

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.

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

(above -15°C) or too cold (below -50°C).

- 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).
- Take action if temp is out of range too warm 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."

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٦U.	-16°C																													
RAT	-17°C																													
MPE	-18°C																													
TEI	-19°C																													
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CEP	-22°C																													
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TION	Write any out-of-range temps (above -15°C or below -50°C) here.																													
A C.	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."



Temperature Log for Freezer – Celsius DAYS 16-31

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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 2 of 2

Facility Name

(above -15°C) or too cold (below -50°C).

- 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).
- Take action if temp is out of range too warm 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."

Da	y of Month	1	6	1	7	18		19	9	2	0	21		22		23	24	4	2	5	2	6	2	7	28	8	2	9	3	C	3	1
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TEMPERATURES	-17°C																															
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ACCEPTABLE	-21°C														1																	
CEP	-22°C																															
	-50°C to -23°C																															
TION	Write any out-of-range temps (above -15°C or below -50°C) here. Room Temperature																															
AC	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."

Vaccine Storage Troubleshooting Record

(check one) CRefrigerator 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 If multiple, related events occurred, see Description of Event below.	Storage Unit Tempe at the time the problem w		Room Temperature at the time the problem was discovered	Person Completing Report										
Date:	Temp when discovered:		Temp when discovered:	Name:										
Time:	Minimum temp:	Title:	Date:											
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) General description (i.e., what happend?) 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 (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!) 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 What happened to the vaccine? W 	'as it able to be used? If not, wa	s it returned to the distribute	or? (Note: For public-purchase vaccine, follow your st	ate/local health department instructions for va	ccine disposition.)									

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Vaccine Storage Troubleshooting Record (check one) O Refrigerator • Freezer O 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.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Tempera at the time the problem was		Room Temperature at the time the problem was discovered	Person Completing Report					
Date: 8/3/2021	Temp when discovered:	13º C	Temp when discovered: 25° ${\cal C}$	Name: Natalie Nurse					
Time: 8:00 am	Minimum temp: –17° ${\cal C}$ N	Maximum temp: 14° ${\cal C}$	Comment (optional):temp is approx.	Title: VFC Coordinator	Date: 8/3/21				

Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.)

• 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 (Pfizer COVID-19 vaccine only)

• 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.

When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 8/3/2021, discovered freezer door slightly ajar. Digital readout on data logger read 13°C. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from -17°C at 5:30 pm (8/2/2021) to 13°C reading discovered when arrived at clinic on Tuesday morning (8/3/2021). Readings hit -14°C at 11 pm (8/2) and 7°C at 2 am (8/3). Total time out of recommended storage temp of -15°C or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).

Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 8/3.

Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)

- 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?

Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic freezer (in exam room #3) at -17°C. Also placed "Do Not Use" note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim's Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~½ of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.

Removed half of freezer packs located in shelf in door, per recommendation. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.

Results

• 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.)

After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained -18° to -17°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as "use first."

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