NEW YORK STATE OF OPPORTUNITY. Department of Health

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# New York State COVID-19 Vaccination Program
# Temperature Excursion Report
**March 5, 2021**

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.

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. Download your digital data logger data to gather information on duration of excursion. 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 vaccinetempexcursion@health.ny.gov.

| Recommended Temperature Ranges | | | | |
|---|---|---|---|---|
| **MANUFACTURER** | **REFRIGERATOR** | **FREEZER** | **ULT FREEZER** | **THERMAL SHIPPER** |
| **PFIZER** | **2°C to 8°C (36°F to 46°F) 120 hours** | **-25°C to -15°C (-13°F to 5°F) 2 weeks cumulative** | **-80ºC to -60ºC (-112ºF and -76ºF) Until expiration date** | **-90ºC to -60ºC * (-130ºF to -76ºF)** |
| **MODERNA** | **2°C to 8°C (36°F to 46°F) 30 days** | **-25°C to -15°C (-13°F to 5°F) Until expiration date** | **N/A** | **N/A** |
| **Janssen** | **2°C to 8°C (36°F to 46°F) Until expiration date** | **N/A** | **N/A** | **N/A** |

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

**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 ☐ off-site/mobile clinic ☐ emergency transport

**What was the warmest temperature:** _____

**What was the coldest temperature:** _____

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

**Description of incident:** _____

_____

**Were affected vaccines involved in a previous temperature excursion**? ☐ No ☐ Yes, date: _____
This information must be communicated to the manufacturer as part of the viability determination.

**Step 2: Record manufacturer's stability determination.**

- Contact the vaccine manufacturer using phone information below.
- Request a case number/reference number for your call and document the number provided.
- Communicate information about this and any prior excursions affecting these doses
- 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 option 8** | ☐ **Yes** ☐ **No** | ☐ **May use** ☐ **May not use** | |
| **MODERNA** | **833-272-6635** | ☐ **Yes** ☐ **No** | ☐ **May use** ☐ **May not use** | |
| **JANSSEN** | **1-800-565-4008** | ☐ **Yes** ☐ **No** | ☐ **May use** ☐ **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: Contact Information**

Facility/Provider Name: _____

NYSIIS COVID PIN#: _____

Name of Person Submitting: _____

Phone Number: _____

Email: _____

**Step 5: 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.