



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 temperatures can occur for many reasons: when a package is left unopened, when vaccine is unrefrigerated upon arrival, when a vial is left on the counter after a dose has been drawn, or when a power outage or other incident causes the refrigerator or freezer to fail.

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**.

WHAT TO DO:

1. **Isolate** the vaccines and **DO NOT USE** until you receive guidance from the NM VFC Program.
2. **Label** the vaccines “DO NOT USE” until the issue is resolved.
3. **Contact** your VFC Regional Immunization Coordinator. If you cannot reach your Regional Immunization Coordinator (contact info. on Temp. Log), leave a message and then call the VFC Health Educator at 505-827-2415.
4. 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.
5. If unable to stabilize temperatures implement your **Emergency Vaccine Management Plan** and **move** the vaccines to a unit with in-range temperatures.
6. **Complete** the NM VFC Troubleshooting Record (TSR).
7. **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 (or minimum) out-of-range temperature?
 - c. What is the worst-case scenario length of time that temperatures were out of range?
 - d. What are the names of the vaccines made by this manufacturer that were affected?
 - e. Have these vaccines been exposed to prior excursions?
 - f. Are the products currently stored under recommended temperatures?
 - g. Have any doses of the affected vaccines been administered since the temperature excursion occurred?
8. **FAX** the completed TSR to your Regional Immunization Coordinator and to VFC/Santa Fe: 505-827-1064.
9. Wait for advice and further instructions from the NM VFC Program. Do not return or discard any vaccines unless you are instructed to do so by VFC. If necessary, you will complete a vaccine return in NMSIIS.

Vaccine Manufacturer’s Quality Control Phone Numbers

Merck 800-672-6372
Gardasil9®
MMR-II®
PedvaxHIB®
ProQuad®
Recombivax®
RotaTeq®
Vaqtac®
Varivax®

Sanofi Pasteur 800-822-2463
ActHIB®
Daptacel®
Fluzone®
IPOL®
Menactra®
Pentacel®
Tenivac®

Seqirus 855-358-8966
Flucelvax®

Pfizer 800-358-7443
Pprevnar 13
Trumenba®

GlaxoSmithKline 866-475-8222
Bexsero®
Boostrix®
Engerix-B®
Flulaval®
Havrix®
Infanrix®
Kinrix®
Menveo®
Pediarix®
Rotarix®



NM VFC Troubleshooting Record



**Follow all steps listed under “What to do” on previous page to ensure the safety of all vaccines.
Do NOT discard or return any vaccines until instructed to do so by the NM VFC Program.**

Date Submitted: _____

Provider Information

VFC Provider Site: _____ VFC PIN: _____

Record prepared by: _____ Email address: _____

Site’s Primary Vaccine Coordinator (if different from Preparer): _____

Event Details

Date or date range of event: _____

Time or timespan of event: _____

Refrigerator – Storage unit # _____ <i>(Required)</i>				Freezer - Storage unit # _____ <i>(Required)</i>					
Event involved refrigerator (check one):	<input type="checkbox"/>	yes	<input type="checkbox"/>	no	Event involved freezer (check one):	<input type="checkbox"/>	yes	<input type="checkbox"/>	no
*Temp:				*Temp:					
*Min. Temp:				*Min. Temp:					
*Max. Temp:				*Max. Temp:					

***Upload data logger files to obtain temperatures**

Describe the incident and indicate how long the temperature was out-of-range. Provide details:

Please obtain manufacturer advice and complete the second page of the Troubleshooting Record.

*Fax this document to 505-827-1064 **AND** to your Regional Immunization Coordinator*

VFC STAFF ONLY:		
VTcKs Return ID: _____	Date Return entered: _____	By: _____

NM VFC Troubleshooting Record

Please print and attach your on-hand inventory from NMIIS

GlaxoSmithKline
866-475-8222

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

Vaccine Name	# of Doses	Advice Given	
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

Pfizer
800-358-7443

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

Vaccine Name	# of Doses	Advice Given	
Prevnar 13			<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

Seqirus
855-358-8966

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

Vaccine Name	# of Doses	Advice Given	
Flucelvax			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Sanofi Pasteur
800-822-2463

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

Vaccine Name	# of Doses	Advice Given	
ActHIB			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Daptacel			<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 (opened) DO NOT RETURN			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MDV IPOL (unopened)			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Menactra			<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

Merck
800-672-6372

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

Vaccine Name	# of Doses	Advice Given	
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			<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