| Co | Temperature Log for Refrigerator – Celsius DAYS 1–15 |
|----|--|
|    | DAYS 1-15  |

| Month/Year    | VFC PIN or other ID # | Page 1 of 3 |
|---------------|-----------------------|-------------|
| Facility Name |                       |             |

## Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
- 2. Record temps twice each workday.
- Record the min/max temps once each workday preferably in the morning.
   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.

| Take action if tem | p is out of | range – too warm (a | above 8°C | ) or too cold | (below 2°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 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<br>(since previous reading)                           |            |            |            |             |             |            |            | 1         |             |            |            |             |            |           |            |
| Danger! Temperat   | ures above | 8°C are to | oo warm! V | ∀rite any o | ut-of-range | e temps an | d room te  | mp on the | lines belov | w and call | your state | or local he | alth depar | tment imm | nediately! |
| 8°C  |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| 0.0<br>0.0<br>0.0<br>0.0<br>0.0<br>0.0<br>0.0<br>0.0<br>0.0<br>0.0 |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| e <sub>C</sub> C   |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| Aim for 5° 5°C   |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| A <sup>®</sup> C   |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| 3°C  |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| 2°C  |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| Danger! Temperat   | ures below | 2°C are to | oo cold! W | rite any ou | t-of-range  | temps and  | l room ter | np on the | lines belov | v and call | your state | or local he | alth depar | tment imm | nediately! |
| Write any out-of-range temps (above 8°C or below 2°C) here:        |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |
| Room Temperature   |            |            |            |             |             |            |            |           |             |            |            |             |            |           |            |

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

| Veek 1 DDL Download Signoff – Signature | Date | Any New Alarms? NO / YES | Week 4 DDL Download Signoff – Signature | Date                   | Any New Alarms? NO / YES |
|---|------|--------------------------|---|------------------------|--------------------------|
| Veek 2 DDL Download Signoff – Signature | Date | Any New Alarms? NO / YES | Week 5 DDL Download Signoff – Signature | Date                   | Any New Alarms? NO / YE  |
| Veek 3 DDL Download Signoff – Signature | Date | Any New Alarms? NO / YES | (If yes, be sure to save supporting     | g documents with tempe | erature logs.)           |

| C° | Temperature Log for Refrigerator – Celsius DAYS 16-31 |
|----|---|
|    | DAYS 16-31  |

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

## 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.

## Take action if temp is out of range – too warm (above 8°C) or too cold (below 2°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 of Month  | 16         | 17        | 18        | 19         | 20          | 21        | 22        | 23        | 24         | 25         | 26          | 27          | 28         | 29         | 30       | 31        |
|---|------------|-----------|-----------|------------|-------------|-----------|-----------|-----------|------------|------------|-------------|-------------|------------|------------|----------|-----------|
| 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    | AM PM     |
| Min/Max Temp<br>(since previous reading)                    |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| Danger! Temperat  | ures abov  | e 8°C are | too warm  | ! Write an | y out-of-ra | inge temp | s and roo | m temp o  | n the line | s below ar | าd call yoเ | ır state or | local heal | th departi | ment imm | ediately! |
| ន្ទ 8°C   |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| 2.0<br>2.0<br>8.0<br>8.0<br>8.0                             |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| 6°C   |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| Aim for 5° 5°C  |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| 4°C   |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| 4°C   |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| 2°C   |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| Danger! Temperat  | ures belov | w 2°C are | too cold! | Write any  | out-of-ran  | ige temps | and room  | ı temp on | the lines  | below and  | d call your | state or l  | ocal healt | h departm  | ent imme | diately!  |
| Write any out-of-range temps (above 8°C or below 2°C) here: |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |
| Room Temperature  |            |           |           |            |             |           |           |           |            |            |             |             |            |            |          |           |

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

| accine Storage Troubleshooting Record (a | check one)   Refrigerator | ☐ Freezer | Page 3 of 3 |
|--|---------------------------|-----------|-------------|
|--|---------------------------|-----------|-------------|

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.

|   |   | ,  | 01 1  | 0 0 1   |                          |  |  |  |  |
|---|---|--|---|---|--------------------------|--|--|--|--|
| Date & Time of Event If multiple, related events occurred, see Description of Event below.  | Storage Unit Tempera at the time the problem wa   | ature<br>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 (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. |   |  |   |   |                          |  |  |  |  |
|   |   |  |   |   |                          |  |  |  |  |
| 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  | placed in proper storage conditi<br>e manufacturer[s].)<br>incident? (For example, superv | ions? (Note: Do not discard the visor, state/local health departme | vaccine. Store exposed vaccine in proper condition      | s and label it "do not use" until after you can o | liscuss with your state/ |  |  |  |  |
|   |   |  |   |   |                          |  |  |  |  |
| Results 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 stat     | te/local health department instructions for vac   | cine disposition.)       |  |  |  |  |
|   |   |  |   |   |                          |  |  |  |  |

DISTRIBUTED BY THE

## 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. |                                      |    | Room Temperature at the time the problem was discovered | Person Completing Report |               |
|--|--------------------------------------|----|---|--------------------------|---------------|
| Date: (see below)  | Temp when discovered: 7              | °C | Temp when discovered: 25° ${\cal C}$                    | Name: Nancy Nurse        |               |
| Time: (see below)  | Minimum temp: 3°C Maximum temp: 12°C |    | 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 3 temperature excursions over the weekend in refrigerator with readings as high as 12°, 10° & 9°C 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 12°C (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 7°C. 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 acceptble for use. He told me that vaccine could therefore be removed from guarantine. 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) ✓ 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. |                                 |                   | Room Temperature at the time the problem was discovered | Person Completing Report |               |
|--|---------------------------------|-------------------|---|--------------------------|---------------|
| Date: 7/16/2013  | Temp when discovered: -2        | °C                | Temp when discovered: 25°C                              | Name: Nancy Nurse        |               |
| Time: 8:00 am  | Minimum temp: -2° $\mathcal{C}$ | Maximum temp: 6°℃ | 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 -2°C. 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 6°C at 8:15 pm (7/15/2013) to -2°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 1°C at 11 pm (7/15) and 0°C 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 5°C). 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 3° to 4°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 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 -50°C. 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.