

### Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the refrigerator's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. 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 #\_\_\_\_\_

Facility Name\_

### Take action if temp is out of range - too warm (above 46°F) or too cold (below 36°F).

- 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.

Da	y of Month		1		2		3	4	4		5		5		7	8	3		9	1(	0	1	1	1	2	1	3	1	4	1	5
Sta	iff Initials																														
Eve	act Time	AM	PM	AM	PM	AM	PM	AM	РM	АМ	РM	AM	РM	AM	РM	АМ	PM	AM	ΡM	AM	ΡM	AM	ΡM	АМ	ΡM	AM	РM	AM	РM	AM	PM
EXc																															
	n/Max Temp nce previous reading)		****		*****		*****		*****		*****				*****		****		*****		****		*****		*****						
Da	nger! Temperatu	res a	bove	46°F	are to	o wa	rm! ۷	Vrite a	any o	ut-of-	range	e tem	ps an	d roo	om te	mp oi	1 the	lines	belov	w and	call	your	state	or lo	cal he	alth o	depar	tmen	t imn	nedia	tely!
	46° F																														
ES	45°F		-												- - - - - - - - - - - - - - - - - - -																
ATUR	44° F																														
2	43°F										-				-																
MPE	42°F																														
TEI	41° F																														
Air	n for 40° 40° F																														
LE	39°F																														
PTAB	38° F																														
CEP	37° F														-																
AC	36° F																														
Da	nger! Temperatu	res b	elow	36°F	are to	оо со	ld! W	rite a	ny ou	t-of-r	ange	temp	os and	l rooi	m ten	np on	the <b>I</b>	ines	belov	v and	call y	your	state	or lo	cal he	alth c	lepar	tmen	t imn	nedia	tely!
<b>LION</b>	Write any out-of-range temps (above 46°F or below 36°F) here:																														
P V	Room Temperature																														

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

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention www.immunize.org/catg.d/p3037F.pdf • Item #P3037F (8/16)

# **F** Temperature Log for Refrigerator – Fahrenheit DAYS 16–31

### Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday preferably in the morning.
- 4. Put an "X" in the row that corresponds to the refrigerator's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. 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 #\_\_\_\_\_

# Facility Name

### Take action if temp is out of range - too warm (above 46°F) or too cold (below 36°F).

- 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.

Da	ay of Month	-	16	1	7	1	8	1	9	2	0	2	1	2	2	2	.3		24	2	5	1	26	2	7	2	8	2	29	3	30	3	31
Sta	aff Initials														- - - - - -										- - - - -								
<b>_</b>		AM	PM	AM	РM	AM	РM	AM	РM	АМ	РM	AM	РM	AM	РM	AM	РM	AM	I PM	AM	PM	AM	РM	AM	РM	AM	PM	AM	PM	AM	PM	AM	PM
EX	act Time																																
	in/MaxTemp nce previous reading)		*****		******				*****		*****		****		*****						****				*****		an a		****				*****
D	anger! Temperat	ures	abov	ve 46	°F are	e too	warn	n! Wr	ite ar	ıy ou	t-of-r	ange	tem	ps an	d roc	om te	emp o	on th	ne line	s bel	ow ai	nd ca	all you	ur sta	te or	loca	l heal	th de	epart	ment	imm	edia	tely!
	46°F																																
ES	45°F																																
L R	44°F																																
RAT	43°F																																
MPE	42°F														- - - - - - - - -										- - - - - - - - -								
TE	41° F														5 5 6 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8										- - - - - - - - - - - - - - - - - - -								
Ai	m for 40° 40° F																																
ГE	39°F																																
PTAB	38°F																																
CE	37°F																																
AC	36° F																																
D	anger! Temperat	ures	belo	w 36	°F ar	e too	cold	Writ	e any	y out	-of-ra	nge t	temp	s and	l rooi	n ter	np oi	n th	e lines	belo	w an	id ca	ll you	ir sta	te or	local	healt	h de	partn	nent	imm	ediat	ely!
LIO N	Write any out-of-range temps (above 46°F or below 36°F) here:																																
ACI	Room Temperature																																

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

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention www.immunize.org/catg.d/p3037F.pdf • Item #P3037F (8/16)

# Vaccine Storage Troubleshooting Record (check one) CRefrigerator 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	<b>ture</b> 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:
<ul> <li>Inventory of affected vaccines, inc</li> </ul>	opened?) event and last documented rea luding (1) lot #s and (2) whethe was in the storage unit? For ex n any storage problems with thi	ding of storage temperature in a er purchased with public (for exa ample, were there water bottles is unit and/or with the affected v	acceptable range (36° to 46°F [2° to 8°C] for refrige ample, VFC) or private funds (Use separate sheet i in the refrigerator and/or frozen coolant packs in t	f needed, but maintain the inventory with this t	roubleshooting record.)
Action Taken (Document thorou	ghly. This information is critic	al to determining whether the	vaccine might still be viable!)		
<ul> <li>When were the affected vaccines p local health department and/or th</li> <li>Who was contacted regarding the</li> <li>IMPORTANT: What did you do to</li> </ul>	e manufacturer[s].) incident? (For example, superv	isor, state/local health departme	vaccine. Store exposed vaccine in proper conditior ent, manufacturer—list all.)	ns and label it "do not use" until after you can o	discuss with your state/
<b>Results</b> • What happened to the vaccine? W	as it able to be used? If not, wa	s it returned to the distributor? (	(Note: For public-purchase vaccine, follow your sta	te/local health department instructions for vac	cine disposition.)
DISTRIBUTED BY THE					

# Vaccine Storage Troubleshooting Record (check one) CRefrigerator Creezer

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		<b>Room Temperature</b> at the time the problem was discovered	Person Completing Report	
Date: (see below)	Temp when discovered: 4	5°F	Temp when discovered: 77°F	Name: Nancy Nurse	
Time: (see below)	Minimum temp: 38°F	Maximum temp: 53°F	Comment (optional): temp is approx	Title: VFC Coordinator	Date: 6/24/13

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 (36° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] 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.

At 8 am on Monday (6/24/13) morning when clinic opened, identified 4 temperature excursions over the weekend in refrigerator with readings as high as 54°, 50°, 49° & 53°F in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.

Total time out of range: approximately 3 hrs - maximum temp 53°F (see attached document of continuous temp readings)

Inventory of vaccines: see attached

Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.

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?

Vaccines currently stored appropriately at 40°F. Refrigerator and vaccines labeled "Do Not Use."

My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain guarantined until we hear back from Victor.

Called electric company and confirmed 2 short power outages during weekend.

Checked refrigerator seals - called refrigerator maintenance company to replace seals.

Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.

Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.

# 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.)

Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.

# Vaccine Storage Troubleshooting Record (check one) CRefrigerator

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		<b>Room Temperature</b> at the time the problem was discovered	Person Completing Report	
Date: 7/16/2013	Temp when discovered: 2	8°F	Temp when discovered: 77°F	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: 28°F	Maximum temp: 42°F	Comment (optional): temp is approx	Title: VFC Coordinator	Date: 7/15/13

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 (36° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] 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 main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read 28°F. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 42°F at 8:15 pm (7/15/2013) to 28°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 34°F at 11 pm (7/15) and 32°F at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.

Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.

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 fridge (in exam room #3 at 41°F). Also placed "Do Not Use" note on main fridge 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 fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.

Called Jim's Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.

Reset data logger on center shelf in fridge with probe in glycol.

#### 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 fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 38°-40°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -58°F. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.

#### DISTRIBUTED BY THE



#### Monitor temperatures closely!

DISTRIBUTED BY THE

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday—preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. 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 #\_\_\_\_\_

# Facility Name

#### Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

- 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.

Da	y of Month	1		2		3	4	4		5		6		7		8		9	10	0	1	1	1	2	1	3	14	4	1.	5
Sta	aff Initials																													
Exa	act Time	AM PM	AM	PM	AM	PM	AM	PM	AM	РМ	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	РМ
	n/Max Temp nce previous reading)			*****		****				****		****				****		****						****			*******			
D	anger! Temperatı	ıres above	• 5°F	are to	o wai	rm! W	/rite a	any oi	ut-of-	range	e tem	ps an	d roo	m ter	np oi	n the	lines	belov	v and	call y	our s	state o	or loc	al hea	alth d	epart	ment	imm	ediat	ely!
ES	5°F																													
URE	4°F																													
ATL	3°F																													
ER	2°F							- - - - - - - - - - - - - - - - - - -						- - - - - - - - - - - - - - - - - - -																
Μ	1°F							-						-																
ЦΕ	0°F																													
Ш	-1°F																													
ABI	-2°F																													
ΡT	-3°F																													
CE	-4° F							-						-																
A C	-58°F to -5°F													- - - - - -																
TION	Write any out-of-range temps (above 5°F or below -58°F) here.																													
A C.	Room Temperature																													

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

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention www.immunize.org/catg.d/p3038F.pdf • Item #P3038F (9/13)



#### Monitor temperatures closely!

DISTRIBUTED BY THE

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- 3. Record the min/max temps once each workday—preferably in the morning.
- 4. Put an "X" in the row that corresponds to the freezer's temperature.
- 5. If any out-of-range temp, see instructions to the right.
- 6. 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 #\_\_\_\_\_

Facility Name

#### Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

- 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	6	1	7	1	8	1	9	2	20	2	1	2	2	2	3	2	.4	2	5	2	6	2	7	2	8	2	.9	3	0	31	1
Sta	ff Initials																																
Fxa	ct Time	AM	РM	АМ	РM	АМ	РM	AM	РM	AM	PM	AM	РM	AM	ΡM	AM	РM	АМ	РM	AM	PM	AM	ΡM	AM	ΡM	AM	PM	AM	РM	AM	PM	АМ	ΡM
			L	ļ	<u> </u>		L		L			ļ	L				L		L_		L				L,								
	n/Max Temp ce previous reading)																																
	Danger! Temperat	tures	abov	/e 5°l	= are	too w	varm	! Writ	te any	y out∙	-of-ra	nge t	emps	s and	roon	n terr	ıp on	the	lines	belov	<i>w</i> and	l call	your	state	e or lo	ocal h	ealth	dep	artme	ent in	nmec	liately	y!
s	5°F																																
RE	4°F																																
RATU	3°F																																
ERA	2°F																																
MP	1°F																																
Ē	0°F																																
Ц	-1°F																																
AB	-2°F																																
EPT	-3°F											ļ																					
U U	-4°F																																
۲	-58°F to -5°F											ļ																					
TION	Write any out-of-range temps (above 5°F or below -58°F) here.																																
U A C	Room Temperature																																

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

Technical content reviewed by the Centers for Disease Control and Prevention www.immunize.org/catg.d/p3038F.pdf • Item #P3038F (9/13)

# Vaccine Storage Troubleshooting Record (check one) CRefrigerator 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 or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

	, v		,	1 8 1	
<b>Date &amp; Time of Event</b> If multiple, related events occurred, see Description of Event below.	Storage Unit Tempera at the time the problem wa	<b>iture</b> as discovered	<b>Room Temperature</b> 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:
<ul> <li>Inventory of affected vaccines, inc</li> </ul>	opened?) event and last documented rea luding (1) lot #s and (2) whethe was in the storage unit? For ex n any storage problems with thi	ding of storage temperature in er purchased with public (for exa ample, were there water bottles is unit and/or with the affected v	acceptable range (35° to 46°F [2° to 8°C] for refriger ample, VFC) or private funds (Use separate sheet i in the refrigerator and/or frozen coolant packs in	f needed, but maintain the inventory with this	troubleshooting record.)
Action Taken (Document thorou) • When were the affected vaccines p local health department and/or th • Who was contacted regarding the • IMPORTANT: What did you do to	olaced in proper storage conditi e manufacturer[s].) incident? (For example, superv	ions? (Note: Do not discard the isor, state/local health departme	vaccine. Store exposed vaccine in proper condition	ns and label it "do not use" until after you can	discuss with your state/
<b>Results</b> • What happened to the vaccine? W	'as it able to be used? If not, wa	s it returned to the distributor?	(Note: For public-purchase vaccine, follow your sta	ate/local health department instructions for vac	ccine disposition.)

DISTRIBUTED BY THE

Page 3 of 3

# Vaccine Storage Troubleshooting Record (check one) CRefrigerator YFreezer

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 or WORD document) 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		<b>Room Temperature</b> at the time the problem was discovered	Person Completing Report	
Date: 7/16/2013	Temp when discovered: 5	<i>5</i> °F	Temp when discovered: 77°F	Name: Nancy Nurse	
Time: 8:00 am	Minimum temp: 2°F	Maximum temp: 57°F	Comment (optional): temp is approx	Title: VFC Coordinator	Date: 7/15/13

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 (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] 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, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 55°F. 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 2°F at 5:30 pm (7/15/2013) to 55°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 6°F at 11 pm (7/15) and 45°F at 2 am (7/16). Total time out of recommended storage temp of 5°F 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 7/15.

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 1°F. 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 O-2°F 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."

DISTRIBUTED BY THE