

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. If using temperature monitoring device (TMD; digital data logger recommended) that records min/max temps, document 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, 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

Month/Year	$_$ VFC PIN or other ID # $_$	Page 1 of 3
Facility Name		

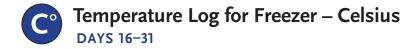
Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- 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).
- 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 "Vaccine Storage Troubleshooting Record" on page 3.

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ES	-15°C																													
2	-16°C																													
RAT	-17°C																													
1 P E	-18°C																													
TEM	-19°C																													
H	-20°C																													
PTAB	-21°C																													
CEP	-22°C																													
ΑC	-50°C to -23°C																													
NOIL	Write any out-of-range temps (above -15°C or below -50°C) here.																													
AC.	Room Temperature																													

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

www.immunize.org/catg.d/p3038C.pdf Item #P3038C (8/18)



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Month/Year	VFC PIN or other ID#	Page 2 of 3
Facility Name		

Take action if temp is out of range – too warm (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).
- 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 "Vaccine Storage Troubleshooting Record" on page 3.

Day	y of Month	1	16		17	1	18	1	9	2	0	21	2	2	2	.3	24	1	2.	5	2	6	2	.7	2	28	29)	3	0	3	31
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2	-16°C																															
RAT	-17°C																															
MPE	-18°C																															
TE	-19°C																															
I E	-20°C																															
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IJΙ	Room Temperature																											一				

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

Vaccine Storage Troubleshooting Record (check one) \square **Refrigerator** \square **Freezer**

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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 troubleshooting record (i.e., editable PDF) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Tempera at the time the problem w	ature as discovered	Room Temperature at the time the problem was discovered	Person Completing Report							
Date:	Temp when discovered:		Temp when discovered:	Name:							
Time:	Minimum temp:	Maximum temp:	Comment (optional):	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 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) 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 thorou When were the affected vaccines plocal health department and/or the Who was contacted regarding the IMPORTANT: What did you do to	olaced in proper storage condit e manufacturer[s].) incident? (For example, superv	ions? (Note: Do not discard the visor, state/local health departme	vaccine. Store exposed vaccine in proper condition	ns and label it "do not use" until after you can o	discuss with your state/						
Results • What happened to the vaccine? W	as it able to be used? If not, wa	is it returned to the distributor? (Note: For public-purchase vaccine, follow your sta	te/local health department instructions for vac	cine disposition.)						

Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☑ 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 troubleshooting record (i.e., editable pdf) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Tempera at the time the problem wa		Room Temperature at the time the problem was discovered	Person Completing Report						
Date: 7/16/2018	Temp when discovered: 13	3°C	Temp when discovered: $25^{\circ}\mathcal{C}$	Name: Nancy Nurse						
Time: 8:00 am	Minimum temp: −17°C	Maximum temp: 14°C	Comment (optional): temp is approx	Title: VFC Coordinator	Date: 7/17/18					

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 & 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)
- 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, 7/17/2018, 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 (7/16/2018) to 13°C reading discovered when arrived at clinic on Tuesday morning (7/17/2018). Readings hit -14°C at 11 pm (7/16) and 7°C at 2 am (7/17). 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 7/17.

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 Surie Supervisor about the issue. Confacted 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 ~1/2 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."