Ontario

Ministry of Health

COVID-19: Vaccine Storage and Handling Guidance

Version 1.0 – September 05, 2025

Highlights of changes:

- Merge of COVID-19 vaccine storage and handling guidance chapters into one document
- Simplification of the guidance material

This guidance provides basic information only. It is not intended to provide medical advice, diagnosis or treatment, or legal advice.

Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document.

The intended audience for this guidance document includes pharmacies, health care providers, distribution centers, hospitals, and public health units that are:

- Storing, distributing and/or administering COVID-19 vaccines;
- Involved in the assessment of temperature excursions, including the vaccine return process;
- Providing education for the storage and handling of ultra-low temperature (ULT) and low-temperature (LT) frozen vaccines and the use of temperature monitoring devices, such as data loggers.

Failure to adhere to vaccine handling and cold chain requirements may increase local reactions at the site of the vaccine administration.

The loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent, and irreversible.

Public health units, distributors and pharmacies should also follow the:

- Vaccine Storage and Handling Protocol, 2018[1]; and
- Individual product monographs on the Government of Canada website. Health care providers should also follow the:
    - Vaccine Storage Handling Guidelines;

[1] Please note Ontario Boards of Health must comply with Ontario Public Health Standards including the Vaccine Storage and Handling Protocol, 2018.

  - Your local public health unit;
  - The Vaccine Supply and Logistics (VSL) unit at vaccinesupplyandlogistics@ontario.ca, if you have already consulted with your public health unit and have further questions;
  - The Vaccine Program, Planning and Performance unit at vacpro@ontario.ca

- Pfizer-BioNTech: https://www.cvdvaccine.ca/
- Moderna: https://modernacovid19global.com/ca/
  - Vial expiration checker: Moderna (modernacovid19global.com)
  - Temperature excursion calculator

Pharmacists to review the following:

- EOC Notices Ontario Public Drug Programs — Executive Officer Communications | ontario.ca
- Pharmacy Playbook OPA Today: Pharmacy Playbook for COVID-19 Vaccine Administration | Ontario Pharmacists Association
- ***Note:** Some of the information in this document is **not** intended for pharmacy stores (i.e., receiving vaccines, freezer information). Pharmacists are to adhere to the EOC notices prepared by the Pharmacy Initiatives and Blood Services Unit. This document is intended only to provide pharmacists with general supplementary information regarding COVID-19 vaccine storage and handling.

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Initial Set-Up of ULT and Freezer Storage Units for COVID-19 Vaccine Products

- All ULT and freezer storage units that will be storing the COVID-19 vaccine are required to be set up so that temperatures are stabilized at the recommended temperature range specified by the manufacturer prior to placing any vaccine into the unit.
- Monitor and document minimum and maximum temperatures for 2 to 7 consecutive days to ensure storage unit stability is appropriate for vaccine storage.
- Please see the following for details:
- Individual product monographs on the Government of Canada website.

Inspections

Facilities storing COVID-19 vaccine in ULT or freezer storage units should ensure that annual inspections (including temperature calibration) and regular maintenance of all ULT or freezer storage units is completed by a certified company. A copy of these inspections from facilities may be requested to ensure that vaccine storage and handling conditions are being adhered to.

Monitoring Vaccine Storage Unit Temperatures at the Point of Distribution

Monitoring vaccine storage equipment and temperatures is a daily responsibility to ensure the safety of the vaccine supply. Facilities should implement routine monitoring activities to identify out-of-range temperatures quickly and take immediate action to correct them to prevent any loss of vaccines. The Vaccine Storage Handling Guidelines, 2021 (or as current) provides details and requirements for monitoring vaccine storage units.

Each facility that receives COVID-19 vaccines should follow the section below on Temperature Excursions in the event of adverse storage conditions for COVID-19 vaccines.

Please note that while the Temperature Log Book identifies refrigerated vaccines, it can also be used for ULT and freezer storage units, twice daily monitoring is required regardless of having continuous systems in place.

Data Loggers

For information on data logger requirements, please refer to the Vaccine Storage and Handling Protocol, 2018 (or as current).

Vaccine Transport

General

Caution should be taken to minimize shaking or agitation of the vaccine during transport due to the fragility of the products, as advised by the manufacturers.

During Vaccine Storage Unit Malfunction/ Electricity Disruption at the Point of Storage

When a malfunction occurs, the facility should follow the steps outlined in the Vaccine Storage and Handling Protocol, 2018 (pages 26-27) and the Vaccine Storage and Handling Guidelines, 2021 (pages 18-19). Note that the protocol and guidelines indicate refrigerated vaccines however the process is the same for frozen vaccines.

Temperature Excursion and Damaged Product

Regardless of what point in the vaccine cold chain (e.g., transport, storage, clinic site etc.) a temperature excursion or product damage occurs, steps should be taken to ensure the appropriate management of the affected vaccine.

Note: vaccine viability and final disposition are determined in consultation with the public health unit and the manufacturer's identified primary contact.

General principles: Incident based temperature excursion and damaged product management processes

Process Steps	Temperature Excursion and Damaged Product Management
Step 1	Quarantine the vaccine in appropriate temperature- controlled conditions, & document the excursion or damaged product in COVaxON
Step 2	Health Care Providers and Pharmacies are to report to their local PHU and include: • The date, time, temperatures (maximum, minimum and current temperature) and the details on the excursion (e.g., length of time); or damage and • Attach the temperature log sheets and photos of the damage (if applicable) The PHU will consult the appropriate vaccine manufacturer (MFG)/ primary contact
Step 3	Follow the PHU direction regarding vaccine viability and disposition. The facility storing the vaccine will mark vaccines involved in a temperature excursion/damage that have been determined to be usable, in order to identify them in case of a future exposure(s).
Step 4	The site at which the excursion or incident occurred will document the outcome in COVaxON (e.g., report wastage) & appropriately dispose of waste (see Appendix B). PHU's are responsible for ensuring the outcome was appropriately documented in COVaxON. If an excursion/incident occurred during transportation from the Manufacturer or the provincial distribution center, the PHU will report the incident to the VSL Unit at: vaccinesupplyandlogistics@ontario.ca (see Appendix A). At the discretion of the PHU, incidents/excursions resulting in large wastage values or the need for an urgent replacement order may also be reported to VSL.

Temperature excursion reporting when vaccine has been in the custody of a distributor or public health unit:

Facilities storing the COVID-19 vaccine should undertake the following if the vaccine storage units (e.g., purpose-built, insulated container(s)) were unable to maintain the required temperatures (temperature excursion):

- When using two or more temperature monitoring devices/systems, determine which will be designated as the primary device/system;
    - Record the maximum, minimum and current temperature and download any data from the storage unit or data logger and save as a PDF file;
    - Download the PDF file to a computer from the data logger;
    - Save this file using standardized file format naming, including the vaccine product, location and date (e.g., Templog_Pfizer_UHN_12- 14-2020; Templog_Moderna_WECHU_12-25-2020).
- In the event that two or more temperature monitoring devices/systems are used, do not average or round the temperature data points. When submitting temperature data, ensure that data from the primary device/system is identified.
- PHUs are to follow the Temperature Excursion Management – Process Steps as outlined above.

Stabilizing Temperatures in New and Repaired Purpose-built Vaccine Storage Units

- For repaired vaccine storage units that experienced a power outage, the vaccine temperatures should be stabilized within the recommended temperature range as specified by the vaccine manufacturer prior to placing vaccine back into the unit; and
- Prior to storing vaccine in new purpose-built storage units, the temperatures should be stabilized within the recommended range as per the vaccine manufacturer. Monitor and document minimum and maximum temperatures for 2 to 7 consecutive days to ensure storage unit stability is appropriate for vaccine storage.

Receipt of Vaccine

Notes:

- Health care provider sites will receive vaccine in a thawed or thawing state, pharmacies and health care providers are to only store vaccine in refrigerated temperatures (e.g., +2ºC to +8ºC).
- Pfizer-BioNTech Comirnaty pre-filled syringes are stored at +2ºC to +8ºC only and are NEVER to be frozen.

When receiving the vaccine at storage sites or clinic sites that will be storing the COVID- 19 vaccine, the receiving sites should:

- Designate one person as the lead for the facility who will be an authorized receiver of the vaccine delivery. This individual should ensure that standard operating policies and procedures related to vaccine storage and handling are in place and are followed.
- Check vaccine expiry dates regularly and after every vaccine order.
    - Remove expired vaccines and dispose of them appropriately (see Appendix B). Record as wastage in COVax$_{ON}$ (see Vaccine Wastage and Returns section below).
- Use the Vaccine Storage Handling Guidelines, 2021 (or as current) to educate and instruct health care providers who store publicly funded vaccines.
- Immediately open all of the transport containers and assess the digital temperature monitoring device(s).
    - Products should be quarantined until all necessary steps have been completed to confirm successful transport (e.g., temperature during transport, condition of product received).
- Examine the shipment for evidence of damage. Quarantine the product immediately if damaged. See section above on Product Damage.

Preparation for Immunization Clinics

Just in Time Vaccine Delivery

- Ensure that only the number of doses of the vaccine needed for the clinic are removed from the storage unit to prevent any unnecessary transport and potential wastage.
- PHUs and distributors should transport Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccines in frozen state (with the exception of Pfizer-BioNTech Comirnaty pre-filled syringes). The vaccines should be thawed at the clinic location according to manufacturer specifications and stored at +2°C to +8°C. Be sure to mark and keep track of the date and time of delivery using a system

that works for your staff.

- Visually inspect the digital temperature monitoring device (i.e., for the temperature, any damage, etc.) each time the insulated container is opened.
- Minimize the number of times that the insulated container is opened during the immunization clinic.

Vaccine Wastage and Returns

- Vaccine doses wasted due to expiration, or damage should not be returned to the local public health unit/the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) and should be disposed of according to local, provincial and/or federal regulations (see Appendix B). However, they should be recorded in COVax$_{ON}$ as wastage. Follow the COVax$_{ON}$ Inventory Job Aid for direction on inventory reconciliations. See Appendix C for COVax$_{ON}$ documentation categories.

Onward Transport of COVID-19 Vaccines beyond the Initial Point of Delivery

For this document, transport refers to taking the vaccine from one site to another using a vehicle on ground, air or water.

This document provides a range of options related to the transport and movement of the vaccine. The operational plan should be tailored to local circumstances, with collaboration sites and public health units.

If possible, air and water transport should be done in a frozen state (with the exception of Pfizer-BioNTech Comirnaty pre-filled syringes). For ground transport at +2^{o}C to +8^{o}C only:

- If applicable, it is recommended that the vaccine is packaged for delivery in a frozen state to be transported to the clinic/facility location using an insulated cooler (e.g., Playmate), that has been preconditioned to a refrigerated temperature of +2^{o}C to +8^{o}C.
- Product should be sent for ‘just in time use’ as part of a planned vaccination clinic versus movement for secondary storage at another facility.
- It is recommended that the vaccine is only transported at +2^{o}C to +8^{o}C once. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2^{o}C to +8^{o}C more than once, per recommended practices, ensuring the following:
    - The cold chain has been properly monitored and documented;
    - There is documentation that captures details at the individual vial level (e.g., labels on vials);

- Vials are packed in order to minimize movement and agitation.

General Precautions for Frozen and Liquid State Transport of the Vaccine

- The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.
- The transport container should be labelled prominently with “Fragile: Handle with Care, Do Not Drop” cautionary statements.
- Vials should be stored in an upright position (i.e., standing up) during transport.
- The transport containers should be secured (strapped/braced) when being transported to prevent unnecessary movement.
- The vaccine should be protected from being dropped.
- Any set of cartons/vials should not be subject to repeated instances of transport, except under exceptional circumstances as noted above. If a carton/vial has been on a transfer once, it should not be sent out again and instead be used at the site, even if the vial has not been in transit for the maximum allowable period. This is a precautionary measure since it will be difficult to keep track of the transportation time “used up” for any specific vial. The vaccine should be transported by staff who are trained in the transport of vaccines or other products requiring cold chain monitoring. The use of courier companies can be considered, but they should specialize in cold chain transport (e.g., bonded and contracted companies). The courier should have systems in place for tracking and monitoring vaccines and the ability to deliver the vaccines to prevent excessive movement or agitation.

The Following Recommendations are to be Considered for the Onward Distribution of Unopened Vials of COVID-19 Vaccine:

- Transport containers should be packed as per the recommendations/specifications for the container (e.g., credo cubes, Stirling coolers).
- Follow the configuration in Vaccine Storage and Handling Guidelines, 2021 Instructions on How to Pre-Condition and Pack an Insulated Container.
- Transport in the largest configuration wherever possible (e.g., box), avoiding individual vial transportation, while considering the minimum number of doses needed at the onward location to avoid wastage.
- Prevent movement in the cooler by surrounding it with dunnage (padding material) inside the container to minimize product movement during transport.
- If transport is conducted at vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product (e.g., wrap the vial in bubble wrap and place it into a medication/pill bottle).
- Keep the vaccine vials upright and protect the vaccine vials from light.

- Label the cooler as “Fragile: Handle with Care, Do Not Drop” and indicate that the contents are temperature sensitive.
- The pack out should be secured in the vehicle so that it does not move around. As much care as possible should be taken to minimize extra movement in the thawed state. The vaccine should be protected from being dropped. Never place the cooler in the trunk of a vehicle.
- The temperature should be maintained and recorded for the duration of the transport per temperature range, ensuring that the transportation locations, dates and times, including the duration of time in transit are recorded.
    - A data logger or minimum-maximum thermometer should be used to monitor temperatures.
    - Download the data logger/record minimum-maximum temperatures as soon as possible to ensure no “unwitnessed” excursions occurred while in transit.
- Upon receipt at onward location, the vaccine should be inspected, inventoried and immediately placed into vaccine fridge, noting the date and time of the vaccine delivery on the storage unit temperature log.
- If the vaccine is to be used for a vaccination clinic immediately then the vaccine should be prepared and used as per the manufacturer’s specifications.
- Do not transport the vaccine at room temperature.
- **Do not refreeze previously frozen vaccine.**

In exceptional circumstances, when transporting a pre-drawn syringe containing a **COVID-19 vaccine**, the following parameters should be considered and adhered to:

- A single dose of vaccine should be transported in a pre-drawn syringe.
- Special attention should be paid to handling and packaging of the syringe to prevent contamination.
- The syringe should be protected from light.
- There should be a tamper evident seal on the pre-drawn syringe or container during transport between locations.
- The pre-drawn syringes and the container should be labeled, identifying information to prevent errors during storage, dispensing, transport, and use. See Appendix D for syringe and vial label examples.
- The syringe should be packed appropriately in a conditioned cooler (transport container) at +2^{o}C to +8^{o}C and the temperature monitored during transport.
    - Note: The vaccine in the syringe can be at ambient temperature, maximum of +25^{o}C. The vaccine should not be at a temperature below +2^{o}C.

- A barrier of bubble wrap or corrugated cardboard (at least 1 inch) may be utilized as a barrier between ice packs and the container with pre-drawn syringes. This is to prevent direct contact between pre-drawn syringes and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.
- The syringe should be packed to cushion it and to protect it from agitation.
- A designated staff member or specialized courier in cold chain transport (e.g., bonded and contracted companies) should be used to transport the syringe. The cooler/transport container should be:
    - Handled with care and protected from shocks, drops and vibration.
    - Labeled prominently with “Fragile: Handle with care, Do Not Drop” cautionary statements.
    - Secured (strapped/braced) during transport.
- An appropriate chain of custody should be in place for the syringe during all phases of transport.
- If the information regarding the beyond use date and total transport time, or the tamper evident seal, or ability to track the syringe in any way is in question, the vaccine should not be administered and documented as wasted.
- Upon receipt of the syringe, it should be visually inspected to confirm that the full dose remains, there is no damage and that there are no particulates or discolouration.
- If the syringe(s) will not be administered by staff from the originating site, the originating site should confirm with the receiving site all details of the transport, as per above, plus confirmation that administration will be completed at the receiving site by onsite personnel.

Ontario

Storage and Handling of COVID-19 Vaccine Formulations Available in Ontario

Table 1. Storage and Handling for COVID-19 vaccine Formulations Available in Ontario

Vaccine Name	**Moderna Spikevax**			**Pfizer-BioNTech Comirnaty**		
Formulation	Multi-Dose Vial (MDV): 6 months < 12 years of age	Multi-Dose Vial (MDV): 12 years of age and older	Pre-Filled Syringe (PFS): 12 years of age and older	Multi-Dose Vial (MDV): 12 years of age and older	Single-Dose Vial (SDV): 5 - 11 years of age	Pre-Filled Syringe (PFS): 12 years of age and older
Dosage	10 doses per vials	5 doses per vial	1 dose per syringe	6 doses per vial	1 dose per vial	1 dose per syringe
Frozen Prior to Use	Store at frozen temperature, -15°C to -50°C until printed expiry date or otherwise noted.			Store at ultra-low temperature freezer at -60°C to -90°C until printed expiry date or otherwise noted.		N/A – DO NOT FREEZE THIS PRODUCT
Thawed Unpunctured Vials/syringes	Thawed vials/pre-filled syringes may be stored in the fridge between +2°C to +8°C for a single period of up to 50 days (not exceeding expiry). The 50-day refrigerated expiry date should be recorded on the carton at the time of transfer. Thawed vials and syringes may be stored between +8°C to +25°C for up to 12 hours.			Thawed vials may be stored in the fridge between +2°C to +8°C for a single period of up to 10 weeks (not exceeding expiry). The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Thawed vials may be stored at room temperature (up to +25ºC) for a total of 12 hours prior to first puncture.		Pre-filled syringes may be stored in the fridge between +2°C to +8°C until the expiration date printed on the carton and syringe labels.

Vaccine Name	Moderna Spikevax		Pfizer-BioNTech Comirnaty		
Thawed Punctured MDVs	If punctured vial is stored between +2°C to +8°C, discard after 24 hours post-puncture. If punctured vial is stored between +8°C to +25°C, discard 12 hours after first dose has been withdrawn. Record the date and time of first use on the vial label. If product is drawn into a syringe, the dose in the syringe should be used as soon as feasible and in accordance with storage requirements.	N/A	After first puncture, the vial should be stored between +8°C to +25°C. Vials should be discarded 12 hours post-puncture. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.	N/A	After removing the tip cap and attaching an appropriate needle, the prefilled syringes should be used immediately. If it cannot be used immediately, it must be used within 4 hours.

Table 2. Thawing COVID-19 Vaccines

Vaccine Name	Moderna Spikevax			Pfizer-BioNTech Comirnaty		
Formulations	MDV: 6 months < 12 years of age	MDV: 12 years of age and older	PFS: 12 years of age and older	MDV: 12 years of age and older	SDV: 5 – 11 years of age	PFS: 12 years of age and older

Vaccine Name	Moderna Spikevax		Pfizer-BioNTech Comirnaty		
Thawing in a refrigerator	Thawing 2.5mL vials in a refrigerator at +2ºC to +8ºC takes 2 hours	Thawing an individual syringe at +2ºC to +8ºC takes 1 hour and 40 minutes. Thawing a carton of 10 syringes at +2ºC to +8ºC takes 2 hours and 40 minutes.	Thaw in the refrigerator at +2ºC to +8ºC. A carton of 10 vials may take up to ***6 hours*** to thaw and thawed vials can be stored in the refrigerator for up to 10 weeks.	Thaw in the refrigerator at +2ºC to +8ºC. A carton of 10 vials may take up to ***2 hours*** to thaw and thawed vials can be stored in the refrigerator for up to 10 weeks.	N/A – DO NOT FREEZE THIS PRODUCT
Thawing at room temperature	Thawing 2.5mL Vials in room temperature at +15ºC to +25ºC takes 45 minutes.	Thawing an individual syringe at +15ºC to +25ºC takes 40 minutes. Thawing a carton of 10 syringes at +15ºC to +25ºC takes 1 hour and 20 minutes. Syringes should not be returned to the fridge after being thawed at room temperature.	If not previously thawed at +2ºC to +8ºC, allow vial(s) to thaw at room temperature (up to +25ºC) for 30 minutes.		N/A - DO NOT FREEZE THIS PRODUCT

Notes:

- After thawing, let vials sit at room temperature for 15 minutes before administering.
- Do not re-freeze vials after thawing.

Swirl the vial gently and between each withdrawal. **Do not shake.**

Table 3. Transport Conditions for COVID-19 Vaccines

Vaccine Name	**Moderna Spikevax**			**Pfizer-BioNTech Comirnaty**		
Formulations	MDV: 6 months < 12 years of age	MDV: 12 years of age and older	PFS: 12 years of age and older	MDV: 12 years of age and older	SDV: 5 years - 11 years of age	PFS: 12 years of age and older

Vaccine During Transport (by vehicle on ground, air or water)	• Frozen state -15°C to -50°C.
	  ○ **If not possible**, then at +2ºC to +8ºC
	• Transportation of vials in the liquid state cannot exceed more than 36 hours. Do not refreeze.
	• Time counts toward the 50-day storage limit.
	• Do not pack thawed vaccine that is at +2ºC and +8ºC with frozen vaccine.
	• Store upright and protect from light.
	• Label as fragile.
	• Protect from shocks, drops, vibration, etc.
				• Transport in ULT.
				• **If ULT not possible**, transport between +2ºC to +8ºC.
				  ○ This time counts toward the 10-week storage limit.
				• Do not pack vaccine that is between +2ºC and
				  +8ºC with frozen vaccine.
				• Store upright and protect from light.
				• Label as fragile.
				• Protect from shocks, drops, vibration, etc.
				No data is available regarding the stability of punctured vials or pre-drawn syringes during transportation.
						• Transport between **+2ºC to +8ºC only**.
						• Do not pack with frozen vaccine.
						• Label as fragile.
						• Protect from shocks, drops, vibration, etc.

Vaccine Name	Moderna Spikevax	Pfizer-BioNTech Comirnaty	
Transportation in Syringes	When at all possible, it is recommended that Moderna's COVID-19 vaccine be transported in an unpunctured vial and that the entire vial be administered in one location rather than transporting pre-drawn syringes. In exceptional circumstances, vaccine may be transported in a syringe whilst careful attention is taken to ensure vaccine safety. The vaccine does not contain a preservative, therefore special attention should be given to handling and packaging of the syringe to prevent contamination. Exceptional circumstances may include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations).	Whenever possible, it is recommended that COVID-19 vaccine be transported in an unpunctured vial and that the entire vial be administered in one location rather than transporting syringes filled with vaccine. In exceptional circumstances, diluted (if applicable) vaccine may be transported in a syringe. The vaccine does not contain a preservative, therefore special attention should be given to handling and packaging of the syringe to prevent contamination. Exceptional circumstances may include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations).	N/A – see above for Pfizer-BioNTech Comirnaty PFS transportation.

See Appendix E for types of mRNA expiration and other product dating examples

Rounding Principles

Based on information from vaccine manufacturers; COVID-19 vaccines at refrigerated temperatures may be rounded to the nearest whole degree:

- Temperatures between +1.5°C and +1.9°C are rounded to +2.0°C
- Temperatures between +8.1°C and +8.4°C are rounded to +8.0°C

COVID-19 vaccines exposed to temperatures between +1.5°C and +8.4°C are considered to be in refrigerated temperatures and the incident does not need to be recorded as a temperature excursion and entered in COVAXON. Troubleshooting should occur to ensure that temperatures are corrected and maintained between +2°C to +8°C.

Appendix A: Contact Information and Reporting Format for Temperature Excursions or Damaged Products

Organization	Primary Contact	Secondary Contact	Hours of Operation
Pfizer Customer Service	mailto:CanadaCSVaccine@pfizer.com	1-800-463-6001	09:00 – 17:00 EST (M-F)
Moderna	mailto:excursions@modernatx.com **or** Temperature Excursion Tool | Moderna	1-866-663-3762	08:00 – 20:00 EST (M-F)
Vaccine Supply and Logistics Unit, Ministry of Health	vaccinesupplyandlogistics@ontario.ca	N/A	09:00 – 17:00 EST (M-F)

Reporting Format

If the vaccine undergoes a temperature excursion or is damaged during transportation from the Manufacturer or Federal/Provincial third-party logistics, the PHU should email the VSL Unit using the following the reporting format:

Date of Incident:	
Vaccine Delivery Site (VDS) Location:	
Vaccine Name:	
Lot Number:	
Expiry Date or Manufacture Date:	
Doses Impacted:	
Manufacturer Recommendations:	
Wastage (number of doses or indicate no wastage):	
Impact on local vaccination efforts:	

Subject line Examples:

Incident	Subject Line
Temperature excursion from manufacturer	Delivery Temp Excursion Report from [PHU – location of incident]
Temperature excursion when in the custody of a vaccine service provider (e.g., hospital, PHU, Pharmacy)	FPT Delivery Temp Excursion Report from [PHU – location of incident]
Product is damaged	COVID-19 Vaccine Damage Report from [PHU – location of incident]

If the request is urgent, include ‘URGENT’ in the email subject line.

Appendix B: Vaccine Vial and Packaging Disposal

Vials, either empty or with vaccine remaining, should be disposed of per regulation and guidelines by the Ministry of the Environment and Climate Change:

- Environmental Protection Act, R.S.O. 1990, c. E.19 | ontario.ca
- C-4: The management of biomedical waste in Ontario | ontario.ca
- Registration guidance manual for generators of liquid industrial and hazardous waste | ontario.ca

Further details can be found in the Vaccine Storage Handling Guidelines, 2021.

Appendix C: COVax$_{ON}$ Wastage Categories

Closed Vial Wastage

Wastage Type	Wastage Code
Damaged Doses	• DE – Defective Product – Manufacturer • WR – SVM – Suspected Vaccine Contamination - Manufacturer • DP – OS – Damaged Product • DP – TAO – Damaged product during transport within PHU or between Authorized Organizations
Expired Doses	• WR – BE – Vaccine vial stored in ult/freezer/fridge temperatures beyond expiry date • WR – RB – Fridge Stable (2 – 8 degrees C) Vaccine Vial Refrigerated beyond use time
Temperature Excursions	• TE – Human Error – Electricity disruption • TE – Human error – Improper storage • TE – Temperature monitoring failure • TE – Cold storage equipment malfunction • TE – Power outage • TE – CCTM – Cold chain failure during transport from manufacturer • TE – CCTDC – Cold chain failure during transportation from distribution center • TE – RF – Vaccine vial refrozen after being thawed • WR – TT – Vaccine transported in thawed state beyond manufacturer recommendations

Open Vial Wastage

- WR - VA - Vaccine Administration Issue
- WR - VAS - Vaccine Ancillary Supply Issue Causing Vaccine Wastage
- WR - ID - Insufficient Dose(s) From a Single/Multi-Dose Vial
- WR - Dose(s) Remaining in a Multi-dose vial
- WR - UN - Unused Pre-drawn Syringe
- WR - RP – Vaccine vial punctured and not used before beyond use time
- WR - SV - Suspected Vaccine Contamination – Human error
- TE – F - Fridge Stable (2 - 8 degrees C) vaccine vial frozen
- WR - RA – Vaccine vial left in room temperature conditions beyond use time

Appendix D: Vial and Syringe Label Examples

Example of Vial Label:

[Trade Name */age range* (doses per

Lot # [XXXXX] **EXP: [YYYY/MM/DD]**

Refrigerated on: [Full Date]

Must Use By: [Full Date]

Puncture Date: [Full Date and

Example of Pre-Drawn Syringe Label:

Trade Name COVID-19 Vaccine <insert age indication>

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

Appendix E: Types of mRNA Expiration and Other Product Dating

Dating Types	Descriptions	*Details and Examples
Expiration Date	The date in which a product remains viable under specific conditions • mRNA products must remain in frozen/ULT state to be viable at the time of expiration	Expiration dates are documented in COVaxON. Some products contain the expiration date on the vial/carton. Some products have extended expiration dates beyond what is on the carton, always confirm expiration date in COVaxON.
Transport Date / Time Limit	mRNA products should be transported in frozen temperatures. If not possible, then transport in fridge temperatures (+2ºC to +8ºC). Transport in fridge temperatures cannot exceed more than the fridge temperature storage limits. Note: Time counts toward the BUD.	The product cannot be transported for longer than 36- hours in fridge temperature (+2°C to +8°C): Transport time begins on July 31, 2024, at 10:00, the product cannot be transported past August 1, 2024, at 22:00
Beyond Use Date (BUD) / Must Use By Date	The date in which mRNA products remain viable once removed from frozen state and remain unpunctured. The BUD should be recorded on the vaccine box. Note: The beyond-use date (BUD) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date has passed.	The product is viable for 50-days from the date of removal from frozen to refrigerator temperature (+2°C to +8°C) if unpunctured: • Removed from freezer on July 31, 2024, the BUD is Sept. 18, 2024 The product is viable for 12-hours at room temperature (+8°C to +25°C) if unpunctured: • Removed from freezer or fridge on July 31, 2023, at 08:00, the BUD is July 31, 2023 at 20:00
Post-Puncture Time	The time in which mRNA products remain viable once the multi-dose vial has been punctured. The post-puncture date/time should be recorded on the vial label. Note: The post-puncture date/time replaces the manufacturer and BUD dates but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or BUD has passed.	The product must be discarded 24-hours post-puncture if in refrigerator temperature (+2°C to +8°C): • Punctured at 08:00 July 31, 2024, must be discarded at 08:00 August 1, 2024 The product must be discarded 12-hours post-puncture if in room temperature (+8°C to +25°C): • Punctured at 08:00 on July 31, 2024, must be discarded at 20:00 on July 31, 2024

Notes:

- Provider must adhere to whichever date/time comes first

*The examples provided do not represent accurate time periods. Please see each product shelf-life and storage conditions details to determine the appropriate dates/times for each scenario.