

## Summary of Cold Chain Management Requirements

Immunization is an important part of the disease prevention activities. All vaccines and biologics are vulnerable, thermo-sensitive products. Vaccines may become inactivated and immunization effectiveness may be jeopardized if proper storage and distribution practices are not followed within a safe and an efficient cold chain system. To ensure the quality of all provincially funded vaccines, Alberta Health (AH) and Alberta Health Services (AHS) require utilization of appropriate cold chain management equipment and practices.

### Refrigerators for vaccine storage:

When choosing a refrigerator for vaccine storage the following should be considered. The refrigerator should:

- Be large enough to hold the year's highest monthly inventory, including influenza vaccine.
- Be dedicated to the storage of vaccines only.
- Be able to maintain required vaccine storage temperatures through all seasons.

### Laboratory-grade refrigerator

A purpose-built vaccine refrigerator (also referred to as a pharmacy, lab-style or laboratory grade refrigerator) is the recommended standard for storing vaccines to keep them within the required +2°C to +8°C range to ensure potency, safety and effectiveness.

**A laboratory-grade refrigerator is required for vaccine storage at sites with \$5000 or greater of vaccine.**

This type of refrigerator excels at vaccine storage for several reasons including:

- Temperature regulation - the temperature regulation mechanism in a purpose-built vaccine refrigerator has a very small temperature tolerance and a quick reaction time to temperatures outside of the set range. A temperature probe for the temperature control is usually located in the path of the return airflow, thereby measuring the temperature of the warmest air in the refrigerator.
- Defrost mechanism – purpose-built vaccine refrigerators have a mechanism to defrost ice from the evaporator without raising the temperature in the unit. This method of regular defrosting also prevents fluctuations of temperatures within the unit.
- Spatial temperature differential – the spatial temperatures are tightly controlled in purpose-built vaccine refrigerators. There is constant fan-forced air circulation within the refrigerated compartments. Generally, the temperature does not vary within the storage area from the set point.
- Effects of changes in ambient temperature - the forced air circulation helps to keep internal temperatures within an acceptable range even when the ambient temperature changes.
- Temperature recovery - the temperature is digitally managed in purpose-built refrigerators. Any deviation in temperatures from the pre-set one is sensed very rapidly.
- **These laboratory-grade refrigerators come in a variety of sizes, including smaller “bar size” units.**

### Domestic refrigerator (May be used for storage of vaccine less than \$5,000.00)

Acceptable domestic combination refrigerator and freezer units must have separate external doors for the freezer and fridge. Manual and cyclic defrost refrigerators should not be used due to the significant temperature variations and the risk of vaccines freezing. Some domestic refrigerators can be used but may require modifications to store vaccine. Vaccine can only be stored in certain areas of the refrigerator and precautions should be taken as temperatures may fluctuate in different compartments of the refrigerator (i.e., not in the door or in vegetable bins).

For more detailed information refer to the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015) can be found at <http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php>.

Limitations with domestic refrigerators:

- Thermostats are generally slow to react to changes in temperatures and have a wide temperature tolerance.
- It is difficult to accurately set temperature.
- No air is circulated when the compressor is off.
- Defrost function can cause temperature fluctuations.

Vaccine should never be transported home and stored in a personal home refrigerator.

The following graphic provides quick reference points for vaccine storage.



The following information must be known if a domestic refrigerator is going to be used to store vaccines:

1. Domestic refrigerators are designed to have various temperature zones for multiple storage functions. The various temperature zones within the compartments must be identified prior to placing vaccines into the refrigerator. To determine temperature zones within your refrigerator:
  - a. Place sealed water bottles in refrigerator to simulate a cold mass.
  - b. Once water bottles are cooled, place a temperature monitoring device, such as a data logger or digital min/max thermometer, in each position (top, bottom, each side, front, back, and centre) for a minimum of 24 hours.
  - c. The length of time needed to determine temperature zones will depend on the type and number of recorders available.
  - d. Monitor current, minimum, and maximum temperature a minimum of twice in the 24 hour period.
  - e. Vaccines are only to be stored in temperature zones which maintain temperature within the recommended vaccine storage temperatures.
2. The air vent location must be known and will differ by manufacturer. Vaccines should be kept away from the air vent to avoid potential freezing. Generally the air from the evaporator is below 0°C.
3. Vaccines are never to be stored in the door, in vegetable bins, or on floor of refrigerator. Remove vegetable bins from refrigerator.
4. Changes in ambient temperature will affect internal fridge temperature. To help stabilize temperature in the unit:
  - a. Refrigerator compartment: store sealed water bottles in the crisper and/or vegetable bin area, the door rack, and / or against the inside walls of the refrigerator.
  - b. Freezer compartment: store frozen packs along the walls, back, and bottom of freezer compartment area and inside the racks of the freezer door.
  - c. The thermostat may need to be reset in summer and winter depending on the ambient temperature.

### **Bar-style refrigerator – NOT ACCEPTABLE**

These units are unpredictable in terms of maintaining temperatures and **MUST NOT** be used for vaccine storage.

Bar fridge temperatures vary greatly within the unit and audits have found ranges from +1°C at the top of the fridge to +12°C at the bottom. Annually, a significant number of cold chain excursions in Alberta are attributable to the use of bar fridges.

### **Temperature Monitoring Devices:**

**Minimum/maximum temperature monitoring is a requirement regardless of the value of provincially funded vaccine stored in the unit or whether the refrigerator is monitored through an external alarm system, chart recorders and / or data loggers.**

Continuous temperature recording devices (e.g., Data Loggers, Chart Recorders) must be in place in refrigerators where vaccine with a value of \$5,000 or greater is being stored.

External alarms with 24/7 monitoring must be in place for refrigerator / freezer units where vaccine with a value of \$10,000 or greater is being stored.

- **Minimum/Maximum (Min/Max) Thermometers (Requirement regardless of value of vaccine):**  
Min/max thermometers are an important device to assist with safe vaccine storage and handling. In the event of a cold chain excursion they assist in determining the length of time a storage compartment has been operating outside recommended temperature ranges.

The min/max thermometers show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset. Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings. They must be manually reset regularly (after properly recording temperatures) for meaningful readings.

There are two types of min/max thermometers, digital with a standard probe and digital with a bio-safe liquid encased probe. Both types are acceptable for monitoring vaccine refrigerator temperatures however the **bio-safe liquid encased probe gives a more relevant reading because they do not react to short fluctuations in air temperature.** If a standard probe min/max thermometer is used the temperature probe should be placed in a diluent or vaccine box to reduce the risk of measuring short air fluctuations when opening the refrigerator door.

MinMax Digital



Digital w/standard probe



Digital w/bio safe liquid encased probe



A refrigerator setting of +5°C provides the best safety margin for temperature fluctuations within +2°C and +8°C.

Thermometers with a min/max feature are easy to read because they display a number indicating the temperature and do not require interpretation. Note: Temperature monitoring is the only way to be certain the unit remains within the recommended range.

**Recommendation: Minimum/Maximum thermometers that have the capacity to provide a more detailed temperature reading to the tenth degree (e.g., 2.3°C) are preferred.**

- **Continuous Temperature Monitors:**

- **Data loggers:** Digital data loggers are miniature, battery-powered, stand-alone temperature monitors that record hundreds or thousands of temperature readings. These are the ideal temperature monitors because they can indicate **when an adverse temperature exposure occurred and how long the vaccines were exposed to the min/max temperatures.**
- **Chart recorders:** A chart recorder is a unit that is attached to a lab grade refrigerator that contains graphs and pens that record temperatures on paper over time. Graph paper must be changed on a weekly or monthly basis. Recommended for monitoring temperatures of vaccine storage units if access to computer and digital units is not feasible. They are more difficult to read and interpret temperatures than the data loggers.

- **Unacceptable Temperature Monitors:**

Other types of thermometers are available but are NOT acceptable. These include:

- Fluid-filled (this is different than a bio-safe liquid encased probe min/max thermometer )
- Bi-metal stem
- Household mercury



Fluid filled  
Bio safe liquid



Bi-metal stem



Household mercury

- **Where to get acceptable vaccine refrigerators and min/max thermometers**

There are many refrigerators and thermometers available that meet the requirements outlined above. AHS does not make recommendations for any specific brand of refrigerator or thermometer. Below is a list of websites to help get you started – please note this list is in no specific order and is not exhaustive.

**RECOMMENDATIONS:**

<b>Vaccine Refrigeration:</b>	<b>Min/Max Thermometers:</b>
<a href="http://www.haiomedical.com/products/preservation/under_counter_pharmacy_refrigerator/">http://www.haiomedical.com/products/preservation/under_counter_pharmacy_refrigerator/</a>	<a href="https://ca.vwr.com/store/product/en/4590446/vwr-traceable-refrigerator-freezer-plus-thermometers">https://ca.vwr.com/store/product/en/4590446/vwr-traceable-refrigerator-freezer-plus-thermometers</a>
<a href="http://www.360medical.ca/Products_Medical_Pharmacy_Research_Vaccine_Laboratory_Fridges_Refrigerators.html">http://www.360medical.ca/Products_Medical_Pharmacy_Research_Vaccine_Laboratory_Fridges_Refrigerators.html</a>	<a href="https://ca.vwr.com/store/catalog/product.jsp?catalog_number=89094-772">https://ca.vwr.com/store/catalog/product.jsp?catalog_number=89094-772</a>
<a href="https://www.panasonic-healthcare.com/us/biomedical/preservation/under-counter-refrigerators/sr-l6111w">https://www.panasonic-healthcare.com/us/biomedical/preservation/under-counter-refrigerators/sr-l6111w</a>	<a href="https://www.deltatrac.com/digital-min-max-thermometers">https://www.deltatrac.com/digital-min-max-thermometers</a>
<a href="http://www.americanbiotechsupply.com/Products/Refrigerators/Pharmacy-Refrigerators/Premier-Pharmacy-Vaccine-Undercounter-Refrigerator/4-6-Cu-Ft-Premier-Pharmacy-Vaccine-Undercounter-Re.aspx">http://www.americanbiotechsupply.com/Products/Refrigerators/Pharmacy-Refrigerators/Premier-Pharmacy-Vaccine-Undercounter-Refrigerator/4-6-Cu-Ft-Premier-Pharmacy-Vaccine-Undercounter-Re.aspx</a>	<a href="https://www.pharmasystems.com/index.php?route=product/product&amp;filter_name=10368&amp;product_id=229">https://www.pharmasystems.com/index.php?route=product/product&amp;filter_name=10368&amp;product_id=229</a>

**Backup Power Requirements:**

Sites where \$10,000 or greater of provincially funded vaccine is stored at any time without backup power must have a written agreement with another facility that has backup power and equipment to store vaccine.

This agreement must include:

- Term of the agreement
- Name of the alternate site
- Physical address of alternate site
- Contact person and phone number
- After hours contact(s) name and phone number
- A statement that the alternate site has the capacity to store the vaccines and they have appropriate temperature monitoring equipment, alarms and backup power as outlined in the AHS Vaccine Storage and Handling Standard
- The process involved in transferring vaccine.