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.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
	When recording temperatures, indicate F (Fahrenheit) or C (Celsius).				
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 (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.

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? 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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Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p3041.pdf ▪ Item #P3041 (8/13)

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 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 Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: (see below)	Temp when discovered: 45°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 (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.

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 45°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 quarantined 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.

Example

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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 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 Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: 7/16/2013	Temp when discovered: 28°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 (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 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.

Example

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☑ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen 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 Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date: 7/16/2013	Temp when discovered: 55°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 0–2°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."

Example

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