

COVID-19 Vaccine Out-of-Range Temperature Incidents

Report **ALL** out-of-range temperature incidents

An *out-of-range temperature incident*, also called a *temperature excursion* is any temperature outside the recommended range for a vaccine. The TOTAL amount of time a vaccine is stored at an out-of-range temperature affects the viability of the vaccine.

OUT-OF-RANGE TEMPERATURE:

Your temperature monitoring device / digital data logger should be set with an audible alarm to alert staff if the storage unit temperatures go outside the manufacturer's recommended temperature range for the vaccine and unit

WHAT TO DO (All steps are *required*):

1. **Isolate** the vaccines and **DO NOT USE** until you receive guidance from the Immunization Program.
2. **Label** the vaccines "DO NOT USE" until you have received authorization from the Immunization Program.
3. **Immediately** restart the data logger if it is found not to be recording for any reason.
4. **Upload the data logger files** from all affected units into New Mexico State Immunization Information System (NMSIIS)
5. **Call the Help Desk 833-882-6454 *and*** send a notification of the event via email to coviddata.compliant@state.nm.us
6. For vaccines stored in a refrigerator or regular freezer ONLY (not ULT freezer) Begin **stabilizing temperatures** in the refrigerator or freezer by slightly turning the thermostat knob. Monitor for 30 minutes; check and record temperature every five minutes until stable. Aim for 40° F in the refrigerator and below 0° F in the freezer.
7. If unable to stabilize temperatures implement your **Emergency Vaccine Management Plan** and **move** the vaccines to another **approved COVID-19 storage unit** with in-range temperatures. ***NOTE: If vaccines are moved, a completed Vaccine Transfer Log is REQUIRED and should be submitted to: coviddata.compliant@state.nm.us***
8. **Complete** the COVID-19 Troubleshooting Record (TSR).
9. **Contact** the vaccine manufacturers. Every temperature excursion requires contacting the manufacturer for further guidance because the characteristics that determine vaccine viability vary. When you call, be prepared to answer these questions:
 - a. The company may ask to speak to a healthcare professional (i.e., medical assistant, nurse, or pharmacist; not a receptionist, or bookkeeper)
 - b. What was the maximum ***and/or*** minimum out-of-range temperature?
 - c. What are the names of the vaccines made by this manufacturer that were affected?
 - d. Have these vaccines been exposed to prior excursions?
 - e. Are the products currently stored under recommended temperatures?
 - f. Have any doses of the affected vaccines been administered since the temperature excursion occurred?
10. **EMAIL** the completed COVID-19 TSR to the Immunization Program: coviddata.compliant@state.nm.us. In the subject line of the email please include your PIN # and "TSR"
11. **Wait for further instruction from the NM Immunization Program.** Keep the vaccines stored properly but isolated and marked "DO NOT USE". Do not administer, return, or discard any vaccines unless you are instructed to do so by the Immunization Program. If advised, you will complete a vaccine return in NMSIIS.

COVID-19 Troubleshooting Record (TSR)

Follow all steps listed under "What To Do" on previous page to ensure the safety of all vaccines.

Incomplete or hand-written Troubleshooting Records will be rejected.

DO NOT administer, discard, or return any vaccines until instructed to do so by the NM Immunization Program.

Date TSR Completed: Click or tap to enter a date.

Provider Information

Site Name: Site PIN#:

TSR prepared by: Email address:

Site's Primary COVID-19 vaccine contact: Name: Email: Cell phone:

Site's Secondary COVID-19 vaccine contact: Name: Email: Cell phone:

Event Details (ALL ARE REQUIRED)

Date range of event: From Click or tap to enter a date. To Click or tap to enter a date.

Timespan of event: From A M P M to A M P M

Description and cause: provide a **detailed** description of the incident, **including the cause** (door left ajar, power outage, etc.):

Refrigerator	Freezer	Ultra-low Transport/storage
Event involved refrigerator	Event involved freezer	Event involved ultra-low transport
*Min. Temp:	*Min. Temp:	*Min. Temp:
*Max. Temp:	*Max. Temp:	*Max. Temp:
*No Temperature Data recorded	*No Temperature Data recorded	*No Temperature Data recorded

*From data logger files

1. Complete the second page of the COVID-19 *Troubleshooting Record*
2. Obtain and *attach written advice* from all manufacturers
3. Locate the .pdf version of the temperature log/s from data logger/s involved in the event
4. *Email this completed document, the manufacturer's WRITTEN advice, and your temperature files to coviddata.compliant@state.nm.us*

COVID-19 Troubleshooting Record

Pfizer 800-438-1985 or www.PfizerMedInfo.com

Manufacturer Representative: _____ Date/Time: _____ Case #: _____

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
Pfizer COVID-19 / 59267-1000-01				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Pfizer COVID-19 /				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Pfizer COVID-19 /				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Moderna 866-MODERNA 866-663-3762 <https://tools.modernamedinfo.com/excursion/>

Manufacturer Representative: _____ Date/Time: _____ Case #: _____

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
MOD COVID-19 / 80777-0273-10				<input type="checkbox"/> OK to Use <input type="checkbox"/> Do NOT Use
MOD COVID-19 /				<input type="checkbox"/> OK to Use <input type="checkbox"/> Do NOT Use
MOD COVID-19 /				<input type="checkbox"/> OK to Use <input type="checkbox"/> Do NOT Use

Janssen / J&J <https://www.janssenmd.com/janssen-covid19-vaccine/interactive-content/stability-information>

Manufacturer Representative: _____ Date/Time: _____ Case #: _____

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
Janssen COVID-19 / 59676-0580-05				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Janssen COVID-19 /				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Novavax 844-NOVAVAX 844-668-2829 <https://www.novavaxmedinfo.com/>

Manufacturer Representative: _____ Date/Time: _____ Case #: _____

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
Novavax COVID-19 / 80631-100-01				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Novavax COVID-19 /				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

****DO NOT administer, discard, or return any vaccines until instructed to do so by the NM Immunization Program**

Do not print form to complete; click on "Enable Editing" then use the **Tab** key to move between fields and enter your information.