

State of Georgia Immunization Office

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 Manager or Georgia VFC Staff at 404-657-5013.
6. Record the following information about the incident:

**Facility Name:** \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**VFC #**\_     \_\_\_\_\_\_ \_\_\_\_

**Reported by:** \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Telephone #**\_     \_\_\_\_\_\_\_\_\_\_\_\_\_**Date Reported**\_     \_\_\_\_\_\_\_\_

**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
1. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
2. 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.)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **VaccineName** | **Manufacturer** | **Lot #** | **ExpirationDate** | **# of Doses** | **Disposition per Manufacturer (i.e., viable, wasted, exp date changed, etc.)** | **Call Ref# or Representative’sName** | **Date of Call** |
|       |       |       |       |       |       |       |       |
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1. 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.
2. If the manufacturer determines 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 email address on file for your site. b) Account for the vaccine on your Monthly Comprehensive Report.
3. To finish this report, provide the following information: Briefly describe the incident:

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

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| **GA Immunization Office use only** |
| Reviewer’s initials/date\_     \_\_\_ \_\_\_\_\_\_\_\_\_\_ |
| Corrective Action required |      \_Yes |      \_No  |
| Completed initials/date      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Vaccine Manager sign-off      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Once completed, return this report to the Vaccine Logistics Associate, Christy Banks, at cdbanks@dhr.state.ga.us (e-mail) or (404) 657-5736 (Fax). 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.**

**Vaccine Manufacturer Contact Information**

GlaxoSmithKline 866-475-8222 MedImmune 877-633-4411

Merck 800-637-2590 Novartis 800-244-7668

Sanofi Pasteur 800-822-2463 Pfizer 800-879-3477