New York State Department of Health Vaccine Program Temperature Excursion Report

PART 1

Instructions. When you identify *any* out-of-range temperature, *regardless of duration:*

- 1. *Immediately* stop administering vaccines and label vials "DO NOT USE." (If applicable, move vaccines to another unit or implement emergency plan and prepare vaccine for transport.)
- 2. On the *same day* the excursion is identified:
 - Download digital data logger (DDL) file(s) for each storage unit that had out-of-range temperatures. You must compile 3 months of DDL data for each unit.
 - Submit part 1 of this report together with DDL file(s) by email to <u>vaccinetempexcursion@health.ny.gov</u> or by fax to 518-449-6912. Clearly indicate your provider site name and PIN(s) on each DDL file.
- 3. Do not resume administering vaccines until you receive a response.
- 4. Depending on the excursion, NYSDOH may determine you need to contact the vaccine manufacturer(s) and submit part 2 of this report.

PIN(s)					
Direct Phone Number (Include extens	sion if applicable)				
ut-of-range temperatures? (Check all the	at annly)				
at or range temperatures: (eneck an the	τι αρριγή				
Ultra-low temperature freezer					
Transport/shipping container					
Room temperature – vaccine inadvertently left out of storage unit					
2. You must attach one digital data logger (DDL) file for <i>each</i> storage unit that had out-of-range temperatures.					
Indicate the number of DDL files attached to this report:					
ort:					
o out-of-range temperatures? Ye	es No				
o NYSDOH Vaccine Program: Ye	s No				
	Direct Phone Number (Include extense ut-of-range temperatures? (Check all the latest of storage unit				



Submit part 1 of this report and all required DDL file(s) by email (vaccinetempexcursion@health.ny.gov) or fax (518-449-6912). Remember to label DDL file(s) with your provider site name and PIN(s). NYSDOH Vaccine Program will determine whether you need to fill out part 2 of this report. **Do not administer any vaccine before you receive a determination from NYSDOH Vaccine Program.**

Provider Site Name:

PIN(s):

TEMPERATURE SUMMARY (to be completed by NYSDOH Vaccine Program)					
Unit 1 Target temperature range:	Actual temperature range:	Notes:			
Refrigerated (2°C to 8°C or 36°F to 46°F)	High: °C °F				
Frozen (-50°C to -15°C or -58°F to 5°F)	Low: °C °F				
ULT (-90 °C to -60 °C or -130 °F to -76 °F)	Cumulative time out-of-range:				
Unit 2 Target temperature range:	Actual temperature range:	Notes:			
Refrigerated (2°C to 8°C or 36°F to 46°F)	High: °C °F				
Frozen (-50°C to -15°C or -58°F to 5°F)	Low: °C °F				
ULT (-90 °C to -60 °C or -130 °F to -76 °F)	Cumulative time out-of-range:				
Unit 3 Target temperature range:	Actual temperature range:	Notes:			
Refrigerated (2°C to 8°C or 36°F to 46°F)	High: °C °F				
Frozen (-50°C to -15°C or -58°F to 5°F)	Low: °C °F				
ULT (-90 °C to -60 °C or -130 °F to -76 °F)	Cumulative time out-of-range:				
Unit 4 Target temperature range:	Actual temperature range:	Notes:			
Refrigerated (2°C to 8°C or 36°F to 46°F)	High: °C °F				
Frozen (-50°C to -15°C or -58°F to 5°F)	Low: °C °F				
ULT (-90 °C to -60 °C or -130 °F to -76 °F)	Cumulative time out-of-range:				
Unit 5 Target temperature range:	Actual temperature range:	Notes:			
Refrigerated (2°C to 8°C or 36°F to 46°F)	High: °C °F				
Frozen (-50°C to -15°C or -58°F to 5°F)	Low: °C °F				
ULT (-90 °C to -60 °C or -130 °F to -76 °F)	Cumulative time out-of-range:				
Reviewed by	Date	Confirmation number			

PART 2 Provider Site Name: PIN(s):

Instructions. If directed to do so by NYSDOH Vaccine Program, contact vaccine manufacturer(s):

- 1. Prepare for manufacturer call(s). For each vaccine exposed to out-of-range temperatures, you will need to know:
 - o Cumulative time out-of-range as calculated by NYSDOH Vaccine Program. Look for this information in the Temperature Summary (page 2).
 - Manufacturer, trade name, lot number, expiration date, and number of doses affected. Use the Vaccine Data and Manufacturer Response table(s) on pages
 4-5 to record these details *prior* to calling each manufacturer. Recommended: When filling out table(s), "group" vaccines according to their manufacturer.
 See reference table on page 6 for a listing of manufacturers and associated vaccine trade names.
- 2. Place manufacturer call(s). For each call, you must:
 - Request the name of the representative you speak with *and* a reference number for the call. Document this information on the Manufacturer Contact Information table (below).
 - Request viability determination for vaccine(s).
 - Evidence supports use = Vaccine is viable; continue to use.
 - No evidence available = Vaccine is non-viable; report as wastage in NYSIIS.
 - Shortened expiration date = Vaccine is viable until new expiration date; label vaccine with new date.
 - o Document viability determination(s) on Vaccine Data and Manufacturer Response table(s) on pages 4-5.
- 3. Submit completed temperature excursion report to NYSDOH Vaccine Program by email (vaccinetempexcursion@health.ny.gov) or fax (518-449-6912).

MANUFACTURER CONTACT INFORMATION					
Manufacturer	Phone Number	Name of Representative You Spoke With	Reference Number		
AstraZeneca	1-800-236-9933				
Dynavax	1-877-848-5100				
GlaxoSmithKline (GSK)	1-866-475-8222				
Grifols	1-888-474-3657				
Janssen (Johnson & Johnson)	1-800-565-4008				
Merck (MSD)	1-800-672-6372				
Moderna	1-866-663-3762				
Novavax	1-844-668-2829				
Pfizer	1-800-438-1985				
Sanofi Pasteur	1-800-822-2463				
Seqirus	1-855-358-8966				

Provider Site Name:

PIN(s):

VACCINE DATA AND MANUFACTURER RESPONSE					
Manufacturer	Trade Name	Lot Number	Expiration Date	# of Doses Affected	Manufacturer's Determination (viable, non-viable, or shortened expiration; if shortened expiration, note new expiration date below and on vaccine)

Provider Site Name:

PIN(s):

VACCINE DATA AND MANUFACTURER RESPONSE					
Manufacturer	Trade Name	Lot Number	Expiration Date	# of Doses Affected	Manufacturer's Determination (viable, non-viable, or shortened expiration; if shortened expiration, note new expiration date below and on vaccine)

REFERENCE TABLE: VACCINE MANUFACTURERS AND TRADE NAMES				
Manufacturer	Trade Names			
AstraZeneca 1-800-236-9933	FluMist Quadrivalent			
Dynavax 1-877-848-5100	Heplisav-B			
GlaxoSmithKline 1-866-475-8222	 Bexsero Boostrix Engerix B Fluarix Quadrivalent FluLaval Quadrivalent PF 	HavrixHiberixInfanrixKinrixMenveo	PediarixPriorixRotarixShingrixTwinrix	
Grifols 1-888-474-3657	• TDVAX			
Janssen (Johnson & Johnson) 1-800-565-4008	COVID-19 vaccine			
Merck 1-800-672-6372	 Gardasil 9 MMR II PedvaxHIB Pneumovax 23 ProQuad 	Recombivax HBRotaTeqVaqtaVarivaxVaxelis	Vaxneuvance	
Moderna 1-866-663-3762	COVID-19 vaccine products (including SPIKEVAX)	;		
Novavax 1-844-668-2829	COVID-19 vaccine			
Pfizer 1-800-438-1985	 COVID-19 vaccine products (including COMIRNATY) Prevnar 13 Prevnar 20 Trumenba 			
Sanofi Pasteur 1-800-822-2463	ActHIBAdacelDaptacelFluzone QuadrivalentIPOL	MenquadfiPentacelQuadracelTenivac		
Seqirus 1-855-358-8966	Afluria QuadrivalentFlucelvax Quadrivalent			