

Tennessee Vaccines for Children (VFC) Program

**2014-15 Vaccine Storage Unit and
Temperature monitoring guidance for
Non-Health Department VFC Facilities**

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Related Forms and Resources

- 1. Digital Data Logger Sign-off Sheet (if using a continuous monitoring device)*
- 2. TIP Paper Temperature logs (if using Min/Max Thermometers)*
- 3. Temperature Excursion Checklist*

Section 1. Vaccine Storage/Monitoring Equipment Purpose and Settings

A) Refrigerators

1. Standard: Free-standing refrigerators of pharmaceutical grade (including such features as a fan for circulating air through the unit)
 - (1) Minimum acceptable unit: household combination unit refrigerator section with separate thermostats (refrigerator section only) . Freezer section of a combination unit is prohibited for storage of frozen vaccine.
2. Purpose: Storage of refrigerated vaccines
3. Recommended temperature range: 2° through 8° C (35° through 46° F)
4. Thermostat setting: Aim average temperature for 5°C (40°F).
5. Maintenance issues: Refer to the equipment owner manual and follow guidance on equipment service and replacement

B) Freezers

1. Standard: Free-standing freezers designed to maintain proper frozen vaccine storage temperatures at all times.
2. Purpose: Storage of frozen vaccines
3. Recommended temperature range -50°C through -15°C (-58°F through +5°F)
4. Thermostat setting: Aim for coldest standard setting (above -50C)
5. Notes: Temperatures below -50°C (-58°F) are to be avoided because they may affect the seal of the natural latex stopper and could theoretically risk contamination (the vaccine would still work).
6. Maintenance issues: Refer to the equipment owner manual and follow guidance on equipment service and replacement

C) Continuous Temperature Monitoring Devices [Digital Data Loggers,]

1. CDC Recommended Certified, calibrated digital data loggers for continuous monitoring of the temperatures in each vaccine storage unit. Each unit has a current certificate of calibration and traceability and requires replacement or recalibration every 24 months or when the manufacturer certificate of calibration expires, if sooner. Data loggers meet all required and recommended specifications published by the Centers for Disease Control and Prevention (CDC).
2. Purpose: Provides detailed information on all temperatures recorded at preset intervals between 15 minutes and 1 hour. Temperatures are considered official and accurate, barring failure of the device. All temperature excursions are defined by the data logger and these are the basis of all decisions made about vaccine after an excursion. A PDF record of the logged temperatures is produced by plugging the device into any USB port on any computer.

Celsius Alarm	Duration	Temperature	Alarm Type
Ref.	00:15	8.0	HI
	00:15	2.0	LO
Freezer	00:15	-15.0	HI
	23:59	-30.0	LO

Fahrenheit Alarm	Duration	Temperature	Alarm Type
Ref.	00:15	46.0	HI
	00:15	35.0	LO
Freezer	00:15	5.0	HI
	23:59	-22.0	LO

D) Back-up Thermometer

1. Effective January 2015, the CDC requires each clinic storing federal vaccine to maintain a back-up certified, calibrated thermometer, stored outside of any storage unit. The thermometer is required to have appropriate current certificate of calibration and traceability that does not expire at the same time as

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- the digital data logger.
- 2. Purpose: The back-up thermometer should be available in case the thermometer in use is no longer working appropriately or if needed for vaccine transport or other reason.
- 3. Note: CDC recommends that the back-up thermometer be stored outside the storage unit until needed to avoid the inevitably slightly different temperature readings in the storage unit leading to confusion.

2) Section 2: Temperature Monitoring Procedures

A. Definitions: 3 Levels of Temperature Excursions (“TEs”)

- a. **Temperature Excursion (generic):** Any time the temperature in a storage unit is outside 2.0°C through 8.0°C (35° through 46°F) or the temperature in a freezer is above -15°C (5°F). Digital data loggers will display an alarm at *any* TE lasting 15 minutes or more, including insignificant TEs that are part of normal activity and do not require reporting or action. Note: For private practices using MIN/MAX Thermometers in a glycol or buffered probe the thermometer will record the high and low temperatures in a 24 hour period.
- b. **Level 1: Insignificant Temperature Excursion:** An unavoidable brief time <60 minutes outside the routine recommended ranges that does not necessitate further inquiry. See specific definition in the first step of the TE response procedure. These are often readily explainable (loading or counting inventory, brief defrost cycle, short power outage or door left ajar). Digital data loggers that record every 15 minutes frequently detect and alarm to these, a feature that cannot be fixed at this time.
- c. **Level 2: Reportable Temperature Excursion:** A TE that could possibly compromise vaccine and should be reported to the Quality Assurance (QA) Team of the Tennessee Immunization Program (TIP) for further evaluation before any affected vaccine is used, as described in the reportable TE protocol below. A reportable TE will not necessarily require calls to manufacturers or action or result in waste of vaccine. However, they do require evaluation by TIP
 - i. **Level 3: Actionable Temperature Excursion:** A subset of reportable TEs that require action, including waste of certain affected vaccines, transfer of vaccines, or replacement or repair of storage unit. Not all reportable TEs end up requiring action.

Resources and references:

CDC Vaccine Storage and Handling website (All of the current guidelines, resources, including the online Vaccine Storage and Handling Toolkit): <http://www.cdc.gov/VACCINES/RECS/storage/default.htm>

To reach TIP, call CEDEP at (615)741-7247 or call (800)404-3006.

B. Data Logger and MIN/MAX Thermometer Routine Temperature Monitoring Procedure

a. Daily Monitoring:

Morning:

- 1) When clinic opens, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units. Note time/initials and whether any new alarms were present on each unit’s Digital Data Logger Sign off Sheet if using data loggers.
- 2) For Non-Data Loggers (Min/Max)thermometers mark on the TIP temperature logs. Report all excursions to TIP.
 - a) Note and clear any alarm issues by quickly scanning the top edge of the device for symbols indicating a date and time of an alarm: 
 - b) If a **new alarm** is present, **proceed to the temperature excursion (TE) protocol of this document (page 10) or the one-page TE checklist.** If not, proceed with brief visual inspection (correct problems if found):
 - i) Food and drinks **not** stored in any refrigerator or freezer used for vaccine storage.
 - ii) Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
 - iii) Vaccines are stacked with at least one (1) inch of air space between the stacks and two (2) inches between stacks and walls of the unit so air can circulate around the vaccines
 - iv) Store bottles of water in the lowest compartment of the refrigerator and in the doors, if space permits, add extra ice packs in the freezer to help maintain temperatures in case of a power outage.
 - v) VFC vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

Afternoon:

- 3) Within about an hour of closing, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units. Note time/initials and whether any new alarms were present on each unit’s sign sheet. For Non-Data Loggers (Min/Max)thermometers mark on the TIP temperature logs Report all excursions to TIP.
 - a) Note and clear any alarm issues by quickly scanning the top edge of the device for symbols indicating a date and time of an alarm
 - b) If a **new alarm** is present, **proceed to the temperature excursion (TE) protocol of this document (page 10) or the one-page TE checklist:**
 - i) Food and drinks **not** stored in any refrigerator or freezer used for vaccine storage.
 - ii) Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
 - iii) Vaccines are stacked with at least one inch of air space between the stacks and two inches between stacks and walls of the unit so air can circulate around the vaccines
 - iv) Store bottles of water in the lowest compartment of the refrigerator and in the doors, if space permits, add extra ice packs in the freezer to help

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- maintain temperatures in case of a power outage.
- v) VFC vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

b. **Weekly Routine Vaccine Monitoring:**

- 1) A supervisor or designee confirms that the digital data logger sign off sheet or the TIP temp logs for the unit indicates that the unit was checked AM and PM each clinic day and any new alerts were noted.
- 2) IF using data loggers, download a report from the device onto a computer (by connecting it to the USB port in any computer) on the same day each week.
 - a) Remember: the device will alarm if it is disconnected for more than 10 minutes.
 - b) Note any alarms on the logger report or the TIP temp log comments page and whether staff responded appropriately, either by indicating the TE was insignificant or by reporting and acting as directed in the TE protocol. All information about a TE, including the data logger report and any follow up, should be filed with the temperature logs for the unit and retained for 3 years, along with those logs.
 - c) If using data loggers, print the download and sign the comments section to show that the weekly report was reviewed. If using MIN/MAX devices, ensure that the TP log is completed weekly and that all out of range issues were documented on the TIP temp log sheet. Signatures on each day are not necessary. This is only to confirm that the report was reviewed for the week.
 - d) Contact TIP Quality Assurance team for any questions.
- 3) Review vaccine inventory. Rotate so vaccines with the shortest expiration dates are used first.

c. **Monthly Routine Vaccine Monitoring:**

- 1) Visually check storage units for correct placement, and check for cleaning and proper function.
- 2) Replace the digital data logger sign off sheet or the TIP temp logs for each storage unit. File the complete sheet with the PDF temperature logs for that unit. These must be maintained for 3 years.
- 3) Inventory: Notify the TIP VFC Operations Unit of VFC vaccine with short expiration dates (expiring within 90 days or 3 months from the current date) if the vaccine is unlikely to be used before it expires. Users of the online Vaccine Ordering Management (OMS) system (or *TennIIS* equivalent) adjust their

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inventory in that system: VFC Operations will be notified by the system.

C. Procedures for Temperature Excursions

a. Is this a **reportable** temperature excursion? Yes, if it meets any one of the 5 criteria below:

(1) Data logger Thermometer indicates refrigerator temperature dipped **below 2.0°C (35.0°F) for at least 15 minutes**. Or MIN/MAX temperature dipped **below 2.0°C (35.0°F)** .

(a) *Why so short? Freezing temperatures below 0°C quickly damage vaccine, and quick intervention may be necessary to save vaccine if temperature begins to get too cold*

(2) Data logger Thermometer indicates refrigerator was **above 9.0°C (48°F) for at least 60 minutes** or MIN/MAX Thermometer indicates refrigerator was **above 9.0°C (48°F)** .

(a) Data logger Thermometer indicates freezer temperature **above -15.0°C (5°F) for more than 60 minutes**. or MIN/MAX Thermometer indicates freezer temperature **above -15.0°C (5°F)** .*Why longer? Because routine defrost cycles may go above -15°C for less than 60 minutes and the vaccine is designed to tolerate that*

(3) Is this TE part of a pattern of frequent excursions, regardless of duration?

(4) Is this TE worrisome for some other reason even though it does not meet the above criteria?

• **If YES to any of the above: Go to reportable TE procedure below.**

• **If NO:** the alarm is insignificant:

1. Clear alarm on data logger or MIN/MAX Thermometer
2. Initial Digital Data Logger Sign Off Sheet and indicate “yes” new alarm was noted or note on the TIP temp logs
3. Write “insignificant” on PDF of data logger report that was reviewed to evaluate alarm or note on the TIP temp logs.
4. File this log with the other temperature logs for that unit and keep for 3 years
5. No further action necessary

b. Reportable Temperature Excursion Response During Business Hours (8AM-4:30PM

Central) If calls to (800)404-3006 are not answered promptly by a person, call the CEDEP main desk at (615)741-7247 and ask the receptionist to locate someone in TIP immediately. The TIP QA team is responsible for making follow-up arrangements if they are not at their desks; follow prompts on their voicemail message for instructions.

1. If TE situation is *ongoing* (vaccine temperatures are currently out of range)
 - a. Take steps to restore proper storage conditions
 - i. Refer to your Routine/Emergency Storage and Handling Plan posted on or beside the unit. Is unit plugged in? Is door closed and sealed adequately? Is unit maintained properly (thermostat setting correct, coils cleaned)?
 - ii. If power out, contact utility company. Determine if time to restoration is acceptable. If restoration expected within 4 hours, do not move vaccine. Keep door closed and monitor. This brief TE may be less harmful than transporting the vaccine.
 - b. Temporarily label vaccines (or unit door) "Do Not Use". Do not administer vaccine until approved by TIP.
2. If the situation is **not** ongoing (vaccine is currently at proper temperatures), proceed to next step:
 - a. Download data from digital data logger to review if using data loggers
 - b. Note how long the temperature was out of range
 - c. Note the maximum temperature or minimum temperatures reached
3. Responsible clinic staff person calls the TIP QA Team directly to report.
 - a. *Why start with a phone call? The best guidance can be provided when TIP QA team can discuss follow up questions about the unit or the situation from those directly involved.*
 - If the TE involves a storage unit, the TIP QA staff member will normally request an emailed copy of the data logger report or the TIP temp logs. .
4. TIP QA staff will take necessary information and follow up with vaccine manufacturers, if needed
 - a. TIP will access inventory of federal vaccine (VFC) online, if needed
 - b. **TIP staff need to know** if there are any *open* multidose vials, whether MMR vaccine is stored in the refrigerator or the freezer, and the lot numbers of varicella vaccine (if involved).
5. TIP QA staff will follow up on each **reportable** TE by phone with the clinic staff person and with a brief **email** summary of the event and guidance on standard template that can be filed with the unit temperature logs.
 - a. The report may be shared by recipients with other staff as necessary.
 - b. A copy should be kept with the temperature records for that unit and maintained for 3 years.
6. If the TE results in transferring vaccine to another location, the clinic staff will follow the steps for packing and monitoring that are detailed in the current Routine and Emergency Vaccine storage plans posted on or near the storage units.

C. Reportable Temperature Excursion Response: After Business Hours (weekends, holidays or after business hours in Nashville)

1. Follow directions of the Routine/Emergency Storage and Handling Plan posted on or near the unit. Follow directions for evaluating power outage and only move vaccine *if indicated*. Vaccine is safer if left in place for a short power outage than it is if moved.
2. Download data logger report and review. If storage unit cannot be used, transfer vaccine to the designated back up location.
3. Contact TIP QA staff after 8AM on the next business day and **before** administering affected vaccine to any patient.
4. In the event that you are unable to properly execute the emergency storage and handling plan or restore vaccine to in range temperature; clearly mark the vaccine "Do Not Use" and contact TIP immediately the next business day. For example: a storm or other hazard may make it unsafe for staff to attempt to go to the health department or to move vaccine to a different location.
5. When do I call TIP after hours and what will be done? This is rarely necessary.
 - (i) Calling (615)741-7247 will provide directions for calling the on-call senior epidemiologist for CEDEP. This person can provide very basic consultation but will not provide advice about whether vaccine may be used. In emergencies, this person will contact Dr. Kelly Moore for follow-up.

D. Transport and monitoring of vaccine for off-site clinics:

Guidance is outlined in the current edition of the CDC Vaccine Storage and Handling Toolkit. The Toolkit is accessible online at: <http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

Transport guidance is located on pages **69-72** of the PDF document and a copy should be filed with this protocol. In addition, job aids from California's EZIZ website are included which contain additional details for packing refrigerated or frozen vaccine for transport. Details of packing also are included in the Routine and Emergency Vaccine Storage Plan located on or near the storage unit.

Contact the TIP QA team with any questions.

Vaccine Storage Unit Digital Data Logger Sign-off Sheet (Back Page)

If a new alarm is noted on the front page, please indicate category below:

Month/ Year _____

New Alarm Day (AM or PM)			Category	
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable
Day: _____	AM	PM	Insignificant	Reportable

The first time a new alarm is noted, download data logger report to evaluate the temperature excursion (TE).

- A. If the TE is **insignificant** under the definition in the current protocol, indicate “insignificant” on the data logger report and place in the temperature monitoring file for the storage unit.
- B. If the TE is **“reportable”** to the TN Immunization Program under the definition in the current protocol, follow reporting procedures and document your actions on the data logger report.

Temperature Excursion Checklist

For Vaccine Refrigerators and Freezers using a Continuous Temperature Monitor (“data logger”)

Step 1. Is this a reportable temperature excursion? Yes, if it meets any one of the 5 criteria below:

- Refrigerator was above 9°C (> 47°F) for at least 60 minutes.
- Refrigerator temperature dipped below 2.0°C (<35°F) for at least 15 minutes.
- Freezer temperature above -15°C (above 5°F) for more than 60 minutes.
- Excursion part of a pattern of frequent excursions, regardless of duration?
- Is this excursion of serious concern even though it does not meet the above criteria?

If YES to any of the above: Go to reportable temperature excursion procedure below.

If NO: the alarm is insignificant: clear alarm on data logger, note that it is insignificant on data logger printout and file in temperature log. No further action necessary.

If Reportable Temperature Excursion Response During Business Hours (8AM-4:30 PM Central)

Step 2. Take steps to restore proper storage conditions. Briefly notify appropriate regional office contact of situation and that TIP is being contacted. If considering transferring vaccine, TIP QA staff can be of assistance in making that decision.

- a. Refer to your Routine/Emergency Storage and Handling Plan posted on or beside the unit to review the basic functioning of the unit.
- b. If power out, contact utility company. If restoration expected <4 hours, do not move vaccine.

Step 3. Have the following information ready when you call TIP Quality Assurance (QA) Team:

- c. Data Logger Report should be downloaded and ready for review with TIP
- d. The time that the temperature was first noted out of range _____
- e. How high or low did the temperature go outside the recommended range? _____
- f. The time that vaccines were returned to proper temperatures _____
- g. Were any open vials of multidose vaccine involved? _____
- h. Have the vaccines been involved in any other reportable temperature excursion? _____
- i. Is your MMR vaccine kept in the refrigerator or freezer?

Step 4a. If freezer is affected, and TIP determines manufacturer must be called, TIP will request varicella doses with LOT number & expiration date at that time.

If calls to (800)404-3006 are not answered promptly by a person, call the CEDEP main desk at (615)741-7247 and ask the receptionist to locate someone in TIP immediately. The TIP QA team is responsible for making follow-up arrangements if away from the office.

Temperature Excursion Checklist (Back Page)

After Hours Reportable Temperature Excursion Response

- a) Follow directions of the Routine/Emergency Storage and Handling Plan posted on or near the unit. If this is due to a power outage, evaluate the situation and move vaccine *if indicated*. Vaccine is safer if left in place for a short power outage than it is if moved.
- b) Mark vaccine temporarily “do not use” until TIP QA staff consulted next business morning
- c) If not already contacted, briefly notify appropriate regional office contact of situation and need to contact TIP. Contact TIP QA staff after 8AM on the next business day **before** administering vaccine.
- d) When do I call TIP after hours and what will be done? This is rarely necessary.
 - i) Calling (615)741-7247 will provide directions for calling the on-call senior epidemiologist for CEDEP. This person can provide very basic consultation but will not provide advice about whether vaccine may be used. In emergencies, this person will contact Dr. Kelly Moore for follow-up.

Follow up:

1. Responsible clinic staff person (or designee) is responsible for alerting staff of the reportable event and ensuring people in the following roles are copied on emails about the excursion, and to ensure they receive a copy of the final recommendations from TIP:
2. TIP QA staff will follow up on each reportable temperature excursion by phone with the clinic staff person and with a brief **email** summary of the report and guidance given.
 - a. The report may be shared with other staff as necessary.
 - b. A copy of the follow up report should be kept with the temperature log records for that unit and maintained for 3 years

Temperature Excursion Checklist

For Vaccine Refrigerators and Freezers using a MIN/MAX Thermometer

Step 1. Is this a reportable temperature excursion? Yes, if it meets any one of the 5 criteria below:

- Refrigerator was above 9°C (> 47°F) .
- Refrigerator temperature dipped below 2.0°C (<35°F).
- Freezer temperature above -15°C (above 5°F)
- Excursion part of a pattern of frequent excursions.
- Is this excursion of serious concern even though it does not meet the above criteria?

If YES to any of the above: Go to reportable temperature excursion procedure below.

If NO: the alarm is insignificant: clear the alarm and make a note in the temperature log. No further action necessary.

If Reportable Temperature Excursion Response During Business Hours (8AM-4:30 PM Central)

Step 2. Take steps to restore proper storage conditions. Briefly notify appropriate regional office contact of situation and that TIP is being contacted. If considering transferring vaccine, TIP QA staff can be of assistance in making that decision.

- a. Refer to your Routine/Emergency Storage and Handling Plan posted on or beside the unit to review the basic functioning of the unit.
- b. If power out, contact utility company. If restoration expected <4 hours, do not move vaccine.

Step 3. Have the following information ready when you call TIP Quality Assurance (QA) Team:

- c. Current Temperature Log should be on hand and ready for review with TIP
- d. The time that the temperature was first noted out of range _____
- e. How high or low did the temperature go outside the recommended range? _____
- f. The time that vaccines were returned to proper temperatures _____
- g. Were any open vials of multi-dose vaccine involved? _____
- h. Have the vaccines been involved in any other reportable temperature excursion? _____
- i. Is your MMR vaccine kept in the refrigerator or freezer?

Step 4a. If freezer is affected, and TIP determines manufacturer must be called, TIP will request varicella doses with LOT number & expiration date at that time.

If calls to (800)404-3006 are not answered promptly by a person, call the CEDEP main desk at (615)741-7247 and ask the receptionist to locate someone in TIP immediately. The TIP QA team is responsible for making follow-up arrangements if away from the office.

Temperature Excursion Checklist (Back Page)

After Hours Reportable Temperature Excursion Response

- a) Follow directions of the Routine/Emergency Storage and Handling Plan posted on or near the unit. If this is due to a power outage, evaluate the situation and move vaccine *if indicated*. Vaccine is safer if left in place for a short power outage than it is if moved.
- b) Mark vaccine temporarily “do not use” until TIP QA staff consulted next business morning
- c) If not already contacted, briefly notify appropriate regional office contact of situation and need to contact TIP. Contact TIP QA staff after 8AM on the next business day **before** administering vaccine.
- d) When do I call TIP after hours and what will be done? This is rarely necessary.
 - i) Calling (615)741-7247 will provide directions for calling the on-call senior epidemiologist for CEDEP. This person can provide very basic consultation but will not provide advice about whether vaccine may be used. In emergencies, this person will contact Dr. Kelly Moore for follow-up.

Follow up:

1. Responsible clinic staff person (or designee) is responsible for alerting staff of the reportable event and ensuring people in the following roles are copied on emails about the excursion, and to ensure they receive a copy of the final recommendations from TIP:
2. TIP QA staff will follow up on each reportable temperature excursion by phone with the clinic staff person and with a brief **email** summary of the report and guidance given.
 - a. The report may be shared with other staff as necessary.
 - b. A copy of the follow up report should be kept with the temperature log records for that unit and maintained for 3 years.



Tennessee Department of Health
Tennessee Immunization Program

Celsius (°C) Temperature Log

VFC PIN # _____

Month and Year _____

Refrigerator # _____

REFRIGERATOR		DAYS 1 - 15																										
Staff Initials																												
Day of Month																												
°C Temp	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
≥11																												
10	Temperature out of range. Take immediate action.																											
9																												
8																												
7																												
6																												
5																												
4																												
3																												
2																												
1																												
0	Temperature out of range. Take immediate action.																											
≤-1																												
FREEZER																												
≥-12																												
-13	Temperature out of range. Take immediate action.																											
-14																												
-15																												
-16																												
≤-17																												

Aim for 5°C

Aim for ≤-17°C

Instructions: Place an "X" in the box that corresponds with the temperature, day of the month, and **am** or **pm**, for your temperature check. Enter your initials in the appropriate boxes. Document all actions taken for temperatures in the gray range on the reverse side of this form

If the temperature is in the gray range:

1. Store the vaccine under proper conditions as quickly as possible. EXCEPTION: If frozen vaccine is completely thawed, store in refrigerator. DO NOT REFREEZE.
2. Call the Tennessee Department of Health **immediately** at 615-741-7247 or 800-404-3006 and speak with Immunization Program staff to determine if vaccine is still good. If emergency consultation is needed outside business hours, leave a voicemail message; the call will be returned by the "on call" physician.
3. Never use refrigerated vaccines (except MMR) exposed to ≤0°C for more than one (1) hour.

Please complete all information for each excursion outside the proper temperature range, i.e. any temperature documented in the gray section of the form.

Day of Month	Time	Temperature	Actions Taken	Print Name

Please complete all information for each excursion outside the proper temperature range, i.e. any temperature documented in the gray section of the form.

Day of Month	Time	Temperature	Actions Taken	Signature

Please complete all information for each excursion outside the proper temperature range, i.e. any temperature documented in the gray section of the form.

Day of Month	Time	Temperature	Actions Taken	Signature



Tennessee Department of Health Tennessee Immunization Program

Fahrenheit (°F) Temperature Log

VFC PIN # _____

Month and Year: _____

Refrigerator # _____

REFRIGERATOR DAYS 16 - 31

Staff Initials																																								
Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31									
°F Temp	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	am	pm	am	pm				
≥49	Temperature out of range. Take immediate action.																																							
48																																								
47																																								
46																																								
45																																								
44																																								
43																																								
42																																								
41																																								
40																																								
39																																								
38																																								
37																																								
36																																								
35																																								
34	Temperature out of range. Take immediate action.																																							
33																																								
≤32																																								

Aim for 40°F

FREEZER

≥8	Temperature out of range. Take immediate action.																															
7																																
6																																
5																																
4																																
≤3																																

Aim for ≤ 3°F

Instructions: Place an "X" in the box that corresponds with the temperature, day of the month, and am or pm, for your temperature check. Enter your initials in the appropriate boxes.

Document all actions taken for temperatures in the gray range on the reverse side of this form.

If the temperature is in the gray range:

1. Store the vaccine under proper conditions as quickly as possible. EXCEPTION: If frozen vaccine is completely thawed, store in refrigerator. DO NOT REFREEZE.
2. Call the Tennessee Department of Health **immediately** at 615-741-7247 or 800-404-3006 and speak with Immunization Program staff to determine if vaccine is still good. If emergency consultation is needed outside business hours, leave a voicemail message; the call will be returned by the "on call" physician.
3. Never use refrigerated vaccines (except MMR) exposed to <32°F for more than one (1) hour.

Please complete all information for each excursion outside the proper temperature range, i.e. any temperature documented in the gray section of the form.

Day of Month	Time	Temperature	Actions Taken	Print Name

Transporting Refrigerated Vaccine

Guidelines for vaccine transport and short-term storage

- This procedure will keep all vaccines except varicella and MMRV within the recommended temperature range for up to 12 hours during transport and/or storage outside the primary storage unit (e.g. in the building, inside a car, etc.). If the storage cooler is exposed to temperatures as low as -4°F (e.g. inside a car trunk), this procedure will safeguard vaccines for up to 1 hour.
- If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 35°F and 46°F for at least 3 to 5 days.

Assemble packing supplies and documents

1. **Cooler.** Use a hard-sided cooler. Attach a “Vaccines: Do Not Freeze” label to the cooler.
2. **“Conditioned” cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they’ve been “sweating.” Cold packs that are not conditioned can freeze vaccine. **Do not use dry ice.**
3. **Thermometer.** Prepare a VFC-compliant thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine. If you normally use a continuous-read monitoring system, you will need a portable thermometer for vaccine transport.
4. **Packing material.** Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.
5. **Transport Log.** Complete a Refrigerated Vaccine Transport Log (IMM-1132) to document the duration and temperature monitoring information.



Pack vaccine and prepare for transport

1. Cold packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.



2. Bubble wrap

& Thermometer

Completely cover the cold packs with a 2-inch layer of bubble wrap. Then, place the thermometer/probe on top of the bubble wrap directly above a cold pack.



3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.



4. Bubble wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.



5. Cold packs

Spread “conditioned” cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.



6. Form & display

Fill the cooler to the top with bubble wrap. Place the thermometer’s digital display and the Refrigerated Vaccine Transport Log on top. It’s okay if temperatures go above 46°F while packing.



Unpack vaccine

When you reach the destination site, record the temperature in the cooler on the Transport Log before removing the vaccine. If it is:

- Between 35°F and 46°F (2°C and 8°C), unpack the vaccine and put it in the refrigerator.
- Below 35°F (2°C) or above 46°F (8°C), call your VFC Representative or the VFC Program immediately at 877-243-8832. Then label the vaccine “Do Not Use” and place it in the refrigerator.

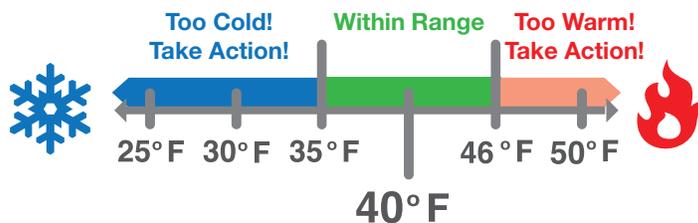
1 Store vaccine at ideal temperature: 40°F



Never freeze refrigerated vaccine!

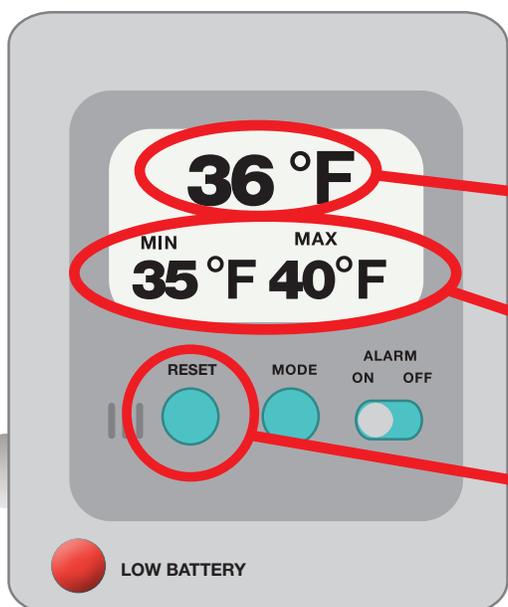
Exception: MMR can be stored in fridge or freezer

Refrigerated Vaccine



Report out of range temperatures immediately!

2 Record daily temperatures



Three Steps - Twice a Day: Temperatures should be checked and recorded first thing in the morning and before leaving at night.

- 1 Current Temperature:** The temperature that the refrigerator is right now.
- 2 Min/Max:** The coldest and warmest the refrigerator has been since you last reset the thermometer.
- 3 Reset:** The button you push after you have checked the Min/Max.



Best Practices

3 Take action if out of range!

- Contact your state or local health department immediately. Or if private vaccine call the manufacturer directly.
- Tell them the total amount of time the refrigerator was out of range.
- **Take your time** - Read and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank** - if a temp was not recorded, leave the space blank!

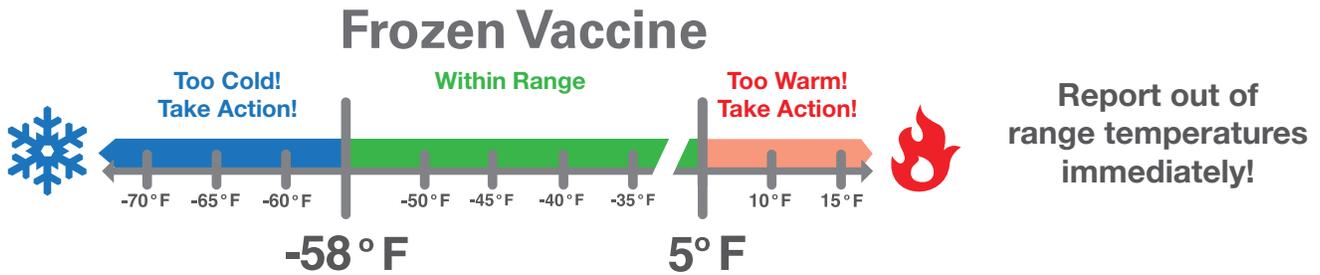


U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

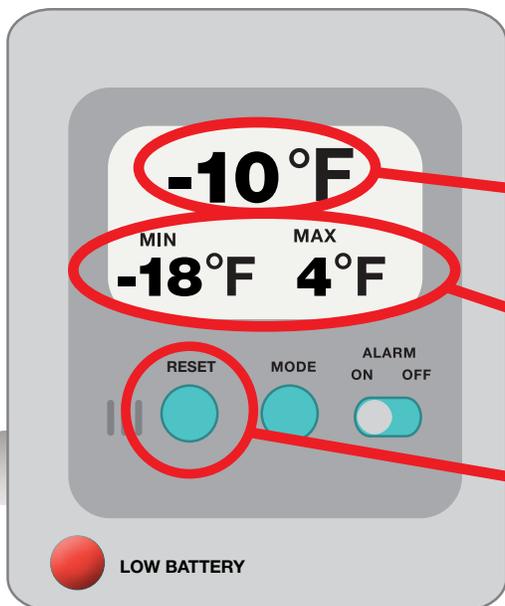
Distributed by

Visit www.cdc.gov/vaccines/SandH
for more information, or your state health department.

1 Store vaccine at ideal temperature



2 Record daily temperatures



Three Steps - Twice a Day: Temperatures should be checked and recorded first thing in the morning and before leaving at night.

- 1 Current Temperature:** The temperature that the freezer is right now.
- 2 Min/Max:** The coldest and warmest the freezer has been since you last reset the thermometer.
- 3 Reset:** The button you push after you have checked the Min/Max.



Best Practices

3 Take action if out of range!

- Contact your state or local health department immediately. Or if private vaccine call the manufacturer directly.
- Tell them the total amount of time the freezer was out of range.
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