Temperature Monitoring

California COVID-19 Vaccination Program

Storage unit temperatures must be checked and recorded twice daily to ensure the viability of your vaccine supply. Implementing routine temperature monitoring can help you quickly identify temperatures outside the recommended temperature range and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Program Requirements

- Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's Vaccine Storage and Handling Toolkit.
- Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.

Pfizer Vaccines Stored in Thermal Shippers

Controlant monitors temperatures 24/7 for vaccination providers storing Pfizer vaccine doses in their original thermal shippers. Controlant will send to the provider a daily summary email reporting temperature status for the previous day. If there is a temperature excursion, Controlant will send an email and a text, and call if no one responds. A non-response will be escalated to CDPH to ensure vaccine cold chain is protected. (Refer to Receiving & Storing Pfizer Vaccine (PDF) for details.)

Manufacturer-Recommended Temperature Ranges

Ensure vaccine products are stored under recommended temperatures:

	Refrigerator	Freezer	ULT Freezer/ Original Thermal Shipper
Pfizer	2°C to 8°C (36°F to 46°F)	-25°C to -15°C (-13°F to 5°F) *	-80°C to -60°C (-112°F and -76°F)
Moderna	2°C to 8°C (36°F to 46°F)	-50°C to -15°C (-58°F to 5°F) **	N/A
Janssen	2°C to 8°C (36°F to 46°F)	N/A	N/A

* These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

** Use of dry ice may subject vials to temperatures colder than -50°C.

Data Loggers

Each vaccine storage unit must have a temperature monitoring device to ensure that vaccines are stored within the recommended temperature range. CDC recommends using digital data loggers. These devices provide the most accurate storage unit temperature information, including details on how long a storage unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Devices using a buffered temperature probe provide the most accurate measurement of temperatures.

Always use data loggers with a current and valid Certificate of Calibration Testing. (See below.)

Backup devices: Providers must have at least one backup data logger in case a primary device breaks or malfunctions, and for transporting vaccines during vaccine redistribution/transfer or off-site/mobile clinics.

Ultra-Cold Temperatures: For accurate ultra-cold temperature monitoring, select data loggers with an air-probe or a probe designed specifically for ultra-cold temperatures. Devices using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59° C) or a glycol mixture with a warmer freezing point, which cannot withstand ultra-cold temperatures.

CDC does not recommend the following devices:

- Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- Bimetal stem devices
- Devices used for food *
- Chart recorders
- Infrared devices
- Devices that do not have a current and valid Certificate of Calibration Testing

* Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the recommended temperature range. Using inaccurate temperature monitoring devices can pose a significant risk of administering vaccines that have been improperly stored and are potentially non-viable.

Data Logger Recommended specifications:

- Active temperature display
- Capacity for continuous monitoring/recording capabilities where the data can be routinely downloaded
- Alarm for out-of-range temperatures
- Current minimum and maximum temperatures on display
- Low battery indicator
- Accuracy of +/- 0.5°C
- Memory storage of at least 4,000 readings
- User programmable logging interval (maximum every 30 minutes, recommended 15 minutes)
- Use of probe that best reflects temperature of vaccine
- Generate a summary report of recorded temperature data since the device was last reset, MIN/MAX temperatures, total time out of range (if any), and alarm settings
- Reports generated as PDF or Secured PDF

Temperature Alarm Setup

Set up your data logger alarm to ensure that it alerts you when vaccines are exposed to out-of-range temperatures. Configure key settings for primary and backup digital data loggers, including device name, low and high temperature alarm limits, and a 30-minute logging interval. Refer to your manufacturer instructions for more assistance. (See Data Logger Setup & Use (PDF).)

Certificate of Calibration Testing

Always use data loggers with a current and valid Certificate of Calibration Testing. Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards. Devices can experience a drift over time that affects their accuracy. Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline.

Mishandling a data logger can affect its accuracy. If a data logger is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated device. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

Certificate of Calibration Testing should include these elements:

- Model/device name or number and serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, refer to CDC's Vaccine Storage and Handling Toolkit (PDF).

Temperature Logs

Record storage unit temperatures on your temperature log at the beginning and end of each workday. Check temperatures when you open storage units. (If you don't have a temperature log, use COVID-19 Temperature Log (PDF).) Record this information on your temperature log:

- Minimum and maximum temperatures
- Date and time
- Name or initials of person who checked and recorded temperatures
- Any actions taken if a temperature excursion occurred

Reporting Temperature Excursions

Staff must immediately prevent use of vaccines exposed to out-of-range temperatures and notify relevant staff. Any temperature excursion must be documented and immediately reported using the myCAvax provider system. The information reported is used by vaccine manufacturers to determine whether a vaccine is likely to be viable and can be administered to patients. Timely and accurate reporting of temperature excursions is essential to a successful determination of vaccine stability. (See Reporting Temperature Excursions (PDF))

Importance of Staff Training

All staff who monitor vaccine storage temperatures—including supervisors who certify staff documentation—must be properly trained on temperature monitoring, use of the practice's data loggers, and the required actions for out-of-range temperatures—even if temperature monitoring is not their routine activity.

Supervisor's Review

Because temperature log review allows supervisors to identify any training gaps, supervisors must be knowledgeable about proper temperature monitoring. Ensure staff know how to

- read and reset data loggers,
- record temperatures,
- identify temperature excursions,
- contact vaccine manufacturers to determine vaccine viability, and
- report temperature excursions.

On-site supervisor should review and sign at the bottom of the temperature log that temperatures were recorded twice daily and temperature excursions were reported.

Guidance for Satellite, Temporary, and Off-Site Clinics

These situations require enhanced storage and handling practices as COVID-19 vaccines are sensitive to light and temperatures. Frequent opening of transport containers increases the risk of temperature excursions and may impact vaccine viability.

Monitor transport container temperatures using a data logger. Record temperatures hourly and check data loggers whenever containers are opened. (See Hourly Temperature Log (PDF) and Guidance for Satellite, Temporary, and Off-Site Clinics (PDF).)

Resources

Resources will be posted to COVID-19 Vaccine Management Resources as they become available.

- How to Record Temperatures (PDF)
- COVID-19 Temperature Log (PDF)
- Reporting Temperature Excursions (PDF)
- Report Temperature Excursion Worksheet (PDF)
- Data Logger Setup & Use (PDF)
- Guidance for Satellite, Temporary, and Off-Site Clinics (PDF)
- Hourly Temperature Log (PDF)