State of Georgia Immunization Program
Georgia Department of Public Health

Vaccine Incident Report

Follow the procedures below when your publicly purchased vaccine has experienced out-of-range storage temperatures. Use a separate report for each affected storage appliance.

1. Do not use or discard the affected vaccine.
2. Isolate the affected vaccine, mark the boxes with an "X," and post a clear "Do Not Use" sign.
3. If the situation is temporary or quickly remedied (w/in 3 hours), keep the vaccine in its original storage unit with the door closed.
4. If necessary, move the vaccine to a working storage unit or your emergency storage location. Be sure to monitor temperatures at this location.
5. Contact the Vaccine Logistics Associate at 404-657-5013.
6. Record the following information about the incident and submit this form within 24 hours of the incident:

Facility Name: _____**VFC #**_____

Telephone #_____ **Date Reported**_____ **Reported by:** _____

Email Address: _____

Storage Unit Involved: _____
(Use a separate report for each affected storage appliance.)

- When was the incident discovered? Date_____ Time_____ am/pm (circle one)
- Room Temperature at time of discovery: _____C / F
- Temperature of storage unit at time of discovery: Refrigerator_____ C / F Freezer_____ C / F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Last known temperature recording prior to incident: Date_____ Time_____ am/pm (circle one)
- Temperature at last known recording: Refrigerator_____ C or F Freezer_____ C or F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Time interval vaccine was exposed to out-of-range temperatures: _____ day's _____hrs_____ minutes
  (Estimate the worst case scenario based on last recorded temperatures. If using a data logger, use the graphing function to determine the exact interval.)
- Has the affected vaccine experienced previous temperature excursions? ____Yes ____No

7. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
8. Contact the manufacturer of the affected vaccine to determine its viability. Use the contact information on page 2. The manufacturer will need the information recorded above to determine vaccine viability. Record the information from the manufacturer in columns 6–8 of the Vaccine Inventory Table

Vaccine Inventory Table (Copy this page if you need more rows in the table.)

Vaccine Name	NDC#	Lot #	Expiration Date	# of Doses	Disposition per Manufacturer (i.e., viable, wasted, exp date changed, etc.)	Call Ref# or Representative's Name	Date of Call

9. If the manufacturer determines the vaccine is viable*: a) Mark the date of this report next to the "X" on the package. This indicates that the vaccine has experienced a temperature excursion and references this report; b) If the expiration date of the vaccine has changed, clearly indicate the new expiration date on the package; and c) Return the vaccine to your inventory. Do not return vaccine to a malfunctioning storage unit until it can reliably maintain vaccine storage temperatures. **VFC will defer to manufacturer guidance regarding vaccine viability. Non-viable vaccine must be returned to McKesson Specialty Care Solutions. Do not dispose of non-viable vaccine except for opened multi-dose vials.*

10. If the manufacturer determines that the vaccine is wasted: a) This form will be used to process your vaccine return. A return confirmation letter will be sent to the primary and secondary email addresses on file for your site. b) Account for the vaccine on your Monthly Comprehensive Report.
11. To finish this report, provide the following information: Briefly describe the incident:

    _____

    _____

    _____

    What steps will be taken to prevent this from happening in the future?

    _____

    _____

    _____

12. Once completed, e-mail this report to the Vaccine Logistics Associate at dph-gavfc@dph.ga.gov or via fax to (404) 657-5736. This report serves as a record of the incident, the steps taken to determine vaccine viability, and the disposition of the affected vaccine. **Keep a copy for your records.**

GA Immunization Office use only
Reviewer's initials/date_____
Corrective Action required ___Yes ___No
Completed initials/date_____
Vaccine Manager sign-off_____

Vaccine Manufacturer Contact Information

GlaxoSmithKline	866-475-8222	Sanofi Pasteur	800-822-2463	Pfizer	800-438-1985
Merck	800-637-2590	Seqirus	855-358-8966 Option 1		