



State of California—Health and Human Services Agency  
California Department of Public Health



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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: 2018 Temperature Monitoring Requirements and Resources

The California Vaccines for Children (VFC) Program has made several important updates to its temperature monitoring requirements and resources. Temperature monitoring is an integral part of ensuring your vaccines are effectively protecting your patients from vaccine-preventable diseases. Review these key changes with all practice staff responsible for storing vaccines and monitoring vaccine storage unit temperatures. VFC vaccines without proper temperature monitoring may be deemed non-viable.

### RECOMMENDED VACCINE TEMPERATURES

The VFC Program has updated several resources, job aids, and temperature logs to align with current recommended vaccine temperature ranges:

- Refrigerated vaccines should now be stored between **36.0°F** and **46.0°F** (2.0°C and 8.0°C) according to vaccine manufacturer recommendations.
- Store frozen vaccines (MMR, MMRV, and VAR) between **-58.0°F** and **5.0°F** (-50.0°C and -15.0°C) according to manufacturer recommendations.

Any temperatures outside manufacturer recommendations, also known as temperature excursions, must be documented and reported on SHOTS (Storage and Handling Online Triage System). Any refrigerator temperature excursions below **36.0°F** must now be reported in SHOTS. This system can be accessed through your MyVFCvaccines.org account.

### VFC TEMPERATURE LOG

The VFC Program's Refrigerator and Freezer Temperature Logs are updated to reflect current recommended vaccine temperature ranges and VFC Program requirements. Begin using the new temperature logs after your current month's temperature log is complete. The new temperature logs can be ordered for free from the [VFC Materials](#)

Store. Monitor and record the current, minimum, and maximum temperatures in vaccine refrigerators and freezers twice daily in VFC Program temperature logs at the beginning and end of each business day--even if using digital data loggers (DDLs).

Some key changes to the temperature logs include the following:

- New header location to record the Month and Year, Vaccine Storage Unit Location/ID, and VFC PIN.
- The recommended temperature range for refrigerated vaccines is now 36.0°F to 46.0°F (2.0°C to 8.0°C).
- Updated instructions if your digital data logger alarm went off.
- A new column to record your Storage and Handling Online Triage System (SHOTS) ID after reporting a temperature excursion on your MyVFCvaccines account.
- Enhanced “Supervisor’s Review” section to ensure the log is completed correctly, DDL data files have been downloaded and reviewed, and actions have been taken.
- A “Notes” section for staff to document any additional information related to temperature monitoring for the two-week log period.

Paper logs and electronic files related to temperature monitoring must be kept on-site for three years according to program requirements. Vaccine stored in units for which temperatures have not been monitored and documented, are missing temperature logs, or altered temperature logs have been noted, are automatically deemed non-viable and considered a negligent vaccine loss. In the event that vaccines are deemed non-viable by vaccine manufacturers, and doses have been administered to patients, revaccination is recommended.

## DIGITAL DATA LOGGER REQUIREMENT

Use of digital data loggers (DDLs) for temperature monitoring of VFC-supplied vaccines is required for all VFC Providers. This means that any refrigerator(s), freezer(s), or transport unit(s) storing VFC-supplied vaccines in your practice must use digital data loggers or similar continuous temperature monitoring devices to monitor temperatures. Use of traditional Min/Max thermometers to monitor temperatures of vaccines that will be administered to VFC-eligible children is no longer acceptable. This requirement also extends to your practice’s back-up thermometer(s). Therefore, at least one VFC-compliant back-up digital data logger device must be readily available on site for use during any instance of vaccine transport or when primary devices fail, or are being calibrated. Store the backup device’s buffer vial and probe in the vaccine storage unit while storing the digital display in a cabinet, and document its location on the practice’s vaccine management plan.

In order to continue participation in the VFC Program in 2018, providers must be compliant with the [digital data logger requirement](#). Non-compliance with the digital data logger requirement will lead to the suspension of vaccine ordering privileges.

Ensure all data loggers in your practice include the following minimum features: a digital display of current, minimum, and maximum temperatures; minimum accuracy of  $\pm 1.0^{\circ}\text{F}$  ( $0.5^{\circ}\text{C}$ ); a buffered temperature probe immersed in a vial filled with up to 60mL liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon<sup>®</sup>, aluminum); an out-of-range temperature alarm; memory storage of 4,000 readings or more; and a programmable logging interval of at least 30 minutes. Note that this logging interval replaces CDC's previous guidance of recording every 15 minutes. Devices must have a current and valid certificate of calibration.

Verify, or update as needed, units' configuration settings to reflect updated HI and LO alarm limits for refrigerated vaccines listed below, and update logging intervals to 30 minutes:

<b>Record every:</b>	30 Minutes
<b>Alarm Trigger</b>	
<b>HI (above/equal):</b>	46.1°F
<b>LO (below/equal):</b>	35.9°F

## VACCINE TRANSPORT

Updated guidelines for transporting refrigerated vaccines highlight the use of conditioned cold packs or conditioned frozen water bottles for preparing vaccine transport. NEVER use frozen cold packs or frozen water bottles which have NOT been conditioned for refrigerated vaccine transport. This will freeze vaccines, even if packaged for a brief period of time. Follow these guidelines and use a VFC compliant DDL during any vaccine transport event. Keep in mind that vaccines should be transported only when absolutely necessary and temperature monitoring during transport is required. The VFC "[Refrigerated Vaccine Transport Log](#)" (IMM-1132) or "[Frozen Vaccine Transport Log](#)" (IMM-1116) must be completed each time vaccines are transported.

## MONITORING STORAGE UNIT TEMPERATURES LESSON

VFC's new Monitoring Storage Unit Temperatures lesson launched with 2018 Recertification reflects new requirements and recommendations. The lesson is required for key practice staff, and any staff with permanent or temporary temperature monitoring, recording, troubleshooting, and reporting responsibilities in your practice. The lesson takes about 20-30 minutes to complete.

## VACCINE STORAGE UNIT REQUIREMENTS

No updates have been made to the VFC Program's current vaccine storage unit requirements: Refrigerator and freezer capacity needs to be large enough to adequately store vaccine inventory. Units need to be replaced if unable to maintain proper temperatures. Very-high-volume providers must use pharmacy- or biologic-grade

refrigerators. Other providers may use refrigerators and freezers that are pharmacy- or biologic-grade, commercial-grade, or household-grade stand-alone.

Never use any of the following for vaccine storage: household-grade combination refrigerator-freezers, compact household-grade stand-alone refrigerators (with capacity of 11 cubic feet or less), dormitory-style or bar-style combined refrigerator/freezers, manual defrost refrigerators, convertible units, or cryogenic (ultra-low) freezers, or any vaccine transport unit for routine storage (including coolers and battery-operated units).

## **UPDATED VACCINE MANAGEMENT PLAN**

The VFC Program's Vaccine Management Plan has been updated for downloading:

- Designate a staff member responsible for updating the management plan.
- Review and update the plan at least once a year, when VFC Program requirements change, and when staff with designated vaccine management responsibilities change.
- Ensure all staff with assigned vaccine management responsibilities review, sign, and date the plan annually and whenever the management plan is updated.
- Conduct regular vaccine management drills to maintain competency and readiness for emergency procedures, such as vaccine transport.

## **TEMPERATURE MONITORING DURING VFC-APPROVED MASS VAX CLINICS**

Any VFC-approved mass vaccination clinic must monitor temperatures using DDLs. Temperatures must be monitored and recorded every hour while off site. A data logger download summary report must be kept with the corresponding vaccine transport log.

If you have any questions about VFC Program requirements, please contact the VFC Program at 877-2GET-VFC (877-243-8832) or your [local VFC Field Representative](#).

Enclosures

[2018 Program Participation Requirements at a Glance \(IMM-1240\)](#)  
[California VFC Program Provider Agreement Addendum \(IMM-1242\)](#)

Refrigerator Temp Logs: [Fahrenheit](#) | [Celsius](#)

Freezer Temp Logs: [Fahrenheit](#) | [Celsius](#)

How to Record Refrigerator and Freezer Temperatures: [Fahrenheit](#) | [Celsius](#)

Reading a Digital Data Logger Display: [Fahrenheit](#) | [Celsius](#)