling fact sheets illustrate best practices for both refrigerated and frozen vaccines. Written in plain language, they include assessments to reinforce key points. While they are CDC-developed and branded fact sheets, each contains an area where you can insert your agency's logo.
 - [Temperature Monitoring Best Practices for Refrigerated Vaccines \[2 pages\]](#) (Feb 2018)
[Fahrenheit \(F\)](#) | [Celsius \(C\)](#)
 - [Temperature Monitoring Best Practices for Frozen Vaccines \[2 pages\]](#) (Feb 2018)
[Fahrenheit \(F\)](#) | [Celsius \(C\)](#)
 - [Storage Best Practices for Refrigerated Vaccines \[2 pages\]](#) (Feb 2018)
[Fahrenheit \(F\)](#) | [Celsius \(C\)](#)
 - [Storage Best Practices for Frozen Vaccines \[2 pages\]](#) (Dec 2020)
[Fahrenheit \(F\)](#) | [Celsius \(C\)](#)

Related Links

[Vaccines & Immunizations](#)

CDC Resources for Staff Education

- Multiple educational products available free through CDC website, including:
 - [You Call the Shots](#) self-study modules
 - [Pink Book](#) webinar series
 - [Current Issues in Immunization](#) webinars
 - Continuing education available for all
- Sign up for e-mail updates



External Resources for Staff Education

- Multiple job aids available free through Immunize.org's website, including:
 - [Vaccine Storage Troubleshooting Record](#)
 - [Emergency response Worksheet](#)
 - [Checklist for Safe Vaccine Storage and Handling](#)
 - [Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!](#)
 - [Ask the Experts: Storage and Handling](#)
 - [Vaccine Handling Tips](#)

Checklist for Safe Vaccine Storage and Handling

Are you doing everything you should to safeguard your vaccine supply? Review this list to see where you might make improvements in your vaccine management practices. Check each listed item with either ☐ YES or ☐ NO.

COVID-19 vaccine storage temperatures may differ from other vaccines, possibly affecting the choice of storage units and temperature monitoring devices. See the COVID-19 Vaccine Addendum in CDC's Vaccine Storage & Handling Toolkit at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

Establish Storage and Handling Policies

- ☐ YES ☐ NO 1. We have designated a primary vaccine coordinator and at least one alternate coordinator to be in charge of vaccine storage and handling at our facility.
- ☐ YES ☐ NO 2. Both the primary and alternate vaccine coordinator(s) have completely reviewed either CDC's Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf) or equivalent training materials offered by our state or local health department's immunization program.
- ☐ YES ☐ NO 3. We have detailed, up-to-date, written standard operating procedures for general vaccine management, including procedures for routine activities and an emergency vaccine retrieval and storage plan for power outages and other problems. Our procedures are based on CDC's Vaccine Storage & Handling Toolkit and/or on instructions from our state or local health department's immunization program.
- ☐ YES ☐ NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Manage New Vaccine Shipments and Inventory

- ☐ YES ☐ NO 5. We maintain a vaccine stock record (see sample in "Resources Section" of CDC's Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)), to log in new vaccine shipments and document the following:
- ☐ YES ☐ NO a. Vaccine name and number of doses received
- ☐ YES ☐ NO b. Date we received the vaccine
- ☐ YES ☐ NO c. Condition of vaccine when we received it
- ☐ YES ☐ NO d. Vaccine manufacturer and lot number
- ☐ YES ☐ NO e. Vaccine expiration date
- ☐ YES ☐ NO 6. We document periodic (e.g., weekly or monthly) inventory checks to verify the quantities and condition of vaccines being stored.

Use Proper Storage Equipment

- ☐ YES ☐ NO 7. We store vaccines in separate, self-contained units that refrigerate or freeze only. If we must use a house-hold-style combination unit, we use it only for storage of our refrigerated vaccines, maintaining frozen vaccines in a separate stand-alone freezer.
- ☐ YES ☐ NO 8. We store vaccines in units with enough room to maintain the year's largest inventory without crowding.
- ☐ YES ☐ NO 9. We never store any vaccines in a dormitory-style unit (a small combination freezer-refrigerator unit with the freezer compartment inside the refrigerator).
- ☐ YES ☐ NO 10. We use an appropriate temperature monitoring device (TMD) for *each* vaccine storage or transport unit.



Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p3035.pdf • Item #P3035 (8/21)

CONTINUED ON THE NEXT PAGE ►

E-mail Your Immunization Questions to Us

NIPINFO@cdc.gov



8

**Common
Questions**

Common Question

How long should we monitor the temperature in a new or serviced unit before storing vaccines in it?

- New unit: 5-7 days of temperatures recorded within the recommended range
- Serviced unit: case dependent
 - Note: the CDC Storage and Handling Toolkit states: “Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.”

Common Question

How often should we monitor storage unit temperatures?

- Use a DDL to document **minimum/maximum temperatures once daily**, in the morning.

Common Question

How long should we keep our temperature tracking logs?

- For three years, unless your state/local jurisdiction requires a longer time period.
- ***Why?***
 - Track recurring problems as the storage unit ages
 - Determine how long and how often this has been occurring
 - Justification for a new refrigerator or freezer

Common Question

How long is a vaccine viable if it has been stored in the refrigerator in a pre-drawn syringe?

- Generally, any unused pre-drawn vaccine syringes should be discarded at the end of the clinic day.
- This does not apply to reconstituted vaccines, which should be reconstituted just prior to use. If it cannot be administered immediately, refer to the package insert or Immunize.org's clinical job aid for time allowed between reconstitution and use.

Common Question

What should we do if **expired vaccine** was inadvertently given to a patient?

- Inform the recipient of the vaccine administration error. The dose should be repeated on the same clinic day, if possible.
- If the error is detected **more than one day later**:
 - For live virus vaccine, you must wait at least 28 days after the previous dose was given before repeating it.
 - If the dose is not a live vaccine, the dose should be repeated as soon as possible.

Additionally...

Common Question

What should we do if **expired vaccine** was inadvertently given to a patient?

- Consult with your state immunization program and/or immunization information system (IIS)
- Report the error to the [Vaccine Adverse Event Reporting System \(VAERS\)](#)
- Determine how the error occurred and implement preventative strategies

[Ask the Experts: Storage and Handling \(immunize.org\)](#)

[Pinkbook: Vaccine Administration | CDC](#)

[Vaccine Administration: Preventing Vaccine Administration Errors \(cdc.gov\)](#)

Common Question

What should we do if **vaccine exposed to inappropriate conditions** was inadvertently given to a patient?

- Consult with your state or local immunization program or the vaccine manufacturer(s) to determine if doses are valid
- If doses are determined to be invalid, follow the same recommendations as expired vaccine for revaccination, documentation, and implementation of preventative strategies

Thank You From Atlanta!



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Post-Test

- Post-test
 - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_6sci72GN2H6QaDY
 - Successfully complete the five-question post-test to receive your certificate
 - Credit for this session will not expire until January 13, 2023.
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations