Ontario

Ministry of Health

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

Version 5.0 –December 22, 2023

Highlights of Changes

- Removal of Moderna's original monovalent and bivalent formulations

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 formulations of the SPIKEVAX® vaccine authorized for use and available in Canada include:

Royal Blue Cap (with coral label border) **XXB.1.5**
See the COVID-19 Vaccine Administration Guidance
 25 mcg/0.25 mL OR 50 mcg/0.5 mL (do not dilute)

Storage and Handling of Moderna COVID-19 Vaccines

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

Storage Condition	**Royal Blue Cap**
Frozen Vials Prior to Use	• 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	Royal Blue Cap
Thawed, Unpunctured vials **Note:** HCPs receive vaccine in a thawed or thawing state**.** Vaccine cannot be refrozen.	• Unpunctured vials may be stored in the refrigerator between +2°C to +8°C for up to 30 days prior to first use. • Vials may be stored at room temperature (+8°C to +25°C) for up to 24 hours. ○ Any time spent within this range is cumulative. The 24-hour countdown starts as soon as the unpunctured vial is removed from refrigerator. The countdown stops when unpunctured vial is returned to the refrigerator, however, unpunctured vial time spent at room temperature must be tracked. • During storage, protect vials from light. • Do not refreeze thawed vials.

Thawed, Punctured Vials	• Punctured vials must be held between +2°C to +25°C and discarded 24 hours after first puncture.
	  ○ 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, time spent at room temperature while unpunctured must be tracked and included in the 24-hour maximum.
	• 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 no later than 24 hours after the vial was first punctured.

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.

Vial Punctures

Moderna states that there is no maximum number of punctures indicated for the XBB.1.5 formulation. If there is additional content remaining in the vial, providers are able to access remaining vial contents to obtain a full dose. For guidance on accessing multiple vials, review the General COVID-19 Vaccine Storage and Handling Guidance on accessing multiple vials to obtain a full dose.

For more information visit: https://modernacovid19global.com/ca/

Thawing

Table 3. Thawing of the Moderna XBB COVID-19 Vaccine

Thawing conditions	**Royal Blue Cap**
Thawing in refrigerator	2.5 mL vials, Royal Blue cap: 2 hours
Thawing at room Temperature	2.5 mL vials, Royal Blue cap: 45 minutes
Note: After thawing, let vials sit at room temperature for 15 minutes before administering.	

Transport Conditions for Moderna COVID-19 Vaccines

Table 4. Vaccine transport by storage condition.

Storage Condition	Royal Blue Cap

Vaccine During Transport
(by vehicle on ground, air, or water)
	• Frozen state -50°C to -15°C.
	• **If not possible**, then
	  ○ at +2°C to +8°C
	  ▪ Transportation of vials in the liquid state cannot exceed more than 12 hours
	  ▪ Time counts toward the 30-day storage limit
	• Exposure at +8°C to +25°C is permitted for up to 24 hours.
	• 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	• While not recommended as routine practice, in exceptional circumstances a single dose of Moderna vaccine may be transported in a syringe whilst careful attention is taken to ensure vaccine safety. • It is not recommended to transport punctured vials. • For further details on syringe transport please visit the COVID-19 Vaccine Storage and Handling Guidance

Transportation of Syringes Containing Moderna COVID-19 Vaccine

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.

However, while not suggested as routine practice, in exceptional circumstances, diluted (if applicable) vaccine maybe 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).

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 (24 hours after puncture):

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 a Playmate 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.

Such transport may be conducted for up 12 hours.

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 12 hours total time is applied. If the transportation is by road and air, a limit of 3 hours by air and 9 hours by road is recommended.

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 a Playmate 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

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.
    - **Note**: If the vaccines do not need to be discarded due to a temperature excursion, these doses need to be used within 30 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).