Georgia Department of Public Health

Georgia Vaccines for Children Program
Equipment Requirements for Vaccine Storage

Revised 03/04/2013

We Protect Lives.

Storage Requirements

- Be large enough to hold the year's largest inventory
- Have enough room to store water bottles and coolant packs
- Have a calibrated thermometer inside each storage unit
- Reliably maintain the appropriate vaccine storage temperatures year-round
- Dedicated to the storage of vaccines. Food and beverages should **NOT** be stored in a vaccine storage unit

What kind of refrigerator should I use?

Household, consumer-grade units		Pharmaceutical-grade units	
Freezerless	Dual-zone	Under-the-counter	Full-sized

Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment

Equipment Requirements for Vaccine Storage

- Refrigerator and freezer must have **externally separate, sealed doors.**
- Refrigerator compartment must maintain temperatures between **35º and 46ºF (2º and 8ºC)**.
- Freezer compartment must maintain temperatures **5ºF (-15ºC)** or colder.
- Household-style units should have **separate thermostat/temperature controls** for the refrigerator and freezer.
- Both the refrigerator and freezer compartments must contain an **NIST- or ASTM-certified thermometer.**

Acceptable:

Household-style used only for refrigerated vaccines

Stand-alone refrigerator (no freezer compartment)

Upright freezer (no refrigerator compartment)

Commercial-style

Under counter refrigerator-only

Under counter freezer-only

NOT Acceptable:

Dorm-style

Units with a freezer compartment housed inside of one external door

CERTIFIED THERMOMETER GUIDELINES

- Providers enrolled in the VFC Program are required to purchase calibrated thermometers for all refrigerator and freezer compartments used for VFC vaccine storage in order to monitor temperatures .

- Each device is to be covered by a valid Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an accredited testing laboratory. Providers must be able to present valid certificates to program staff upon request.

- Thermometer calibration must be tested annually or according to manufacturer recommendations. (If calibration testing indicates that your thermometer is no longer accurate within, +/-1°F (+/-.5°C) then your thermometer should be replaced.)

- CDC recommends use of a digital thermometer with a biosafe glycol-encase probe that will measure liquid temperature.

- CDC recommends continuous recording thermometers able to provide continuous data monitoring information in an active display and be placed on the outside of the unit door to allow for reading temperatures without opening the unit door.

CERTIFIED THERMOMETER GUIDELINES

- The digital data logger should also include the following:
  - ✓Alarm for out of range temperatures;
  - ✓Current temperature, as well as minimum and maximum temperatures;
  - ✓Reset button
  - ✓Low battery indicator
  - ✓Accuracy of +/- 1°F (0.5°C)
  - ✓Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full
  - ✓User programmable logging interval (or reading rate)

- Additional information regarding thermometers is available in the Vaccine Storage and Handling Toolkit located at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

Thermometers "**NOT**" Recommended

- Fluid filled biosafe liquid thermometers
- Bi-metal stem thermometers
- Food thermometers and household mercury thermometers
- Chart recorders
- Infrared thermometers
- Thermometers **not** calibrated

CERTIFIED THERMOMTER CERTIFICATE REQUIREMENTS

CERTIFICATES MUST INCLUDE:
A title, such as "test report," "calibration certificate," or "calibration report"
Name/address of the laboratory where the tests/calibrations were carried out
A unique identification number on the report (and way for you to match this back to the thermometer)
Identification of method used & indication that the measurement standards/instruments used during the calibration are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency.
Test results and date of the calibration
Date the results are valid until (i.e., expiration date)
Identification (signature/name/title) of person(s) authorizing the calibration certificate

EXAMPLES OF CERTIFIED THERMOMETERS

Products and vendors are referenced for informational purposes only; listing in this document does not imply endorsement.

- CDC recommends using only certified calibrated thermometers for measuring vaccine storage unit temperatures. All thermometers are calibrated during manufacturing, meaning that they are given a temperature scale. Certified calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency. Thermometers and temperature monitoring equipment should be calibrated and come with an individually numbered traceable certificate that indicates that the product's calibration is traceable to standards provided by the National Institute of Standards and Technology (NIST) (a U.S. Government agency within the Commerce Department) or a laboratory recognized by NIST. This document is different from the manufacturer's warranty. Traceability requires the establishment of an unbroken chain of comparisons to stated references. NIST assures the traceability of results of measurements or values of standards that NIST itself provides, either directly or through an official NIST program or through collaboration. Keep in mind that calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process.

- When purchasing thermometers, consider the cost of recalibration as well as purchase price. For some less expensive thermometers, periodic replacement may be more cost-effective than recalibration. Again, verification or calibration of thermometers shall be by an approved NIST procedure or ASTM procedure.

- Below are links to NIST traceable thermometers. This is by no means an exhaustive list, and you may find other sources. Scientific and laboratory supply houses are generally good sources for certified thermometers. Thermometers obtained through appliance suppliers are less likely to be certified.

- **"Bottle" thermometers**
- http://www.alphamultiservicesinc.com/page/444217592
- http://www.streck.com/product.aspx?p=Temp-Chex

- **"Min/max" (digital)**
- http://www.streck.com/product.aspx?p=Temp-Chex%20Digital
- http://www.fishersci.com/ecomm/servlet/fsproductdetail?aid=203749&&storeId=10652
- http://www.control3.com/4048p.htm