IHS COVID-19 Vaccine Temperature Excursion Worksheet

Utilize this worksheet to gather the information vaccine manufacturers will need to make a stability determination. Download all applicable data logger information, as well as gather temperature logs or other details of the excursion.

Recommended Temperature Ranges (preferred temperature ranges highlighted below)

Manufacturer	Refrigerator	Freezer	Ultracold Freezer	Thermal Shipper
Pfizer	2°C to 8°C‡ (36°F to 46°F)	-25°C to -15°C‡ (-13°F to 5°F)	-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
J & J/Janssen	2°C to 8°C (36°F to 46°F)	N/A	N/A	N/A

‡Storage under this condition may shorten the original expiration date; refer to manufacturer's proper storage information for details.

*Storage within this temperature range is not considered an excursion if following the recommended storage guidance for thermal shippers.

Step 1: Record the temperature excursion details.

Immediately mark the vaccines as "Do Not Use" and sequester them in the most appropriate storage condition (fridge/freezer/Ultracold Freezer). Include details on the sequestered vaccine about the potential excursion, including the name and phone number of the individual working to determine the viability of the vaccine. Store vaccines that have had a potential temperature excursion per manufacturer's recommendations until steps 2-4 have been completed.

Affected vaccine: □ **Pfizer** □ **Moderna** □ **J&J/Janssen** **# of doses:** _____ **If applicable:** □ **Prime** □ **Boost**
Lot number: _____ **Original Expiration:** _____ **Beyond Use Date/Time (if applicable) :** _____
Affected vaccines WERE stored in (at the time of the excursion):

☐ refrigerator ☐ freezer ☐ Ultracold freezer ☐ Ultracold thermal shipper ☐ transport container

Affected vaccines CURRENTLY stored in:

☐ refrigerator ☐ freezer ☐ Ultracold freezer ☐ Ultracold thermal shipper ☐ transport container

Check if related to:

☐ redistribution to another site ☐ off-site/mobile clinic ☐ emergency transport

Excursion start date & time: _____ **Excursion end date & time (or time of discovery):** _____

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

Temperatures out of range: ☐ too cold ☐ too warm **Warmest or coldest temperature:** _____ °F or °C

Potential cause: ☐ thermometer/data logger malfunction ☐storage unit malfunction ☐ power outage

☐ door left open ☐ unit unplugged ☐ compromised transport ☐ vaccines stored improperly ☐ other

Details of the excursion:_____

_____

_____

_____

_____

_____

Were the affected vaccines involved in a previous temperature excursion? ☐ No ☐ Yes, Date:_____

If yes, provide details and resolution of the excursion:_____

_____

Step 2: Alert the IHS COVID-19 Vaccine Task Force of the potential excursion.

- Immediately email the Vaccine Task Force at IHSCOVIDVaccine-Distribution@ihs.gov and the Area Vaccine Point of Contact. Briefly describe the event with I/T/U name, contact, and phone number.

Step 3: Record manufacturer's stability determination.

- Contact the vaccine manufacturer using the phone information below.
- Request a case or reference number for your call and write the number provided in the space below.
- Request internal stability information from the manufacturers.
- Document the manufacturer's resolution on this form.

Manufacturer	Phone/Email	Doses Administered?	Stable to Use?	New Expiration Date?	Case/ Reference #
Pfizer	**800-666-7248** **cvgovernment@pfizer.com**	**□Yes □No**	**□Yes □No**	**□Yes: _____** **□No**	
Moderna	**866-MOD-ERNA** **excursions@modernatx.com**	**□Yes □No**	**□Yes □No**	**□Yes: _____** **□No**	
J & J/Janssen	**800-565-4008** **jsccovidtempexcursion@its.jnj.com**	**□Yes □No**	**□Yes □No**	**□Yes: _____** **□No**	

Step 4: Finish processing the vaccines.

If manufacturer determines vaccines are viable and okay to use:

- Remove "Do Not Use" sign, ensure vaccine is placed in appropriate storage and alert your team.
- Mark the boxes noting that there was an excursion for future reference.
- Vaccines are okay to administer. Rotate back into stock.
- Attempt to address the root cause of the excursion and ensure safeguards are in place for the future.

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

- Follow guidance for return or disposal of non-viable vaccines. Discard vaccine vials according to local waste procedures and reverse distribution.
- Reach out to your Area Vaccine Point of Contact to determine next steps for getting additional vaccine.
- Document wastage in the VTrckS Provider Ordering Portal (VPoP).

If the manufacturer provides an unclear recommendation, contact the IHS Vaccine Task Force for review.

Step 5: Submit documentation and attach relevant data reports.

☐ Gather any relevant data reports, including:

☐ Data logger report (summary or section showing excursions), temperature log or vaccine transport log

☐ Email all documents with the relevant details of the event and the disposition of the vaccine to the:

- The Area Vaccine Point of Contact
- IHS COVID-19 Vaccine Task Force at: IHSCOVIDVaccine-Distribution@ihs.gov

Step 6: Keep all records for six years, including supporting information.

Name: _____ **Signature:** _____ **Date:** _____

I/T/U Facility:_____ **Phone:**_____ **Email:**_____

Questions? Contact the IHS COVID-19 Vaccine Task Force at: IHSCOVIDVaccine-Distribution@ihs.gov