Ministry of Health

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

Version 2.2 – September 22, 2022

### Highlights of Changes

- Age indications and dosage per cap colour added
- Additional guidance on bivalent vial punctures added

The scope for this chapter includes information pertaining to the storage and handling of Moderna’s COVID-19 Vaccines.

**Table 1. Moderna formulations of the SPIKEVAX® vaccine authorized for use in Canada include:**

<table>
<thead>
<tr>
<th>Red Cap (with light blue label border)</th>
<th>Royal Blue Cap (with purple label border)</th>
<th>Royal Blue Cap (with green label border)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For primary series, for ages:</td>
<td>• For primary series, for ages:</td>
<td>• <strong>Eligibility as per COVID-19 Vaccine</strong></td>
</tr>
<tr>
<td>o 6 to 11 years (50mcg, 0.25mL)</td>
<td>o 6 months to &lt; 5 years (25mcg,</td>
<td>Guidance</td>
</tr>
<tr>
<td>o 12 years+ (100mcg, 0.5mL)</td>
<td>0.25mL) and,</td>
<td></td>
</tr>
<tr>
<td>• For booster doses for ages 18 years and older (50mcg, 0.25mL)</td>
<td>o 6 years to 11 years (50mcg, 0.5mL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For booster doses, for ages 18 years or older (50mcg, 0.5mL)</td>
<td></td>
</tr>
<tr>
<td>5mL, 0.2mg/mL</td>
<td>2.5mL, 0.1mg/mL</td>
<td>2.5mL, 0.1mg/mL</td>
</tr>
</tbody>
</table>
Health care providers and organizations should also follow the:

- Direction from the manufacturer’s site: https://modernacovid19global.com/ca/
- COVID-19 Vaccine Storage and Handling Guidelines
- Vaccine Storage Handling Guidelines;
- Individual product monographs on the Government of Canada website.

In addition, health care providers and organizations who have questions should contact their local public health unit or the ministry of health at vacpro@ontario.ca

### Storage and Handling of Moderna’s COVID-19 Vaccines

### Storage and Handling

#### Table 2. Storage and Handling for Moderna COVID-19 Vaccines

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Red Cap and Royal Blue Caps</th>
</tr>
</thead>
</table>
| 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 |
| Thawed, Unpunctured Vials | • 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 between +8°C to +25°C for up to 24 hours  
• During storage, protect vials from light.  
• Do not refreeze thawed vials. |
| Thawed, Punctured Vials | • After the first dose has been withdrawn the vial should be held between +2°C to +25°C for a maximum of 24 hours.  
• Record the date and time of first use on the vial label  
• Vaccine from the red cap or royal blue cap may be stored in a syringe or vial for a maximum of 24 hours. |
Vial punctures

Moderna states not to puncture its vials more than:

- 10 times for the 2.5mL vial (Royal blue cap, purple border)
- 20 times for the 5mL (Red cap, light blue border).
- There is no maximum number of punctures indicated in the bivalent product (Royal blue cap, green border) monograph
  - 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.

Note: if the vial stopper has been punctured 10 or 20 times respectively, discard the vial and its contents. Moderna has confirmed there is overfill in its product; once the puncture limit has been reached, the vial and remaining contents are to be discarded.

To track punctures of each vial you may use the vial puncture chart found here: https://eua.modernatx.com/covid19vaccine-eua/providers/vial-puncture-tracker.pdf

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

Thawing

Table 3. Thawing Moderna's COVID-19 Vaccines

<table>
<thead>
<tr>
<th>Thawing conditions</th>
<th>Red Cap &amp; Royal Blue Caps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thawing in refrigerator</td>
<td>2.5 mL vials, Royal Blue caps: 2 hours</td>
</tr>
<tr>
<td></td>
<td>5 mL vials, Red cap: 2 h 30 minutes</td>
</tr>
<tr>
<td>Thawing at room Temperature</td>
<td>2.5 mL vials, Royal Blue caps: 45 minutes</td>
</tr>
<tr>
<td></td>
<td>5 mL vials, Red cap: 1 hour</td>
</tr>
</tbody>
</table>

Note: After thawing, let vials sit at room temperature for 15 minutes before administering.
Transport Conditions for Moderna COVID-19 Vaccines

Transport time vaccine movement should not exceed 12 hours of cumulative time. This includes a limit of 3 hours by air and 9 hours by road should be adhered to.

Table 4. Vaccine transport by storage condition.

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Red Cap and Blue Cap</th>
</tr>
</thead>
</table>
| 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  
  ▪ 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 |

Transport of Open-Vials or Syringes Containing Moderna COVID-19 Vaccine

Moderna recommends that their vaccine be shipped in a frozen state as per the product monograph and specifications.

While not recommended as routine practice, in exceptional circumstances a single dose of Moderna vaccine may be transported in a syringe.
• Exceptional circumstances could 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). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.
• It is recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the mRNA in the vaccine is more likely.

Example of pre-drawn syringe and container labels:

<table>
<thead>
<tr>
<th>Moderna SPIKEVAX COVID-19 Vaccine (100 mcg/0.5 mL) IM suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility name and phone number:</td>
</tr>
<tr>
<td>Quantity of syringes:</td>
</tr>
<tr>
<td>Date prepared &amp; Time to discard (24 hours after puncture):</td>
</tr>
<tr>
<td>Lot #:</td>
</tr>
<tr>
<td>Initials of preparer:</td>
</tr>
</tbody>
</table>

**Transport Scenarios**

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

**Scenario 1: 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).
Scenario 2: 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 3: 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.

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).