

Ministry of Health

Chapter 2: Storage and Handling of Moderna COVID-19 Vaccines

Version 6.0 –September 24, 2024

Highlights of Changes

- Updated KP.2 Formulation Storage and Handling

The scope for this chapter includes information pertaining to the storage and handling of Moderna's COVID-19 Vaccines. The intended audience for this guidance document includes all health care providers (HCP) 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 frozen vaccines and the use of temperature monitoring devices, such as data loggers.

Additional resources available:

- Moderna: <https://modernacovid19global.com/ca/>
- [COVID-19 Vaccine Storage and Handling Guidelines](#)
- [Vaccine Storage Handling Guidelines](#);
- Individual product monographs on the [Government of Canada website](#).
- Vial expiration checker: [Moderna \(modernacovid19global.com\)](#)
- [Temperature excursion calculator](#)

In addition, health care providers and organizations who have questions should contact their [local public health unit](#) or the ministry of health at vaccinesupplyandlogistics@ontario.ca

Table 1. Moderna formulation of the SPIKEVAX[®] vaccine authorized for use and available in Canada:

SPIKEVAX[®] KP.2 Variant
See the COVID-19 Vaccine Administration Guidance
 0.1 mg/mL (2.5mL multi-dose vial) 6 months of age and older

Storage and Handling of Moderna COVID-19 Vaccines

Table 2. Storage and Handling for the Moderna COVID-19 XBB Vaccine

Storage Condition	KP.2
Frozen Vials Prior to Use	<ul style="list-style-type: none"> Can be stored frozen between -50°C to -15°C until the expiry date. Do not store on dry ice or below -50°C.

Storage Condition	KP.2
<p>Thawed, Unpunctured vials</p> <p>Note: HCPs receive vaccine in a thawed or thawing state. Vaccine cannot be refrozen.</p>	<ul style="list-style-type: none"> • Unpunctured vials may be stored in the refrigerator between +2°C to +8°C for up to 50 days prior to first use. • Unpunctured vials may be stored at room temperature (+8°C to +25°C) for up to 12 hours. • During storage, protect vials from light. • Do not refreeze thawed vials.
<p>Thawed, Punctured Vials</p>	<ul style="list-style-type: none"> • 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.

Rounding Principles

Based on information from Moderna; 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

Moderna 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 COVAX_{ON}. Troubleshooting should occur to ensure that temperatures are corrected and maintained between +2°C to +8°C.

Thawing

Table 3. Thawing of the Moderna KP.2 COVID-19 Vaccine

Thawing conditions	KP.2
Thawing in refrigerator +2°C to +8°C	2.5 mL vials take: 2 hours
Thawing at room Temperature +15°C to +25°C	2.5 mL vials take: 45 minutes
<p>Notes:</p> <ul style="list-style-type: none"> • 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. 	

Types of mRNA Expiration and Other Product Dating

Table 4. mRNA Expiration and Other Product Dating

Date/Time Types	Descriptions	Details and Examples
Expiration Date	<p>The date in which a product remains viable under specific conditions</p> <ul style="list-style-type: none"> • mRNA products must remain in frozen state (-50°C to -15°C) to be viable at the time of expiration 	<p>Expiration dates are documented in COVaxON. Some products contain the expiration date on the vial/carton.</p> <p>Some products have extended expiration dates beyond what is on the carton, always confirm expiration date in COVaxON.</p>

Date/Time Types	Descriptions	Details and Examples
Transport Date / Time Limit	<p>As feasible, mRNA products should be transported in frozen temperatures (-50°C to -15°C). If not possible, then transportation in refrigerator temperatures (+2°C to +8°C) are permitted.</p> <p>Transportation of vials in refrigerated temperatures cannot exceed more than 36 hours.</p> <p>Note: Time counts toward the 50-day BUD.</p>	<p>The product cannot be transported for longer than 36-hours in refrigerator temperature (+2°C to +8°C):</p> <p>Transport time begins on July 31, 2024, at 10:00, the product cannot be transported past August 1, 2024, at 22:00</p>
Beyond Use Date (BUD) / Must Use By Date	<p>The date in which mRNA products remain viable once removed from frozen state and remain unpunctured.</p> <p>The BUD should be recorded on the vaccine box.</p> <p>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.</p>	<p>The product is viable for 50-days from the date of removal from frozen to refrigerator temperature (+2°C to +8°C) if unpunctured:</p> <p>Removed from freezer on July 31, 2024, the BUD is September 18, 2024</p> <p>The product is viable for 12-hours at room temperature (+8°C to +25°C) if unpunctured:</p> <p>Removed from freezer or fridge on July 31, 2023, at 08:00, the BUD is July 31, 2023 at 20:00</p>

Date/Time Types	Descriptions	Details and Examples
Post-Puncture Time	<p>The time in which mRNA products remain viable once the multi-dose vial has been punctured.</p> <p>The post-puncture date/time should be recorded on the vial label.</p> <p>Note: The post-puncture date/time replaces the manufacturer and BUD dates but NEVER extends it.</p> <p>Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use date has passed.</p>	<p>The product must be discarded 24-hours post-puncture if in refrigerator temperature (+2°C to +8°C):</p> <p style="padding-left: 40px;">Punctured at 08:00 July 31, 2024, must be discarded at 08:00 August 1, 2024</p> <p>The product must be discarded 12-hours post-puncture if in room temperature (+8°C to +25°C):</p> <p style="padding-left: 40px;">Punctured at 08:00 on July 31, 2024, must be discarded at 20:00 on July 31, 20234</p>

Note: Provider must adhere to whichever date/time comes first

Example of Vial Label:

[Brand Name /age range (doses per vial)]	
Lot # [XXXXX]	EXP: [YYYY/MM/DD]
Refrigerated on: [Full Date]	
Must Use By: [Full Date]	
Puncture Date: [Full Date and time]	

Transport Conditions for Moderna COVID-19 Vaccines

Table 4. Vaccine transport by storage condition.

Storage Condition	KP.2
Vaccine During Transport (by vehicle on ground, air, or water)	<ul style="list-style-type: none"> • Frozen state -50°C to -15°C. <ul style="list-style-type: none"> ○ If not possible, then at +2°C to +8°C • 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 +2°C and +8°C with frozen vaccine. • Store upright and protect from light. • Label as fragile. • Protect from shocks, drops, vibration, etc.
Syringe Transport	<p>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 syringes filled with vaccine.</p> <ul style="list-style-type: none"> • However, while not suggested as routine practice, in exceptional circumstances, vaccine may be transported in a syringe whilst careful attention is taken to ensure vaccine safety. • For further details on syringe transport please visit the COVID-19 Vaccine Storage and Handling Guidance

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).

Moderna recommends that their vaccine be shipped in a frozen state as per the product monograph and specifications additional shipping instruction is outlined in the product monograph.

Example of pre-drawn syringe and container labels:

Moderna SPIKEVAX COVID-19 Vaccine IM suspension

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

Transport Scenarios

The following scenarios may assist with planning for the onward transport of the vaccine.

Scenario 1: Ground Transport between Locations or Facilities

Transport from one public health unit to a congregate living setting.

Transport in an insulated hard-shell cooler may be carried out using a car, van or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Avoid sudden movements/braking as much as possible.

Scenario 2: Medium and Long Duration Ground PLUS Air Transport

Transport is recommended in the frozen state. If the transport can only be done at +2°C to +8°C, a limit of 36 hours total time is applied.

Scenario 3: Short Duration Movement within a Facility or Campus

Movement of the vaccine that is stored at a long-term care home but needs to be walked over to an attached retirement home (e.g., on the same campus/property).

Movement in an insulated hard-shell cooler using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked only, no running).

Following general precautions described above, such movement may be conducted for a short period (i.e., up to 15 minutes).

Vaccine Storage Post-Temperature Excursion or Unit Malfunction

Follow the temperature excursion process steps outlined in the [General COVID-19 Vaccine Storage and Handling guidance](#). If the vaccine was placed in a portable freezer unit (-50°C to -15°C), the vaccines can go back into a freezer unit. To the extent possible, vials should be kept in the boxes during transport. If this is not possible, any individual vials need to be securely stored (not rolling around) in the storage device. If the Moderna was stored in a portable -20°C freezer unit (and not thawed), return to a purpose-built

freezer unit.

- If placed in an insulated container for +2°C to +8°C temperature range, the vaccines should go back into a refrigerator and not be refrozen.
 - o **Note:** If the vaccines do not need to be discarded due to a temperature excursion, these doses need to be used within 50 days, minus any time in the container.

If an alternative storage facility cannot be identified within a reasonable timeframe, place the vaccine in the ULT/freezer portable unit and/or insulated containers with appropriate packaging material and digital temperature monitoring devices and record the temperature at the facility by:

- Labelling the insulated containers; and
- Continuing to monitor the temperatures inside the insulated container at 30- minute intervals using a temperature monitoring device that allows temperature viewing without opening the insulated container (e.g., in/out thermometer).