

Reporting Temperature Excursions

California COVID-19 Vaccination Program



Report all temperature excursions in vaccine storage units, thermal shippers, and transport containers. The information reported is used by vaccine manufacturers to determine whether a vaccine may be administered to patients. Timely and accurate reporting is essential to a successful determination of vaccine stability.

Program Requirements

- Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions. (P.A. #7C)
- 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. (P.A. #7E)

Key Points

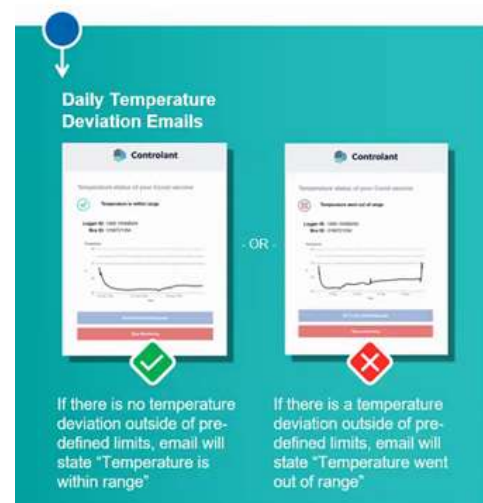
- Monitor and record storage unit temperatures twice daily on a temperature log with current, min, and max readings, or use the [COVID-19 Temperature Log](#).
- Report every temperature excursion.
- Report length of temperature excursion, MIN and MAX temperatures, and possible cause.
- Don't administer vaccines exposed to out-of-range temperatures until stability is determined.
- Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC) recommend revaccination if doses are exposed to improper temperatures.

Storing Vaccine in Pfizer Shippers (Pfizer 12+ Years, Retired 12/23/21)

Controlant monitors shipper temperatures for you and sends a daily temperature report. If there is a temperature excursion, Controlant will send an email and/or text and call if no one responds. Email will state "Temperature went out of range."

- **Temperatures > -70°C for more than 1 hour**
Action: Add more dry ice if storing vaccines beyond 3 days.
- **Temperatures > -65°C for more than 1 hour**
Action: Add more dry ice ASAP for continued use.
- **Temperatures > -60°C for more than 1 hour**
Action: Quarantine doses and contact Pfizer to determine if doses are OK to administer. Do not administer doses until manufacturer determines stability.

Controlant Customer Service: (855) 44-CONTROL



For Pfizer 12+ Years Purple Cap Only: Follow these instructions when notified by Controlant that temperatures went out of range.

Step	Description
1.	Label vaccines “Do not use” and notify your supervisor.
2.	Complete the Report Temperature Excursion Worksheet to record details provided in Controlant’s temperature deviation email and/or text.
3.	Contact Pfizer to determine stability and provide the excursion details from the worksheet.
4.	Once a determination has been made, finish processing the vaccines. If manufacturer determines vaccines are okay to use: <ul style="list-style-type: none">Remove “Do Not Use Vaccines” sign and alert your supervisor. Vaccines are okay to administer. If manufacturer determines vaccines are NOT okay to use: <ul style="list-style-type: none">Follow guidance for return or disposal of non-viable vaccines. Guidance to follow.
5.	Login to myCAvax and click Vaccine Inventory to report the excursion to CDPH.

Storing Vaccine in Storage Units

Data logger setup: [Set up your data logger](#) to alert you when vaccines are exposed to out-of-range temperatures. Refer to your manufacturer instructions for more assistance.

If a temperature alarm goes off repeatedly: Do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your operating procedures. A repair technician should check your equipment to determine the need for repair or replacement.

Repercussions of Improper Temperature Monitoring

- Patients might receive non-viable vaccines and remain unprotected from vaccine-preventable diseases.
- Patients could need to be recalled and revaccinated, wasting clinic resources, manpower, and time.
- Spoiled vaccines could amount to an enormous monetary loss to the COVID-19 Vaccination Program.






Resources

- [Report Temperature Excursion Worksheet](#)
- [COVID-19 Temperature Log](#)
- [Data Logger Setup & Use](#)

Instructions

Follow these instructions to report temperature excursions in vaccine storage units.

VFC/VFA Providers: Temperature excursions for COVID-19 vaccines will not be reported to SHOTS. Follow these instructions to report temperature excursions for COVID-19 vaccines.

Step	Description	Image
1.	<p>Clear the MIN/MAX and any alarm symbol.</p> <p>Tip. This step ensures staff don't report the same excursion for the next recording; skip if your device resets automatically.</p>	
2.	<p>Post the "Do Not Use Vaccines".</p> <p>Tip. This step ensures vaccines are not administered until the manufacturer determines vaccine stability.</p>	
3.	<p>Alert your supervisor that vaccines may have been damaged by out-of-range temperatures and that you're reporting the storage incident.</p>	
4.	<p>Download and save the data logger's temperature data file to the folder created for the device.</p>	
5.	<p>Look in the data file for any excursion details (alarm results that show temperatures outside the device's configured alarm limits).</p> <p>Tip. Refer to the device's product guide or video to learn how to identify temperatures outside the HI/LO alarm limits in the data file.</p>	
6.	<p>Return the data logger to its original location and ensure it's now recording storage unit temperatures.</p> <p>Tip. Some devices might need to be reconnected and restarted. Check device product guide for instructions.</p>	

7.	Complete the Report Temperature Excursion Worksheet to record temperature excursion details.																	
8.	Contact manufacturer to determine if vaccines may be used.																	
9.	<p>Finish processing the vaccines.</p> <p>If manufacturer determines vaccines are okay to use:</p> <ul style="list-style-type: none"> Remove “Do Not Use Vaccines” sign and alert your supervisor. Vaccines are okay to administer. <p>If manufacturer determines vaccines are NOT okay to use:</p> <ul style="list-style-type: none"> Report Doses Spoiled, Expired, or Wasted and follow its guidance to dispose of spoiled vaccines. 																	
10.	Report temperature excursions daily in myCAvax.																	
11.	<p><i>If using the COVID-19 Temperature Log:</i> Record a check in the last column of the temperature log to indicate that the storage incident has been resolved.</p> <p>Reminder: Save electronic and paper forms for three years.</p>	<table border="1"> <thead> <tr> <th>CURRENT</th> <th>MIN</th> <th>MAX</th> <th>Incident Resolved</th> </tr> </thead> <tbody> <tr> <td>-75.2 C</td> <td>-76.5 C</td> <td>-73.8 C</td> <td></td> </tr> <tr> <td>-58.6 C</td> <td>-76.2 C</td> <td>-58.6 C</td> <td>✓</td> </tr> <tr> <td>2.4 C</td> <td>0.6 C</td> <td>4.1 C</td> <td>✓</td> </tr> </tbody> </table>	CURRENT	MIN	MAX	Incident Resolved	-75.2 C	-76.5 C	-73.8 C		-58.6 C	-76.2 C	-58.6 C	✓	2.4 C	0.6 C	4.1 C	✓
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Vaccine Stability Determination

Contact the vaccine manufacturer to determine if vaccines stored in storage units may be used after exposure to out-of-range temperatures.

Manufacturer	Contacts
Pfizer	(800) 438-1985 **NEW** Online (Look for “Interact with Medical Information Digital Assistant” under Comirnaty Quick Finder)
Moderna	866-MOD-ERNA or 1-866-663-3762 Email: excursions@modernatx.com Online
Janssen	800-565-4008 (or) 1-908-455-9922 Email: JSCCOVIDTEMPEXCURSION@its.jnj.com Online