



Immunization Program

Vaccine Incident Report – Data Loggers (Continuously Monitoring Thermometers)

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. Contact your Vaccine Coordinator or Alternate Vaccine Coordinator (if primary is unavailable).
3. Isolate the affected vaccine, mark the boxes with an “X,” and post a clear “Do Not Use” sign.
4. If the situation is temporary or quickly remedied (w/in 1.5 hours), keep the vaccine in its original storage unit with the door closed. Keep the Data Logger with the vaccine.
5. If necessary, move the vaccine to a working storage unit or your emergency storage location. Be sure to move the Data Logger with the vaccine and continue to monitor the temperatures.
6. Contact the Montana Immunization Program 444-5580.
7. 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
- Room Temperature at time of discovery: _____ C F
Storage unit temperature at time of discovery: Refrigerator _____ C F Freezer _____ C F
(Record temperature for refrigerator and freezer if a combined unit.)
- Follow the instructions on page 7 of your *Data Logger Instruction Manual* to download and view your data.
- Number of temperature excursions above or below thresholds (dotted lines) since last download: _____
 - If >5 temperature excursions since last download, contact the Montana Immunization Program for help interpreting your data. (444-0277 or lhutchinson@mt.gov. Attach Data Logger data file if emailing or fax graph to 444-2920.)
 - If ≤5 temperature excursions since last download, use your Data Logger graph to fill in the information below:

Excursion	Date	Start Time	Stop Time	Maximum Out-of-Range Temperature	Minutes Out-of-Range (per excursion)	Total Minutes (Add 1–5)	Average Temperature since Last Download*
1							
2							
3							
4							
5							

*Estimate or export data to Excel and calculate the average.

- Has the affected vaccine experienced previous temperature excursions? Yes No
- 8. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
- 9. Contact the manufacturer of the affected vaccine to determine its viability. Use the contact information on page 3. The manufacturer will need the information recorded above to determine vaccine viability.
- 10. Record the information from the manufacturer in columns 6–8 of the Vaccine Inventory Table (next page).

11. **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.
12. **If the manufacturer determines that the vaccine is wasted:** a) Fill out a Wasted and Expired Vaccine Return Form and follow the instructions on the form for returning the vaccine to McKesson. Download the form from our website at www.immunization.mt.gov under the VFC link; b) Contact the Montana Immunization Program (444-5580) for a shipping label; c) Account for the vaccine on your Monthly Vaccine Report.
13. 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?

14. Once completed, Fax, email, or mail this report to the Montana Immunization Program, PO Box 202951, 1400 Broadway, Helena, Montana 59620, Fax 444-2920, email: hhsiz@mt.gov. 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	800-806-9364	MedImmune	877-633-4411
Merck	800-637-2590	Novartis	800-244-7668
Sanofi Pasteur	800-822-2463	Wyeth	800-934-5556

MT Immunization Program use only. Incident # _____

Review initials/date _____

Corrective Action Required Yes No

Completed initials/date _____

Vaccine Manager sign-off _____

Entered in temp excursion database: _____

Data Logger File Name(s): _____
