

Out-of-Range Temperature Incidents

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

A *temperature excursion* is any temperature outside the recommended temperature 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 the **refrigerator** data logger 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. **Move** the vaccines to a unit with in-range temperatures.
4. **Contact** your VFC Regional Immunization Coordinator. Their contact information is listed on the temperature logs.
5. Begin **stabilizing temperatures** in the refrigerator or freezer by slightly turning the thermostat knob. Monitor every 30 minutes until stable. Aim for 40° F in the refrigerator and below 0° F in the freezer.
6. **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?
7. Complete the NM VFC **Troubleshooting Record**.
8. **FAX** the Troubleshooting Record to the Regional Immunization Coordinator and to VFC/Santa Fe at (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 the return in NMSIIS.

Vaccine Manufacturer’s Quality Control Phone Numbers

Merck
800-672-6372
*Comvax [®]
Gardasil9 [®]
MMR-II [®]
PedvaxHIB [®]
Pneumovax [®]
ProQuad [®]
Recombivax [®]
RotaTeq [®]
Vaqta [®]
Varivax [®]

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

MedImmune
877-633-4411
Flumist [®]

Pfizer
800-358-7443
Prevnar 13
Trumenba [®]

GlaxoSmithKline
866-475-8222
Bexsero [®]
Boostrix [®]
*Cervarix [®]
Engerix-B [®]
Fluarix [®]
Havrix [®]
Infanrix [®]
Kinrix [®]
Menhibrix [®]
Menveo [®]
Pediarix [®]
Rotarix [®]

*Comvax and Cervarix are no longer available for order.

NM VFC Troubleshooting Record



Store Vaccines in the refrigerator/freezer unit with in-range temperatures. Label "DO NOT USE". 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: _____

Prepared by: _____ Email address: _____

Primary Vaccine Coordinator (if different from Preparer): _____

Event Details

Date & Time of Incident: _____

Refrigerator	Freezer
Temp: _____	Temp: _____
Min. Temp: _____	Min. Temp: _____
Max. Temp: _____	Max. Temp: _____

Press Min/Max on the thermometer to obtain the MIN and MAX temperatures for that day. If the incident occurred outside of business hours, obtain the last recorded temperature and min/max temperature readings on the temperature log.

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.

FOR VFC STAFF ONLY:

VTrcKs Vaccine Return ID: _____

Date Return entered: _____

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
Cervarix			<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
Fluarix			<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
Menhibrix			<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

MedImmune
877-633-4411

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

Vaccine Name	# of Doses	Advice Given	
Flumist			<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 MDV or Syringe (opened) <small>DO NOT RETURN</small>			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
Fluzone MDV or Syringe (unopened)			<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
MDV IPOL (opened) <small>DO NOT RETURN</small>			<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