



COVID-19 VACCINE SHIPPING, RECEIVING AND HANDLING GUIDELINES

Department of Health and Community Services, Public Health Branch
Government of Newfoundland and Labrador

This document is meant to provide guidance on the storage and transport of COVID-19 vaccine throughout the province of Newfoundland and Labrador. The table below provides a quick reference guide, more detailed information on transport preparation for each vaccine is provided below.

	Pfizer-BioNTech Comirnaty XBB.1.5 containing mRNA Vaccine			Moderna Spikevax XBB.1.5 containing mRNA Vaccine
Product Distinction and Age Authorization	Maroon cap 6 months – 4 years of age	Blue cap 5 – 11 years of age	Grey cap 12 years of age and older	Royal blue cap with coral blue label 6 months of age and older
Dosage	3mcg (0.2mL)	10mcg (0.3mL)	30mcg (0.3mL)	25mcg (0.25mL) for individuals 6 months to 11 years of age. 50mcg (0.5mL) for individuals 12 years of age and older.
Storage	Ultra frozen until expiry. Do not store vials at -25°C to -15°C. Refrigerator (2°C to 8°C) for 10 weeks. Room temperature: no more than a total of 12 hours before first puncture and no more than 12 hours after first puncture Do not refreeze once thawed.			Frozen (-50°C to -15°C) until expiry Refrigerated (2°C to 8°C) for up to 30 days prior to first use. Room temperature (8°C to 25°C) for up to 24 hours unpunctured. Once punctured use within 24 hours. Do not refreeze once thawed.
Transport (More detailed information on preparing for transport is noted below table)	Before puncture: If local redistribution is needed, full cartons containing unpunctured vials may be transported at -90°C to -60°C; full cartons or individual unpunctured vials may also be transported at 2°C to 8°C.			Before puncture: Frozen transport preferred at -50°C to -15°C. Refrigerated at 2°C to 8°C for up to 12 cumulative hours in qualified containers permitted.

	Pfizer-BioNTech Comirnaty XBB.1.5 containing mRNA Vaccine			Moderna Spikevax XBB.1.5 containing mRNA Vaccine
Product Distinction and Age Authorization	Maroon cap 6 months – 4 years of age	Blue cap 5 – 11 years of age	Grey cap 12 years of age and older	Royal blue cap with coral blue label 6 months of age and older
Transport Cont.	After puncture: There is not enough data to support transportation of open vials and loaded syringes.			After puncture: Open vials and syringes may be transported at 2°C to 25°C for up to 24 hours.
Reconstitution	Reconstitution is required with 2.2 mL sterile 0.9% Sodium Chloride	No reconstitution required.		No reconstitution required.
Syringe and Needle Selection	Preferentially use a low dead space (LDS) syringe and/or needle. 22- to 25-gauge needle is preferred for administration. If LDS syringe is not available, a 1cc syringe should be utilized.			
Product Presentation	After dilution, multi-dose vial (10 doses) preservative-free	Multi-dose vial (6 doses) preservative-free.		Multi-dose vial – number of doses contained in the vial would depend on dosages used (minimum of 5 doses of 50mcg, maximum of 10 doses of 25mcg).

Pfizer-BioNTech Comirnaty COVID-19 Vaccine

The person handling the vaccine in the thermal shipper should be appropriately trained on the use of appropriate personal protective equipment for [managing dry ice](#) (eye protection and appropriately insulated gloves, and their skin should be covered).

Upon receipt of the thermal shipper, it should be inspected, and the data logger stopped by pressing and holding the stop button for 5 seconds (directions may defer with some data loggers, check information provided with the thermal shipper for accuracy). Stopping the data logger will trigger an email from the manufacturer providing a record of the temperature of the shipment and indicate if there have been any concerns with temperature excursions during transit. Verification that vaccine has

been cleared for use will be provided by the manufacturer via email to the vaccine depot clerk. If not received, check with the Provincial Communicable Disease Registered Nurse Specialist.

Under extenuating circumstances, the thermal shipper can be used to store vaccine. If using the thermal shipper for storage, replenish the dry ice upon receiving the vaccine and then up to five additional times, 5 days apart for up to a total of 30 days. A new data logger is required to monitor the temperature after stopping the data logger that came with the thermal shipper during initial transport. A mechanism should be put into place to record the appropriate dates and times related to storage in the thermal shipper and dry ice replenishments.

When finished with the thermal shipper, the dry ice should be left to sublimate in an open, well-ventilated area. The thermal shipper must be returned to the manufacturer with the data logger that came with it within 30 days of receipt of the shipment.

THAWING

1. Ensure that appropriate personal protective equipment (thermal gloves or tongs) is used when touching products in the ultra-low temperature (ULT) freezer.
2. Only thaw sufficient numbers of vials that are expected to be used in the required time frame. Do not refreeze thawed product. Thaw vaccine based on the recommendations noted in the table above.
3. The date and time brought into room temperature or the refrigerator should be recorded so that product is not used beyond the appropriate time.

AVOIDING WASTAGE

Only thaw vaccine that is expected to be used within the appropriate time frames for storage at 2-8 degrees as noted above. Only dilute vaccine if expected to be used within the appropriate timeframe following dilution. Have a plan to administer any vaccine that may be nearing the time period beyond when it can be used.

TRANSPORTATION

The recommended transportation of Pfizer/BioNTech vaccine is from the ULT freezer or thermal shipper to a vaccine cooler or credo cube which maintains temperature at +2°C to +8°C to allow vaccine to thaw during transport (Note: this form of transportation would not require a cold mark sheet). Do not transport vials that have been diluted.

The **temperature must be maintained and recorded** during transport; also record the transportation locations, dates and times, including the duration of time in transit.

In extenuating circumstance and with consultation with HCS, Pfizer/BioNTech can be transported in ultra low frozen form using dry ice and thermal shippers.

Pfizer/BioNTech Vaccine: Preparation for Transport

Supplies required for vaccine transport:

(1) Credo cube with panel or vaccine cooler. Vaccine cooler can also be used for transportation of less than 1 hour and space for 4-5 chill packs.

(2) TempTale or Vaccine Thermometer if TempTale unavailable

(3) Container to store vaccine in upright position

(4) Insulation (i.e., Bubble wrap or paper to place around vaccine container). These are used to keep Pfizer/BioNTech vaccine taken out of a tray in an upright position. Options could include a plastic container (i.e., Tupperware) or small cardboard box. Paper or paper towel can be used for cushioning/insulation. Note that Credo Cube maximum size is 11"x11"x11"

(5) Warm mark sheet

(6) Cold mark sheet if transporting vaccine already maintained at +2°C to +8°C

(7) Ice packs & chill packs if transporting in vaccine cooler (note: most credo cubes do not require ice packs or chill packs, please check manufacturing guidelines). Chilled packs can be placed in direct contact with the box containing the vaccine and then a layer of paper is placed between the frozen packs and container.

(8) Shipping Labels

(9) Diluent, if not shipped directly to vaccine depot

At least 24 hours prior to the anticipated transport of vaccine:

- Condition the vaccine cooler by placing it in the vaccine fridge.

- If using a credo cube for transport, ensure the appropriate measures are taken to maintain vaccine temperatures.
 - Credo Cube specifications (could vary depending on type of credo cube):
 - The white TIC panels must be frozen so no liquid can be heard inside the panel.
 - Needs to be in freezer for minimum of 24 hours.
 - The panels should then be removed from the freezer for 40 minutes to bring the temperature up to 4 degrees Celsius. Panels should be placed on a rack that will allow air flow around the panel.
 - A panel is then placed on the bottom of the Credo, four more around the sides and one on top with the insulator panel placed on the TIC panel last.
 - The payload area is 12"x12"x12", a square cardboard box is ideal.

- Condition TempTales by chilling the TempTale inside a fridge to bring it to +2°C to +8°C. Storage of a few TempTales inside a vaccine regulated fridge will ensure quick access to a conditioned TempTale.

Day of transport:

- 15-45 minutes prior to departure, sweat frozen ice packs by taking ice pack out of freezer until condensation appears on the pack.
- Prepare warm and/or cold mark sheet(s) (Cold mark sheet should be used if transporting vaccine already maintained at +2° C to +8° C. It is not needed for transporting frozen vaccine). Refer to manufacturing guidelines to ensure warm and cold marks are appropriately stored.
- Prepare return label and label identifying destination address.
- If vaccine diluent is stored at the same location, ensure adequate vaccine diluent is packaged separately for transport. Diluent can be stored and transported at room temperature.
- If using a vaccine cooler for transport, Gel Packs that have been stored in the fridge at +5° C are needed. Gel Packs do not require sweating.

Prepare vaccine for transport:

- Remove the appropriate number of vials to cover the number of doses required from the storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). **Vaccine will begin to thaw if left at room temperature beyond 5 minutes. It is important to ensure vaccine is appropriately packaged within this timeframe.**
- Place vials in a container that will maintain vaccine in an upright position during transport. Some jostling is expected during transport but cushioning of the vials is paramount to avoid excessive jostling which could cause breakage in transit. Firmly inserting paper among the vials would be the best action.
- Remove the TempTale from the vaccine fridge. Start the TempTale as per manufacturer guidelines then add to the credo cube or vaccine cooler. TempTales should be programmed to a 30-minute delayed start time. If a TempTale is not available, place vaccine thermometer inside the vaccine cooler. The data logger or thermometer is placed as deep inside the bulk of vaccine to prevent the logger from coming in contact with the ice packs.
- Add warm mark sheet (and cold mark if required) inside the container of vaccines next to the TempTale before cover is placed on it. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport.
- Add 4-5 chill packs to vaccine cooler used for transport. If using credo cubes, chill packs and ice packs may not be necessary.
- Add the vaccine to the credo cube or cooler.
- Add 4-5 ice packs to the vaccine cooler.
- Place cover on vaccine cooler with return label and the address of the destination.

Moderna Spikevax COVID-19 vaccine

Upon receipt of the thermal shipper, it should be inspected, and the data logger stopped by pressing and holding the stop button for 5 seconds. Stopping the data logger will trigger an email from the manufacturer providing a record of the temperature of the shipment and to indicate if there have been any concerns regarding the temperature in transit. Verification that Moderna vaccine is cleared for use will be provided by the manufacturer via email to the vaccine depot clerk. If not received, check with the Provincial Communicable Disease Registered Nurse Specialist.

THAWING

1. The date and time removed from freezer to room temperature OR date and time removed from freezer to refrigerator AND refrigerator to room temperature should be recorded (not on vial) so that product is not used beyond the appropriate time.
2. Once the product has been thawed, it **can not be refrozen**.

AVOIDING WASTAGE

Only thaw vaccine that is expected to be used within the appropriate time frames for storage at 2-8 degrees as noted above. Have a plan to administer any vaccine that may be nearing the time period beyond when it can be used.

TRANSPORTATION

The recommended transportation of Moderna vaccine is from the freezer to a vaccine cooler or credo cube which maintains temperature at +2°C to +8°C to allow vaccine to thaw during transport (Note: this form of transportation would not require a cold mark sheet). Moderna can also be transported in frozen form (-25°C to -15°C; can be as cold as -40°C) in a credo cube regulated for temperatures as low as -40°C.

The **temperature must be maintained and recorded** during transport; also record the transportation locations, dates, and times, including the duration of time in transit.

VACCINE TRANSPORT FOR HOME BOUND CLIENTS

Individuals who are home bound and unable to attend a clinic setting should have access to vaccine. Moderna vaccine can be transported to offer vaccine to home bound clients. Punctured vials or prefilled syringes can be transported using the guidelines for transporting vaccine noted above. As a TempTale can be very sensitive, the use of a warm mark and cold mark with a thermometer can be utilized when transporting vaccine for home bound clients. Planning of vaccine utilization to home bound clients must be considered to avoid wastage.

Moderna Vaccine: Preparation for Transport

Supplies required for vaccine transport:

- (1) Credo cube with panel or vaccine cooler

Vaccine cooler can also be used for transportation for less than 1 hour.

(2) TempTale or Vaccine Thermometer if TempTale unavailable

(3) Container to store vaccine in upright position

(4) Insulation (i.e., Bubble wrap or paper to place around vaccine container). These are used to keep Moderna vaccine taken out of a tray in an upright position. Options could include a plastic container (i.e.: Tupperware) or small cardboard box. Paper or paper towel can be used for cushioning/insulation. Note that Credo Cube maximum size is 11"x11"x11"

(5) Warm mark sheet

(6) Cold mark sheet if transporting vaccine already maintained at +2°C to +8°C

(7) Ice packs & chill packs if transporting in vaccine cooler (note: most credo cubes do not require ice packs or chill packs, please check manufacturing guidelines)

Chilled packs can be placed in direct contact with the box containing the vaccine and then a layer of paper is placed between the frozen packs and container.

(8) Shipping Labels

At least 24 hours prior to the anticipated transport of vaccine:

- Condition the vaccine cooler by placing it in the vaccine fridge.
- If using a credo cube for transport, ensure the appropriate measures are taken to maintain vaccine temperatures.
 - Credo Cube specifications (could vary depending on type of credo cube):
 - The white TIC panels must be frozen so no liquid can be heard inside the panel.
 - Needs to be in freezer for minimum of 24 hours.
 - The panels should then be removed from the freezer for 40 minutes to bring the temperature up to 4 degrees Celsius. Panels should be placed on a rack that will allow air flow around the panel.
 - A panel is then placed on the bottom of the Credo, four more around the sides and one on top with the insulator panel placed on the TIC panel last.
 - The payload area is 12"x12"x12", a square cardboard box is ideal.
- Condition TempTales by chilling the TempTale inside a fridge to bring it to +2°C to +8°C. (Note: Storage of a few TempTales inside a vaccine regulated fridge will ensure quick access to a conditioned TempTale.)

Day of transport:

- 15-45 minutes prior to departure, sweat frozen ice packs by taking ice pack out of freezer until condensation appears on the pack.
- Prepare warm and/or cold mark sheet(s) (Cold mark sheet should be used if transporting vaccine already maintained at +2° C to +8° C. It is not needed for transporting frozen vaccine). Refer to manufacturing guidelines to ensure warm and cold marks are appropriately stored.

- Prepare return label and label identifying destination address.
- If using a vaccine cooler for transport, Gel Packs that have been stored in the fridge at 5° C are needed. Gel Packs do not require sweating.

Prepare vaccine for transport:

- Remove the appropriate number of vials to cover the number of doses required from storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). **Vaccine will begin to thaw if left at room temperature beyond 5 minutes. It is important to ensure vaccine is appropriately packaged within this timeframe.**
- Place vials in a container that will maintain vaccine in an upright position during transport. Some jostling is expected during transport but cushioning of the vials is paramount to avoid excessive jostling which could cause breakage in transit. Firmly inserting paper among the vials would be the best action.
- Remove the TempTale from the vaccine fridge. Start the TempTale as per manufacturer guidelines then add to the credo cube or vaccine cooler. TempTales should be programmed to a 30-minute delayed start time. If a TempTale is not available, place vaccine thermometer inside the vaccine cooler. The data logger or thermometer is placed as deep inside the bulk of vaccine to prevent the logger from coming in contact with the ice packs.
- Add warm mark sheet (and cold mark if required) inside the container of vaccines next to the TempTale before cover is placed on it. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport.
- Add 4-5 chill packs to vaccine cooler used for transport. If using credo cubes, chill packs and ice packs may not be necessary.
- Add the vaccine to the credo cube or cooler.
- Add 4-5 ice packs to the vaccine cooler.
- Place cover on vaccine cooler with return label and the address of the destination.

Preparing prefilled syringes of Moderna vaccine for transport to home bound clients:

- Remove the appropriate number of vials to cover the number of doses required from storage unit (ultra-low freezer, regulated vaccine fridge or thermal shipper). If vaccine is in frozen form, allow 2.5 hours at +2° C to +8° C or 1 hour at room temperature for time to thaw.
- Using aseptic technique, withdraw the number of doses needed to complete arranged home visits for vaccination. If an entire vial is not utilized, date and time of puncture must be clearly marked on the vaccine vial, and it should be stored immediately in a regulated vaccine fridge.
- Using a cooler large enough to store the vaccine or prefilled syringes and 4-5 chill packs, pack items for transport and cover appropriately.

- Place the prefilled syringes into the vaccine cooler used for transport. Prefilled syringes should be cushioned into place to limit the amount of jostling during transit. Inserting paper among the prefilled syringes would be the best action.
- Add a thermometer inside the container next to the prefilled syringes. If a thermometer is not available, a cold mark and warm mark can be used. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport. Temperatures must be maintained at +2° C to +25° C for up to 24 hours.
- Place cover on vaccine cooler. Prefilled syringes must be utilized within 6 hours of when source vial was punctured.
- If it is recognized that not all the prefilled syringes or vaccine arranged to be administered that shift will be used every effort should be made to use any vaccine remaining in pre-filled syringe.

THERE IS NO GUIDANCE AT THIS TIME FOR PREFILLED SYRINGES FOR OTHER COVID-19 VACCINES

Other COVID-19 Vaccine Authorized for Use in Canada

Nuvaxovid COVID-19 Vaccine

Storage

Unopened vials of Nuvaxovid vaccine should be stored in a vaccine-regulated refrigerator between +2°C to +8°C to a maximum of nine months. Vaccine should be stored in its original packaging to protect from light. Nuvaxovid vaccine cannot be frozen. Once punctured, Nuvaxovid vaccine can be stored between the temperatures of +2°C to +25°C and is considered stable for a maximum of 6 hours. Remaining vaccine in a vial must be discarded 6 hours after its first puncture.

Transportation

Vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring device should be utilized as well as a warm mark and cold mark. Punctured vials can also be transported and must follow the stability requirements mentioned above.

AstraZeneca/COVISHIELD COVID-19 Vaccine

This vaccine is currently not available for use in Canada.

STORAGE

AstraZeneca/COVISHIELD vaccine should be stored at +2°C to +8°C until its expiry date. Once punctured, AstraZeneca/COVISHIELD vaccine is stable for:

- 24 hours at room temperature (up to +25°C).
- 48 hours in a refrigerator at +2°C to +8°C.

- An opened vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 24 hours, and the total cumulative storage time must not exceed 48 hours.

TRANSPORTATION

AstraZeneca/COVISHIELD vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring device should be utilized as well as a warm mark and cold mark. Punctured vials can also be transported and must follow the stability requirements mentioned above.

Janssen COVID-19 Vaccine

This vaccine is currently not available for use in Canada.

Storage

Janssen vaccine can be stored frozen at -25°C to -15°C until its expiry date identified on the carton. Janssen vaccine can also be stored at +2°C to +8°C for 6 months, but no longer than the expiry date identified on the carton. The vial must be kept in the original package in order to protect from light during storage. Janssen vaccine cannot be refrozen. Once punctured, Janssen vaccine is considered stable at +2°C to +25°C for 3 hours. Janssen vaccine is also considered stable at +2°C to +8°C for 6 hours, but only if not exposed to room temperatures. If stored refrigerated after the first puncture, the vaccine can be moved to room temperature for brief periods of time for dose withdrawal. This does not impact the maximum 6-hour stability period in the refrigerator.

Transportation

Vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring device should be utilized as well as a warm mark and cold mark (if shipping in frozen form, a cold mark would not be required). Punctured vials can also be transported and must follow the stability requirements mentioned above.

Covifenz COVID-19 Vaccine

This vaccine is currently not available for use in Canada.

Storage

Unopened vials of Covifenz antigen and adjuvant should be stored in a vaccine regulated refrigerator at +2°C to +8°C. Covifenz is considered stable in this form until the shortest expiry date noted on the vials (or carton), to a maximum of 6 months. Covifenz vaccine cannot be frozen. Once antigen and adjuvant are mixed, the vaccine must be stored at room temperature (+20°C to +30°C) and be used within 6 hours. Once reconstituted, the vaccine cannot be refrigerated.

Transportation

Vaccine can be prepared for shipment and transported in a vaccine container that maintains temperatures at +2°C to +8°C. A temperature monitoring device should be utilized as well as a warm mark and cold mark. Punctured vials cannot be transported.

Important Considerations for COVID Vaccines

- Health care providers receiving the vaccine should be made aware of the time vaccine was removed from the ultra-low freezer or vaccine fridge as well as the expected time of arrival to their facility. If there is a temperature excursion above +8°C, this time will be used to calculate the timeframe vaccine may have been exposed to room temperature and if the vaccine remains safe for use.
- Planning should consider the availability of fridges or freezers at the vaccine destination.
- Back up plans should be in place in case there is a temperature excursion to vaccinate as many people as possible in shelf-life timeframe to ensure no vaccine is wasted.
- Plans should consider frequent shipments with less vaccine so that vaccine can be administered within appropriate timeframes.
- Frozen COVID-19 vaccine can be removed from a freezer to a container regulating temperatures at +2°C to +8°C (or to room temperature under specified timelines), but it cannot be re-frozen.
- For vaccine stored in a vaccine cooler bag for a clinic setting, temperature should be monitored with a vaccine thermometer and/or warm/cold mark. If a vaccine thermometer is not available, a TempTale can be utilized but minimizing opening of the cooler bag should be considered due to the sensitivity of the TempTale.
- When preparing all COVID-19 vaccines for transport, care should be taken into the correct placement of TempTales in the transporting container. TempTales are very sensitive and can record temperature fluctuations that may not necessarily indicate a temperature excursion and subsequent cold chain break.
- When vaccine has been transported or stored in a vaccine cooler bag in a clinic environment and a TempTale identifies a temperature excursion, it is important to consider all possible contributing factors prior to determining if a cold chain break occurred. Downloading and reviewing the temperature recordings of the TempTale during transit as well as considering if a warm/cold mark was activated during transit should be considered when determining if an actual cold chain break has occurred.
- RHAs can consult with the Provincial Communicable Disease Control Registered Nurse Specialist (mirandaodriscoll@gov.nl.ca) if questions arise related to cold chain breaks. External vaccine providers should contact the Provincial Disease Control Registered Nurse Specialist if a cold chain break has occurred to determine if vaccine is still safe for use.