

Out-of-Range Temperature Incidents

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

IMPORTANT: Any period for which there is **no temperature data** is considered an out-of-range temperature and these steps **MUST BE FOLLOWED**



An *out-of-range temperature incident*, also called a *temperature excursion* is any temperature outside the recommended range for a vaccine or a complete lack of temperature monitoring/data. 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:

- When your digital data logger (DDL) alarms/ the display shows an “X” next to the temperature
- When the **refrigerator** thermometer indicates the temperature is **below 36° or above 46° Fahrenheit**
- When the **freezer** temperature is **above 5° Fahrenheit**

NO TEMPERATURE DATA:

- If it is discovered that a data logger is turned off, or is not recording for any reason, **immediately** restart data logger and follow all steps below:

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

1. **Isolate** the vaccines and **DO NOT USE** until you receive guidance from your VFC Immunization Regional Coordinator.
2. **Label** the vaccines “DO NOT USE” until you have received authorization from your VFC Immunization Regional Coordinator.
3. **Immediately** restart the data logger if it is found not to be recording for any reason.
4. **Upload the data logger temperatures** from all affected unit into NMSIIS.
5. **Contact** your VFC Regional Immunization Coordinator. If you cannot reach your Regional Immunization Coordinator (contact info. on Temp. Log), leave a message then notify the VFC Health Educator at 505-827-2415.
6. 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 a **VFC-approved unit** with in-range temperatures. **NOTE: If vaccines are moved, a completed Vaccine Transport Report is REQUIRED**
8. **Complete** the NM VFC 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? (both must be reported)
 - 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 TSR to your VFC Immunization Regional Coordinator: In the subject line of the email, you should include your PIN # and “TSR”.
11. **Wait for advice and further instruction from your VFC Immunization Regional Coordinator.** 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 VFC Program. If necessary, you will complete a vaccine return in NMSIIS.



NM VFC Troubleshooting Record



Printing this form to complete it is *not* recommended.

Click on "Enable Editing" then use the **Tab** key to move between fields and enter your typed information.

Follow all steps listed under "What To Do" on previous page to ensure the safety of all vaccines. Incomplete Troubleshooting Records will be rejected.

DO NOT administer, discard, or return any vaccines until instructed to do so by your VFC Immunization Regional Coordinator.

Date Submitted:

Provider Information

VFC Site Name: VFC PIN#:

TSR prepared by: Email address:

Site's Primary Vaccine Coordinator:

Event Details (ALL ARE REQUIRED)

Date or date range of event:

Time or timespan of event:

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

Refrigerator: Storage unit name (Required)		Freezer: Storage unit name (Required)		Ultra-low Transport/storage: Storage unit name (Required)	
<input type="checkbox"/>	Event involved refrigerator	<input type="checkbox"/>	Event involved freezer	<input type="checkbox"/>	Event involved ultra-low transport
*Min. Temp:		*Min. Temp:		*Min. Temp:	
*Max. Temp:		*Max. Temp:		*Max. Temp:	
*No Temperature Data recorded	<input type="checkbox"/>	*No Temperature Data recorded	<input type="checkbox"/>	*No Temperature Data recorded	<input type="checkbox"/>

*From data logger files

1. Complete the second page of the *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 document, the manufacturer's WRITTEN advice, and your temp logs to your VFC Immunization Regional Coordinator*
- 5.

NM VFC Troubleshooting Record

Please print and attach your on-hand inventory from NMSIIS.

GlaxoSmithKline 866-475-8222

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
Bexsero			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Boostrix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Engerix-B			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Flulaval			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Havrix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Infanrix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Kinrix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Menveo			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Pediarix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Rotarix			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

AstraZeneca 800-236-9933

Manufacturer Representative: Date/Time: Case #

Vaccine	# of Doses	Advice Given	Manufacturer's response**
Flumist			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Grifols 888-474-3657

Manufacturer Representative: Date/Time: Case #

Vaccine	# of Doses	Advice Given	Manufacturer's response**
Td Vaccine			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Pfizer 800-358-7443

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
Prevnar 20			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Trumenba			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
ActHib			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Beyfortus			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Fluzone Syringe			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MDV IPOL (Punctured) Return in NMSIIS (Do Not physically return to manufacture)			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MDV IPOL (Unpunctured Full Vial)			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MenQuadfi			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Pentacel			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Tenivac			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
Gardasil9			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MMR-II			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Pneumovax 23			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
PedvaxHIB			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Proquad			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Recombivax			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Rotateq			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Vaqta			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Varivax			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Vaxelis			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Vaxneuvance-PCV15			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use



NM VFC COVID-19 Troubleshooting Record

Please print and attach your on-hand inventory from NMSIIS.



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

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
Covid-19 (3 dose vial) 6 mos.- 4yrs.			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Covid-19 5 yrs.- 11 yrs.			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Covid-19 (Comirnaty) 12 yrs.- 18 yrs.			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Moderna 866-663-3762 or www.ModernamedInfo.com

Manufacturer Representative: Date/Time: Case #

Vaccine Name	# of Doses	Advice Given	Manufacturer's response**
Covid-19 6 mos.-11 yrs.			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Covid-19 (Spikevax) 12 yrs. -18 yrs.			<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 your VFC Immunization Regional Coordinator.**