

Temperature Incident Troubleshooting Record

Complete this report to gather information vaccine manufacturers will need to make a stability determination. For vaccines in question, label the vaccine "DO NOT USE" and if applicable, move it to a unit where it can be stored at the correct temperature. Do not administer any affected vaccine until you have determined its efficacy with the manufacturer and report the excursion to the New York State Department of Health Vaccine Program at mamacarai@health.nyc.gov

Recommended Temperature Ranges				
MANUFACTURER	REFRIGERATOR	FREEZER	ULT FREEZER	THERMAL SHIPPER
PFIZER	2°C to 8°C (36°F to 46°F)	N/A	-80°C to -60°C (-112°F and -76°F) -	-90°C to -60°C * (-130°F to -76°F)
MODERNA	2°C to 8°C (36°F to 46°F)	-25°C to -15°C (-13°F to 5°F)	N/A	N/A
JANSSEN	2°C to 8°C (36°F to 46°F)	-20°C (-4°F)	N/A	N/A

*Storage within this temperature range is not considered an excursion from the recommended storage condition.

Low Red 35.9° F or lower	Low Yellow 36° - 37° F	Green 38° - 44° F	High Yellow 45° - 46° F	High Red 46.1° F and over
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Step 1: Record the temperature excursion details.

Select affected vaccine: Pfizer Moderna Janssen

Temperatures out of range: too cold too warm

Excursion start date: _____ **Excursion end date:** _____

Affected vaccines stored in: refrigerator freezer ULT freezer thermal shipper transport container

Check if related to: redistribution transfer to another provider off-site/mobile clinic emergency transport

What was the warmest temperature: _____

What was the coldest temperature: _____

Total duration of excursion: _____ **(hrs./mins.)**

Identify possible cause: _____

Step 2: Record manufacturer's stability determination

- Contact the vaccine manufacturer using phone information on next page.
- Request a case number/reference number for your call and document the number provided.
- Request stability letters of electronic reports from the manufacturers; keep for your records for three years.
- Document the manufacturer's resolution on this form.

MANUFACTURER	Phone	Doses Administered?	Stability Determination	Case or Reference #
PFIZER	800-666-7248	<input type="checkbox"/> Yes <input type="checkbox"/> No	1. May use 2. May not use	
MODERNA	866-663-3762	<input type="checkbox"/> Yes <input type="checkbox"/> No	1. May use 2. May not use	
JANSSEN	800-565-4008	<input type="checkbox"/> Yes <input type="checkbox"/> No	1. May use 2. May not use	

Resolution:

Step 3: Determine viability

If manufacturer determines vaccines are okay to use:

- Remove “DO NOT USE” sign and alert your supervisor. Vaccines are okay to administer.

If manufacturer determines vaccines may not be viable and are NOT okay to use:

- Dispose of the non-viable vaccine as medical waste, such as by placing in a sharps container.
- Document wasted doses in NYSIIS.

Step 4: Additional Information

- # of vials in fridge at time of excursion _____
- What type of vaccine in fridge at time of excursion [i.e. Pfizer, Moderna, etc.] _____
- Lot # of vaccine involved during excursion _____
- Delivery date of vaccine located on box _____
- Time of transfer to backup cooler _____
- Time of excursion recovery _____
- Time of vaccine transfer back to fridge and temperature at transfer _____

Step 5: Contact Information

Facility/Provider Name: _____

NYSIIS COVID PIN#: _____

Name of Person Submitting: _____

Phone Number: _____

Email: _____

Step 6: Submit the Temperature Excursion Report and attach relevant documents

Submit this report to vaccinetempexcursion@health.ny.gov and include any supporting documentation such as data logger summary report (or section showing excursions), vaccine transport log, temperature log, etc.