

Vaccine Incident Report and Worksheet Instructions

Refrigerator: 36.0° to 46.0° F/2.0° to 8.0° C - Aim for 40.0° F/5.0° C

Freezer: - 58.0° to 5.0° F/-50.0° to -15.0° C - Aim for below 0° F/-20.0°C

If recorded temperatures are not within acceptable ranges and are indicated by “Too Warm” or “Too Cold” on the temperature log, follow the steps below:

1. If vaccine temperatures are out of recommended ranges for **less** than 30 minutes during temperature logging, take immediate action to correct the problem.
 - Document corrective action taken on the temperature log and recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable ranges. If there is not enough space on the temperature log to document corrective action taken, write action taken on a separate sheet of paper and attach to the temperature log. Retain this information for three years.

2. If vaccine temperatures are out of recommended ranges for **more** than 30 minutes, immediately call the vaccine manufacturers. Complete the Vaccine Incident Report and Worksheet within five days of the incident. Also, complete any returns or waste in PIERS as needed.
 - List all details on the incident report.
 - Include description of incident.
 - Describe incident resolution.
 - Include corrective action plan.
 - Answer all questions on the report.
 - List all vaccines that were in the affected storage unit at the time of the incident (i.e., name, lot number, expiration date, number of doses).
 - Record manufacturers’ recommendations, along with case number if available. List vaccine doses keeping, destroying, and returning.
 - Attach copy of temperature log to completed Vaccine Incident Report and Worksheet and fax to 717-214-7223 or scan/email to RA-pavfc@pa.gov.

Notify the VFC Program at 888-646-6864 or email RA-pavfc@pa.gov in the event of a cold chain failure, if you have any questions, or if you need assistance.

Vaccine Incident Report and Worksheet
 Pennsylvania Department of Health
 Vaccines for Children Program

Date:	VFC PIN:
Demographics	
Site Name:	
Address:	Phone:
	County: District:
Incident Criteria	
Date/Time of Incident:	
Type of Incident: (Power failure, refrigerator/freezer failure, improperly stored, digital data logger malfunction, shipping/transporting error, etc.)	
Reported By:	Reported To:
Temperature Data	
Refrigerator -- circle appropriate unit below	Freezer -- circle appropriate unit below
Pharmaceutical Commercial Standalone	Pharmaceutical Commercial Standalone
Make/Model:	Make/Model:
Date/Time: Temperature:	Date/Time: Temperature:
Min: Max:	Min: Max:
Total time temps out-of-range:	Total time temps out-of-range:
Temperatures are reviewed and documented twice daily during operating hours? YES NO	
Water bottles are stored in both refrigerator and freezer? YES NO	
Dose your facility have an emergency back-up generator? YES NO	
Description of Incident (Write a narrative giving details of the incident; attach additional sheet of paper if needed.)	
Incident Resolution (Circle all appropriate responses and/or write a narrative giving details of actions taken after a problem was detected; attach additional sheet of paper if needed.)	
Refrigerator, Freezer, Digital Data Logger repaired replaced	Date: _____
Notified VFC immunization nurse of storage repairs/replacements	Date: _____
Manufactures contacted immediately	YES NO
Completed incident report sent within five days	YES NO

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Temperature Log and Calibration Certificate	
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- NIST-certified temperature monitoring device/buffered probes are placed in the center of each unit
- Current calibration certificate included with incident report; provide expiration date: _____
- Temperature logs complete and copy included with the incident report
- Action taken with OOR temperature noted on temperature log

Vaccine Waste

- | | | |
|---|------------|-----------|
| Was it necessary to return or waste vaccine because of the incident? | YES | NO |
| <input type="checkbox"/> Details of contact with manufacturers are documented on vaccine worksheet. | | |
| <input type="checkbox"/> Return or Waste completed in PIERS. | | |

Revaccination (Complete only if revaccination is necessary.)

- | | | |
|---|------------|-----------|
| Were any compromised vaccines administered to patients requiring revaccination? | YES | NO |
| If revaccination is necessary, how many patients need revaccination? _____ | | |
| Were patients notified of need for revaccination? | YES | NO |
| Interim/Final Status Report of Corrective Actions Following Cold Chain Failure completed?
Note: All letters and emails must be approved by BOI prior to being sent out | YES | NO |

Emergency Disaster Plan

- | | | |
|--|------------|-----------|
| Does your site have an up-to-date emergency handling procedures and disaster recovery plan? | YES | NO |
| Was the emergency plan implemented during this incident?
(if yes, proceed to next question, if no skip to corrective action plan) | YES | NO |
| Was the emergency plan effective?
(if no, proceed to next question) | YES | NO |
| Will you be making any adjustments to your emergency plan per the outcome of this incident?
(please feel free to elaborate on your updated plan in the corrective action section) | YES | NO |

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Pennsylvania Department of Health
Vaccines for Children Program

Date:

VFC PIN:

Corrective Action Plan (Write a narrative giving details of actions taken; attach additional sheet of paper if needed.)

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 Pennsylvania Department of Health
 Vaccines for Children Program

Vaccine Incident Report and Worksheet Instructions

If temperatures are out of range **less than 30 minutes:**

Take immediate action to correct the problem.
 Document corrective action on Step 3 of the temperature log.
 Recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable range.

If temperatures are out of range **more than 30 minutes:**

Mark vaccine "Do Not Use." Immediately contact manufacturers.

VACCINE	MANUFACTURER	TELEPHONE #
DTaP (Daptacel), DTaP-IPV (Quadracel), DTaP-IPV-Hib (Pentacel), Polio (IPOL), Hib (ActHIB), MCV4 (MenQuadfi), RSV (Beyfortus), Td (Tenivac), Tdap (Adacel), FLU (Fluzone)	Sanofi Pasteur www.sanofi.us	1-800-822-2463
DTaP-IPV-Hib-HepB (Vaxelis), Hep A (Vaqta), Hep B (Recombivax), HIB (PedvaxHIB), HPV (Gardasil), MMR (M-M-R II), MMRV (ProQuad), PCV15 (Vaxneuvance), PPV23 (Pneumovax 23), Rotavirus (RotaTeq), Varicella (Varivax)	Merck www.merck.com	1-800-444-2080
DTaP (Infanrix), DTaP-IPV (Kinrix), DTaP-IPV-HepB (Pediatrix), Hep A (Havrix), Hep B (Engerix B), HIB (Hiberix), MenB (Bexsero), MCV4 (Menveo), MMR (Priorix), Rotavirus (Rotarix), Tdap (Boostrix), FLU (Fluarix, FluLaval)	GlaxoSmithKline https://us.gsk.com	1-888-825-5249
MCV4-MenB (Penbraya), PCV20 (Pevnar 20), MenB (Trumenba), RSV (Abrysvo), COVID-19	Pfizer www.pfizer.com	1-800-879-3477
Hep B (Heplisav-B)	Dynavax https://www.dynavax.com	1-877-848-5100
Hep B (PreHevbrio)	VBI https://www.vbivaccines.com	1-888-421-8808
MPOX (Jynneos)	Bavarian Nordic https://www.bavarian-nordic.com	1-800-675-9596
COVID-19	Moderna https://www.modernatx.com	1-866-663-3762
COVID-19	Novavax https://www.novavax.com	1-844-668-2829
FLU (FluMist)	AstraZeneca https://www.astrazeneca-us.com	1-800-236-9933
FLU (Flucelvax, Afluria)	Seqirus www.seqirus.com	1-855-358-8966