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, gather temperature logs, transport logs, or other details of the excursion.

Recommended Temperature Ranges (preferred temperature ranges highlighted below for longest beyond use date/expiry date)

Manufacturer	Refrigerator	Freezer	Ultracold Freezer	Expiry Date
Pfizer-BioNTech Tris Products **MAROON (6mos-4yrs)** **ORANGE (5-11yrs) & GRAY (12+)**	**2°C to 8°C‡** **(36°F to 46°F)**	**N/A**	**-90°C to -60°C** **(-130°F and -76°F)**	**Pfizer-BioNTech Expiry Checker**
Pfizer-BioNTech **PURPLE (Must Dilute 12+)**	**2°C to 8°C‡** **(36°F to 46°F)**	**-25°C to -15°C‡** **(-13°F to 5°F)**	**-90°C to -60°C** **(-130°F and -76°F)**	**Pfizer-BioNTech Expiry Checker**
Moderna **(All vial preparations)**	**2°C to 8°C‡** **(36°F to 46°F)**	**-50°C to -15°C** **(-58°F to 5°F)**	**N/A**	**Moderna Expiry Checker**
Janssen/J&J	**2°C to 8°C** **(36°F to 46°F)**	**N/A**	**N/A**	**Janssen/J&J Expiry Checker**
Novavax	**2°C to 8°C** **(36°F to 46°F)**	**N/A**	**N/A**	**Novavax Expiry Checker**

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

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). Include details on the sequestered vaccine about the potential excursion, including contact information of the individual determining viability of the vaccine. Store vaccines with a potential temperature excursion per manufacturer's recommendations until steps 2-4 have been completed.

Affected vaccine: _____ **# of doses:** _____ **Lot number:** _____ (Use separate form if >1 lot #)

Original Exp Date: _____ **Beyond Use Date/Time (if applicable):** _____

Vaccine storage at time of the excursion: ☐ refrigerator ☐ freezer ☐ ultracold freezer ☐ thermal shipper ☐ transport container

Affected vaccines CURRENTLY stored in: ☐ refrigerator ☐ freezer ☐ ultracold freezer ☐ thermal shipper ☐ transport container

Check if related to: ☐ redistribution to another site ☐ off-site/mobile clinic ☐ emergency transport ☐ other: _____

Excursion start date/time: _____ **Excursion end date/time:** _____ **Total duration:** _____

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 and actions taken:

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 contact information below.
- Document the Case/Reference number in the space below.
- Request internal stability information from the manufacturers.
- Document the manufacturer's recommendations and the final disposition of the vaccine below.

Manufacturer	Contact Info	Doses Administered?	Stable to Use?	New Beyond Use Date?	Case/ Reference #
Pfizer-BioNTech	800-438-1985	☐Yes ☐No	☐Yes ☐No	☐Yes: _____ ☐No	
Moderna	866-MOD-ERNA Temp Excursion Tool	☐Yes ☐No	☐Yes ☐No	☐Yes: _____ ☐No	
Janssen/J&J	800-565-4008	☐Yes ☐No	☐Yes ☐No	☐Yes: _____ ☐No	
Novavax	844-NOV-AVAX	☐Yes ☐No	☐Yes ☐No	☐Yes: _____ ☐No	

Manufacturer's recommendations:

Final disposition of vaccine:

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 disposal of non-viable vaccines. Discard vaccines according to local waste procedures or reverse distribution.
- Reach out to your Area Vaccine Point of Contact to determine next steps for getting additional vaccine.
- Document wastage in the Health Partner Order Portal (HPoP) and note that the excursion was reported to the Vaccine Task Force.

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.
- ☐ Submit any documentation received from the manufacturer regarding viability and stability.

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