

Yukon Immunization Program Manual

Section 7- Storage and Handling of Biological Products



SECTION 7 – STORAGE AND HANDLING OF IMMUNIZATION AGENTS

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1.0 COLD CHAIN

“Cold chain” refers to the process used to maintain optimal temperature conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client (1).

Vaccines are sensitive biological products; protection of vaccine potency and stability is important (2). The recommended temperature for vaccine storage and handling is, at all times, between +2°C to +8°C. Biologicals may be inactivated by exposure to excess light or heat or freezing, depending on the nature of the product, the temperature reached and the duration of exposure. Any loss of vaccine potency is permanent and irreversible. Damage from successive exposures to adverse conditions is cumulative. It is important to know the correct storage conditions for each biological product and to ensure that each is kept under the recommended conditions.

It is extremely important to have a thermometer calibrated to an accuracy of +/- 1°C or better. Place the thermometer probe centrally (in the middle of the middle shelf) in the refrigerator, where temperatures are more constant and less likely to fluctuate.

All biological products freeze at temperatures below 0°C; products that have been exposed to temperatures below 0°C may not be usable, therefore, complete product list to pharmacy is necessary.

The Vaccine Stability Chart is a reference provided to Biological Products Consultants to guide product use when biologicals are exposed to temperatures outside the acceptable range (3). This chart contains updated stability information from the vaccine product monographs and the manufacturers. No vaccine should be removed from cold chain conditions nor returned to Yukon Immunization Program until it has been determined that the product cannot be used.

2.0 STORAGE AND HANDLING OF IMMUNIZATION AGENTS

COMPETENCY: Implement the [Canadian Guidelines](#) when storing, handling or transporting vaccines (1).

Failure to maintain the cold chain may result in a vaccine losing its effectiveness, failure of the vaccine, and a potential for increased local reactions post administration of a vaccine (4). **Freezing** reduces the potency of inactivated vaccines. **Light** compromises the stability of live virus vaccines.

2.1 ORDERING PROCEDURES

- Order only enough vaccine for your client population, maintaining a **two**-month stock of vaccine. All efforts will be made to ensure that vaccine is hand delivered to the ordering community regardless of the season. **No** vaccines will be “shipped” during the winter months except with persons reliable in maintaining cold chain that transport the package in the cab of the vehicle. **Do not** place vaccines inside the trunk of a vehicle.
- Panorama reminder recall report can be run to help determine pediatric quantities for the next two months (as available).
- Vaccines are ordered on the Formulary approved order sheets accompanied by the monthly inventory and waste records when submitted to the Immunization Program.
- All vaccine orders will be reviewed by the Immunization Program Manager or delegate.
- All other supplies are ordered through employer (e.g. temperature markers, thermometers, sticker, etc.).
- Vaccines orders are only to be submitted monthly (**before the last working day of the month**) and there are no rush orders available except in the case of outbreak management.
- Vaccines that are being ordered for a specific patient at the patient’s cost are to be paid for prior to order being placed (e.g. travel vaccines in smaller centres that do not routinely stock these vaccines).

2.2 RECEIVING SHIPMENTS OF IMMUNIZING AGENTS

Vaccine shipments require immediate attention.

- **Unpack and refrigerate biological products immediately upon their arrival.**
- Check the **cold** and **warm mark** monitors (refer to section on cold and warm mark monitors). Check vaccines for any damage, evidence of freezing or excessive heat.
 - Notify immunization program manager if there is damage, evidence of freezing and excessive heat.
- Freezing affects, the physical form of aluminum-adsorbed vaccines (6). It is thought that freezing causes the adsorbent to form larger, heavier granules that will gradually settle at the bottom of the vial when the vial is shaken.
- Place vaccines in the fridge **immediately** upon receipt.
- Rotate stock- Place new stock at the back of the fridge. Place vaccines with the longest expiry dates behind shorter-dated vaccine.
- Separate adult and pediatric vaccines.
- Label adult vaccines with stickers “Not for Pediatric Use”.
- On the packing slip: initial, note the date received and if anything is missing, then **fax the packing slip** to the Immunization Program Manager at 867- 393-4357.

2.3 VACCINE STORAGE

- Store all vaccines between +2°C and +8°C (4). CLEARLY separate pediatric and adult vaccines.
- Place vaccines at least six inches away from the cooling vent at the back of the fridge (these areas are very sensitive to temperature fluctuations).
- Rotate stock according to expiry date. Place vaccines with the longest expiry dates behind shorter-dated vaccine.
- **“First to expire, first out”**. Use shorter dated product first.
- Vaccines that are light sensitive are to remain in their **original packaging** or in **light sensitive bags** (2).
- **All product monographs** can be found through the Health Canada Drug Product Database Online Query available at: <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp> .
- The following vaccines are light sensitive:

BEXSERO	MENVEO	SHINGRIX
FLUVIRAL	MODERNA COVID-19	SYNFLORIX
FLULAVAL	MMRII	TUBERSOL
FLUZONE QUADRIVALENT	PFIZER COVID-19	TYPHERIX
GARDASIL 9	PRIORIX	TYPHIM VI
INFANRIX HEXA	PROQUAD	VARILRIX
IXIARO	PRIORIX-TETRA	ZOSTAVAX II
MENJUGATE		

- Leave space between products in the refrigerator to allow air to circulate.
- **Only vaccines are stored in the vaccine fridge. Do not** store drugs, food or specimens in the vaccine fridge.
- Place bottles of water on bottom shelf or empty shelf.
- Place freezer packs in vaccine freezer portion.
- Check vaccine door to ensure it is closed properly after each time it is opened.

2.4 HANDLING VACCINES

- Remove vaccines from the refrigerator just **prior** to administration.
- Vaccines will be kept in the fridge until required except for mass satellite clinics.
- Limit opening the refrigerator door unnecessarily. Note on fridge temperature log if door was open for longer than normal (e.g. adding new stock or completing inventory).
- Mark the date on all multi-dose vials of vaccines and biologicals (PPD) including the box when first opened. Use within 30 days of opening unless otherwise specified by the manufacturer.
- Reconstitute products using **ONLY** the diluents for the specified products.

2.5 VACCINE DISPOSAL

- Vaccines expire at the end of the month listed on the vial (i.e. Sept/09 = September 30, 2009)
Note: Talecris products- expiry date is noted as dd-MMM-yy (day-month-year).
- Dispose of expired and unused vaccines in the drug expiry box. Vaccines are not hazardous material.
 - Complete a refrigerator inventory **once** a month and **check** expiry dates. Discard any expired products and note this on the waste record.

2.6 SECURITY OF VACCINES

- Vaccine fridges are to be placed in the Drug Storage room wherever possible to ensure a secure environment.
- Where vaccine fridges cannot be stored in the Drug Storage room they must be placed where there is minimal access by the public and the fridge is to be locked at all times with the keys to kept in a secure location.

3.0 COLD CHAIN BREAK MANAGEMENT

Any temperature outside of the +2°C to +8°C temperature range requires immediate action.

- **DO NOT CALL THE MANUFACTURER.**
- Isolate and label vaccines with “Quarantine” and date of cold chain break. Store the vaccine at appropriate temperatures and monitor the storage unit conditions. Transfer vaccine to an alternative storage unit/cooler if storage unit has failed.
- Identify the source of the failure (breakdown, power outage, human error, etc.).
- Record the following information (1):
 - a. Vaccine name, lot number, expiry date
 - b. Date and time of incident
 - c. The issue (e.g., exposure to inappropriate temperature or exposure to light)
 - d. Length of time the vaccine may have been exposed to inappropriate conditions
 - e. The room temperature where the vaccine storage unit is located
 - f. Current temperature inside the vaccine storage unit (and freezer)
 - g. Minimum and maximum temperature readings inside the vaccine storage unit (and freezer)
 - h. Presence of water bottles in the refrigerator
 - i. Presence of frozen packs in the freezer
- Report cold chain breaches to the Pharmacist at WGH or the pharmacist on call for direction.
- Contact the Immunization Program Manager to inform of the breach and the recommendations from the pharmacist.

4.0 EQUIPMENT

4.1 VACCINE FRIDGES (7)

See the [Canadian Immunization Guide: Part 1 – Key Immunization Information](#) for detailed information on vaccine fridges. Also refer to the [National Vaccine Storage and Handling Guidelines for Immunization Providers](#) where you can find a maintenance checklist in Appendix H.

4.1.1 Care of Standard Fridge (Whitehorse General Hospital- Employee Health Program)

- Store all vaccines between +2°C and +8°C.
 - Record on fridge log **twice** daily temperature readings. Record minimum, maximum and current temperature on the log sheet. Note on fridge temperature log if door was open for longer than normal (e.g. adding new stock or completing inventory). See [Appendices](#).
 - Store vaccines in the middle portion of the fridge. Never store vaccines on the fridge door shelves.
 - Place fridge at least 10 cm from wall to ensure adequate ventilation.
 - Protect fridge from direct sunlight.
 - Ensure the door is closed tightly at all times.
 - Place gel packs on the lowest shelf and any empty shelf to increase fridge temperature stability.
 - Place freezer packs in freezer to increase fridge temperature stability.
 - Freezers must be defrosted when there is a build-up of 1 cm or more of ice. When defrosting the freezer the vaccines must be moved to another fridge as the fridge temperature will fluctuate during the defrosting process
- NOTE:** If you must open the fridge door for a prolonged period of time (i.e. to stock fridge), note this on your temperature log.
- Consult with WGH pharmacist for advice when vaccines have been exposed to temperatures outside of +2°C to +8°C. Do **not** call the vaccine manufacturer.
 - Do not use your vaccine refrigerator to store drugs or lab specimens.
 - Have the refrigerator connected to a secure power source or one with a backup supply in case of power failure.

Ensure fridge is connected to a plug covered by the emergency generator. A sign is to be placed above the electrical outlet “**VACCINE REFRIGERATOR- DO NOT UNPLUG- DO NOT SWITCH OFF.**”

4.1.2 Care of Vaccine Fridge (All Facilities)

- Store all vaccines between +2°C and +8°C.
- Check the temperature at minimum **twice** a day.
- Record on log twice daily temperature readings. Record minimum, maximum and current temperature on the log sheet. Note on fridge temperature log if door was open for longer than normal (e.g. adding new stock or completing inventory). See [Appendices](#).
- Place fridge at least 10 cm from a wall or other structures to ensure adequate ventilation.
- Protect fridge from direct sunlight.
- Ensure the door is closed tightly at all times.
- Place bottles of water on lower shelf and any empty shelf to increase fridge temperature stability.
- Place freezer packs in freezer to increase fridge temperature stability.
- Freezers must be defrosted when there is a build-up of 1 cm or more of ice. When defrosting the freezer the vaccines must be moved to another fridge as the fridge temperature will fluctuate during defrosting the freezer.

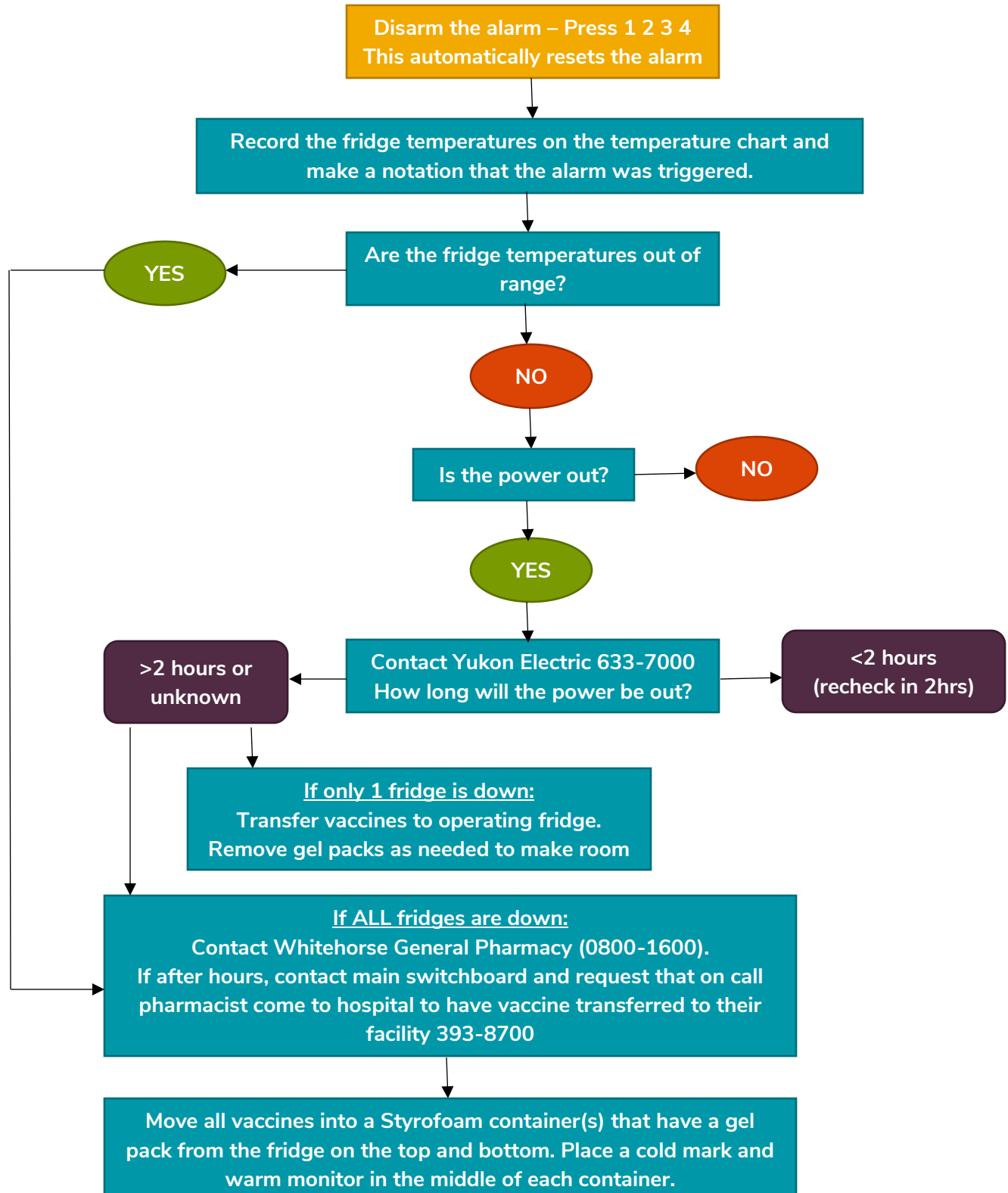
NOTE: If you must open the fridge door for a prolonged period of time (i.e. to stock fridge), note this on your temperature log & reset the thermometer.

- Consult with your PHCNIC/NIC or WGH pharmacist for advice when vaccines have been exposed to temperatures outside of +2°C to +8°C. Do **not** call the vaccine manufacturer.
- Do not use your vaccine refrigerator to store drugs or lab specimens.
- Leave space between products in the refrigerator to allow air to circulate.
- In the event of a prolonged power outage (more than two hours) the vaccines should be placed in an insulated cooler with ice packs. Warm and cold markers are also to be placed in the cooler. (*Whitehorse Health Centre has a different protocol, please see below*)
- Ensure fridge is connected to a plug covered by the emergency generator. A sign is to be placed above the electrical outlet “**VACCINE REFRIGERATOR- DO NOT UNPLUG- DO NOT SWITCH OFF**”

For **Whitehorse Health Centre** follow 4.1.2 and in addition:

- Refrigerator is to be connected to alarm system.
- In the event of a prolonged power outage (more than two hours) the vaccines will be transferred to Whitehorse General Hospital. [Refer to 4.1.3 Fridge Alarm Procedure](#).

4.1.3 Fridge Alarm Procedure – Whitehorse Health Centre



4.1.4 Troubleshooting- Vaccine Fridges

Fridge Door Seal

To check that the vaccine storage unit door is sealing properly:

1. Place a thin paper strip against the cabinet front.
2. Close the door.
3. Pull the paper strip. If it moves easily or falls away by itself, the door and the rubber-like seal need to be adjusted.
4. Check all the way around the door. Pay particular attention to the corners.
5. To be done a minimum of twice yearly.

Figure 1: Vaccine Fridge



Figure 2: Vaccine Fridge Alarm and Temperature Monitoring



4.2 TEMPERATURE MONITORING

4.2.1 Checking Thermometer Placement

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated in the center of the fridge, adjacent to the vaccine. If the thermometer is placed near the coils, walls, floor or door, it may indicate colder or warmer temperatures than a thermometer appropriately placed in the center of the compartment where the vaccines should be kept.

4.2.2 Checking if the Thermometer Works

A slight variation in temperature is often seen from one thermometer reading to another, even when the vaccine storage unit thermostat is set at a particular temperature. If the thermometer reading does not fluctuate at all over several readings, temporarily remove the thermometer from the storage unit and place it outside the unit at room temperature. Check whether the temperature reading rises. If no change in the temperature reading occurs, check the batteries. **Batteries are to be changed in June of each year** and documented on the fridge temperature recording sheet.

If there continues to be a problem with the thermometer order a new thermometer through your employer.

Thermometers should be checked **annually** to ensure:

- Temperature measurement is accurate; batteries are functioning; cables or probes are not damaged.

4.2.3 Checking the Accuracy of the Thermometer

Slush test (Digital Thermometer)

The accuracy of a thermometer can be checked using the following test. This test is to be done **every June** (after new batteries have been installed in thermometer) and documented on the fridge temperature recording sheet.

- Fill a polystyrene or plastic cup two-thirds with cold water. Place the cup in the freezer until a fine layer of ice forms on top and a small section of ice forms within the fluid (about 2 hours). If ice is present, this ensures the mixture is 0°C. Place the temperature probe in the middle of the cup (do not touch the sides). Observe the temperature after 2 minutes. The temperature should drop to 0°C within 2 minutes. If the temperature does NOT drop to 0°C order a new thermometer.

4.2.4 Instruction for Use of the Digital Fridge Thermometer

- Submerge the external probe in a container of diluent (i.e. a blood tube filled with tap water) in the centre of the middle shelf. This is done to reduce the risk of measuring short air fluctuations when opening the refrigerator door.
- To obtain the current reading, read the current temperature showing on the thermometer.
- To obtain the minimum temperature, push the min button and read the temperature on the screen.
- To obtain the maximum temperature, push the max button and read the temperature on the screen.
- To reset the thermometer, push the reset button and both the minimum and maximum temperatures will be reset to the current temperature.

NOTE: The Digital Thermometer is very sensitive to temperature changes. Therefore, if the door is left open for more than a few seconds reset the thermometer. Reset the thermometer after unpacking vaccines and placing them in the fridge.

Figure 3: Min Max Thermometer – Digital



4.2.5 Instructions for Use of Wireless Thermometer/Hygrometer

To set up unit

1. Set channel on sensing unit.
2. Set same channel on receiving unit.
3. Set alarm parameters; make sure switch on back of receiver is set to Celsius - 2 degrees for a low parameter, 8 degrees for high parameter. Turn alarm on.
4. Place sensor unit inside refrigerator; place in centre location out in open on middle shelf.
5. Set receiver in a DEDICATED location where readings can be recorded and alarms can be heard.

To record readings

1. Read top temperature window for current temperature reading.
2. Push 'MEM' button to record high reading, 'MAX' will appear next to temperature
3. Push 'MEM' button again to record low reading, 'MIN' will appear next to the temperature.
4. Push 'MEM' button once more to reset.

Figure 4: Wireless Thermometer/Hygrometer



4.2.6 Cold and Warm Mark Monitors – Accepting and Rejecting Shipments

Cold and Warm Mark monitoring strips are to be used year round.

COLD MARK

Note: The Cold Mark will activate at 0°C

Accept vaccine shipment if color of bulb is clear or black

Reject vaccine shipment if color of bulb is **black & bulb** has burst.

If vaccine shipment is rejected, label “**Do not use**” and store the vaccines in the vaccine fridge away from other vaccines.

Follow directions listed in [3.0 COLD CHAIN BREAK MANAGEMENT](#).

DO NOT CALL THE MANUFACTURER.

Figure 5: Cold Mark Monitor



WARM MARK

Note: The Warm Mark will activate at 10°C

The Warm Mark Temperature tag has five windows. The rate of blue colour movement from box 1 to 5 is dependent on the exposure time to temperatures above the threshold. i.e. box 1 is blue- exposure to a temperature over 10°C.

Accept vaccine shipment if:

1. All windows are clear.
2. #1 window alone is colored blue.

Reject vaccine shipment if:

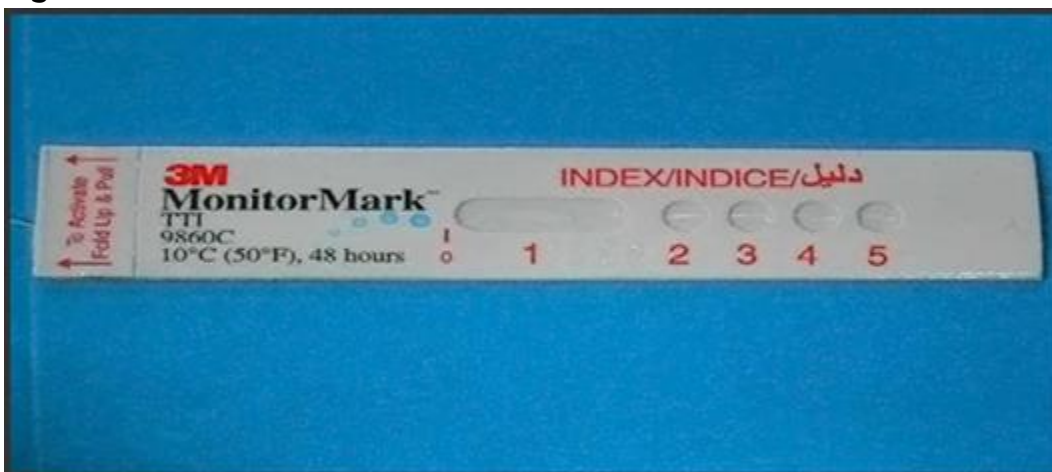
1. # 2-5 windows are blue

If vaccine shipment is rejected, label “**Do not use**” and store the vaccines in the vaccine fridge away from other vaccines.

Follow directions listed in [3.0 COLD CHAIN BREAK MANAGEMENT](#).

DO NOT CALL THE MANUFACTURER.

Figure 6: Warm Mark Monitor



4.3 POWER SUPPLY

- Plug Fridge into an outlet that cannot be activated by a wall switch.
- Ensure vaccine fridge is connected to emergency generator (outlet may have a red dot indicating connection to emergency power).
- Place a warning sign at the plug and on the storage unit alerting others not to unplug the unit. **“DO NOT UNPLUG FRIDGE”**.

4.3.1 Power Outage (Excluding Whitehorse Health Centre)

Scheduled and time limited outage (when backup generator not in service)

- Do not open the refrigerator or freezer door until the power is restored.
- Monitor the temperatures inside the vaccine fridge to ensure they remain between +2° and +8°C.
- If the temperature inside the refrigerator exceeds the recommended +8°C remove the vaccines from the fridge and place the vaccine in cooler packs (using freezer packs and warm/cold marks).
- Only when power has been restored and the vaccine fridge is back in the +2° to +8°C range are vaccines to be placed back in the fridge.
- Establish at least one alternate storage facility in your community where vaccine can be appropriately, securely stored and monitored. Ideally, this facility would have a backup generator.

5.0 TRANSPORTATION AND MANAGEMENT OF VACCINES FOR CLINICS

Consider the amount of vaccine to be transported, the external air temperature, and the length of time the vaccine will be in an insulated container. This will help to determine packing requirements.

Packing vaccines for clinic use:

- Keep vaccines in original packaging.
- Place a thermometer with the vaccine in the cooler when vaccine will be in the cooler for more than 4 hours. Note: A minimum/maximum thermometer is recommended for monitoring temperature inside large coolers during mass immunization clinics.
- Provide a protective barrier of insulating material such as a flexible insulating blanket, between the vaccines and the frozen packs.
- Place frozen packs at the top of the cooler. See below [6.1 Instructions for Packing an Insulated Container](#). Specific packing configurations should be developed at the local level, considering locally available equipment and supplies.
- Consider local testing of packing configurations using available supplies and monitoring the temperatures in a cooler over time to determine the appropriate vaccine load and packing requirements that will maintain the temperature within the + 2°C to + 8°C range. Consider the length of times vaccines may be in the field in your specific region (locations of outside clinics and travel times to clinics).
- Packing configurations will vary on a seasonal basis. It is most important to prevent vaccines from freezing. In winter conditions, fewer or no frozen packs may be needed to maintain the required temperature; more frozen packs may be needed for summer conditions.
- Maintain the packing configuration when removing vaccines from or returning vaccines to the cooler.
- Refrigerate diluent for 24 hours in the refrigerator if you are planning on transporting it in the cooler with the vaccines. Diluent that is not refrigerated before being placed in a cooler may warm the temperature in the cooler. If you have not refrigerated the diluent, transport diluent separately from vaccines.
- Keep coolers out of direct sunlight.
- Do not place coolers in the trunk of a car where temperatures cannot be monitored and may be significantly different from interior vehicle temperatures.
- When weather temperatures are below +2°C, transport in a vehicle where the temperature can be kept higher than +2°C to avoid freezing. Do not place coolers by the car heater.

Packaging process:

- When possible provide the vaccine in an original box that has the correct lot number and expiry date for the product.
- A package insert (copy or original) should be provided. You do not need a product monograph.
- INFANRIX hexa® **must** be supplied in an original box because PEDIARIX™ is added as a diluent to the vial containing a Hib pellet. The two components are lot specific with respect to the final "combined" product.
- When live vaccines such as MMR and varicella are packaged with the appropriate diluent, a lot number is only required for the MMR or varicella antigens. The number of vials of vaccine should be equal to the number of vials of diluent, and the correct diluent should be included for each product.
- If a vaccine cannot be supplied in its original box, single doses should be carefully wrapped in bubble wrap and placed in a padded envelope. This protects the vaccine from breakage, light, prevents direct contact with ice packs and reduces the variability of the temperature close to the vaccine.
 - The envelope should be labeled with the name of the vaccine, lot number and expiry date.
 - To maintain the vaccine temperature between 2-8° C refrigerate the diluent prior to packaging. Wrap both the diluent and the vaccine and place in the same envelope.

5.1 PACKING AN INSULATED CONTAINER

Figure 6: Packing Shipping Containers

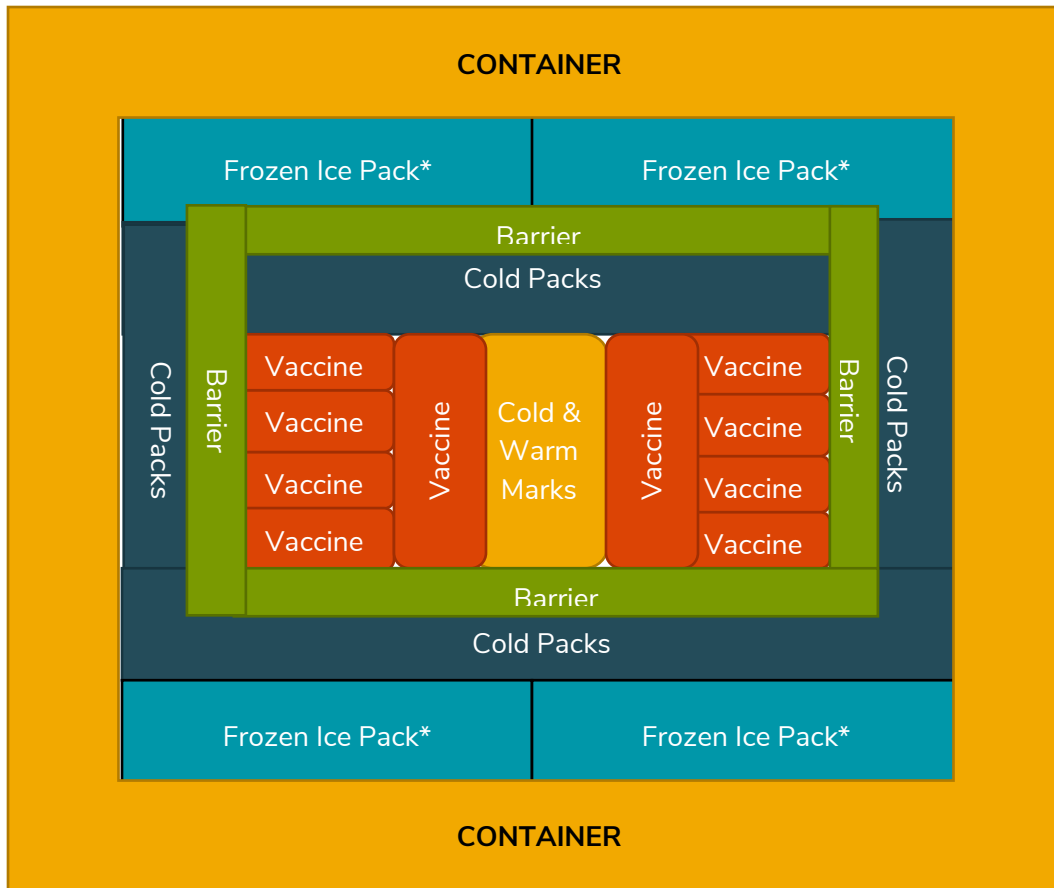


Figure 6 shows an example of how a shipping container can be packed (2).

Note that packing configurations may vary according to time of year, length of shipment, and jurisdiction. Frozen ice packs do not need to be used in the winter season.

5.2 INSULATED CONTAINERS

- Insulated containers (coolers) are used to transport quantities of vaccine off-site during one working day, or to store quantities of vaccine needed for immunization onsite during a working day, thus avoiding frequent opening of the refrigerator.
- The cooler must be able to maintain vaccine temperature between +2°C to +8°C during transport and throughout clinics.
- The temperature inside the cooler is maintained with ice/gel packs, and insulating materials.
- The cooler should meet the following criteria:
 - large enough to store vaccines, ice/gel packs, and insulating materials during transport;
 - external surface material is strong and durable;
 - lid is tight fitting.

5.3 ICE PACKS/GEL PACKS

- Keep enough frozen ice packs and/or refrigerated gel packs (at +2°C to +8°C) ready to meet the vaccine transport needs of your clinic or health unit.
- Set ice packs on their edge and allow space between them for air circulation in the freezer. Stacking ice packs on top of each other in the freezer may result in uneven or partial freezing, and decrease the efficacy of the ice packs.
- Ensure that ice packs are completely frozen before use.

5.4 INSULATING MATERIALS

- Insulating materials are used as a barrier to prevent direct contact between vaccines and frozen ice packs.
- Insulating materials include blue pads, flexible insulating blankets and gel packs at refrigerator temperature, bubble wrap, crumpled packing paper or Styrofoam peanuts.
- A layer of paper toweling is not sufficient as a barrier to protect vaccines from contact with frozen material.

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