

	Name of Activity: Transportation of Moderna Spikevax® Vaccine in Frozen or Thawed State		
	Role Performing Activity: Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, Indigenous Services Canada, Ministry of Health		
WORK STANDARD	Location: COVID-19 Immunization Manual		Department: Population Health Branch
	Document Owner: Vaccine Management Team		Region/Organization where this Work Standard originated: Ministry of Health Population Health Branch
	Date Prepared: 2021-01-20	Last Revision: 2025-09-18	Date Approved:

Work Standard Summary: This work standard outlines the guidelines for transportation of:

- Moderna Spikevax® (0.1mg / mL), Multidose Vial (MDV)
- Moderna Spikevax® (50 mcg / 0.5 mL) Single-dose Pre-filled Syringe

Essential Tasks:	
1.	Transportation Recommendations <ul style="list-style-type: none"> • Moderna's recommendation is to transport their COVID-19 vaccine in a frozen state (-50°C to -15°C) but allow the vaccine to be transported in a thawed state, subject to additional transportation precautions outlined in this work standard. • When the required cold chain equipment is not available for frozen transport, the vaccine can be transported in a thawed or thawing state as outlined in this work standard. • In exceptional circumstances Moderna Spikevax® may be transported in an open vial as outlined in this work standard.
2.	<ul style="list-style-type: none"> • For additional information on vaccine storage and handling, refer to: <ul style="list-style-type: none"> ➤ <i>COVID-19 Vaccine Storage and Handling and Cold Chain Break Procedures work standard</i> found on the COVID-19 Immunization Manual webpage. ➤ The Saskatchewan Immunization Manual, Chapter 9: Management of Biological Products https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf
3.	Guidelines for Transporting Moderna Spikevax® in a Frozen State <ul style="list-style-type: none"> • Transport vaccine between -50°C to -15°C in the original carton/box. • Vaccine must be shipped in a validated shipping container (i.e. intended to transport frozen vaccine or drugs), such as a Credo Cube™. DO NOT use dry ice. <ul style="list-style-type: none"> ➤ Assemble and condition the shipping container according to manufacturer instructions. ➤ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze Vaccine Immediately on Arrival).

	<ul style="list-style-type: none"> ➤ Label the shipping container with a cautionary statement pertaining to fragility (e.g. “FRAGILE- HANDLE WITH CARE”). ➤ A data logger is placed at the centre of the shipping container and programmed to alert cold chain excursions colder than -50°C and warmer than -15°C. ➤ Additional vaccine packing information is outlined in #5. • Upon arrival at the destination, immediately place in a temperature monitored freezer between -50°C to -15°C or in a temperature monitored refrigerator between 2°C to 8°C. NOTE: Moderna vaccines are stable for up to 50 days in the refrigerator between 2°C to 8°C. It is important to record the date and time the vaccine is removed from the freezer. • Immediately analyze the data logger for cold chain excursion outside of -50°C to -15°C. If a cold chain excursion occurred, follow the Ministry of Health’s cold chain management work standard: Vaccine Storage & Handling and Cold Chain Break Procedures for COVID-19 Vaccines.
4.	<p>Guidelines for Transporting Moderna Spikevax® in a Thawed State (+2°C to +8°C) NOTE: The 50-day stability timeline in a thawed state begins once Moderna vaccine is removed from the freezer. ONCE THAWED, DO NOT REFREEZE.</p> <p>Open Vial Transport:</p> <ul style="list-style-type: none"> • Transportation of punctured MDV of Moderna Spikevax® COVID-19 vaccines is permitted in exceptional circumstances to reach clients who cannot attend an immunization clinic and when there are not enough individuals to immunize to use a full vial of vaccine at an off-site location. • Open/punctured vials must be stored at the appropriate temperature (+2°C to +8°C): <ul style="list-style-type: none"> ○ and must be used within 24 hours. ○ The guidelines for transporting thawed vaccine must be applied to open vial transport as outlined in this work standard. • Transport thawed vaccine at between 2°C to 8°C. <ul style="list-style-type: none"> ➤ Place the vaccine directly from the freezer or refrigerator into a vaccine insulated container/cooler. Follow local/organizational work standard for packing the vaccine bag. Record the date and time vaccine is removed from the freezer. <ul style="list-style-type: none"> ○ The container must be able to maintain vaccine between 2°C to 8°C for at least the duration of the intended transport. ○ A label stating DO NOT REFREEZE must be on the transport container. ○ A label stating FRAGILE- HANDLE WITH CARE or equivalent must be on the transport container. NOTE: It is acceptable to transport vaccine while thawing during transport (i.e. when vaccine is placed directly from freezer into container/cooler), however ensure not to refreeze thawed vaccine. ➤ Place vials in an upright position. ➤ Take measures to ensure thawed vaccine does not come into contact with any frozen-packs within the container. ➤ Transport vaccine in the original carton/box whenever possible. The carton should be surrounded by bubble wrap or paper inside the container to minimize product/carton movement during transport. <ul style="list-style-type: none"> ○ For transportation of single or multiple vials (out of the carton/box), refer to #5.

	<ul style="list-style-type: none"> ➤ Add a temperature monitoring device to the centre of the cooler. <ul style="list-style-type: none"> ○ It is strongly recommended to use a data logger for temperature monitoring. Program the device to alert cold chain excursions under 2°C and over 8°C. ○ If a data logger is not available, a minimum/maximum thermometer may be used. It is important to manually reset the minimum and maximum temperatures to the current temperature immediately prior to being used for transport. ➤ See #5 below for additional vaccine packing information. ● Cumulative transport time¹ must be less than 36 hours. In addition, the 36 hours is subtracted from the 50 day stability timeline between 2°C to 8°C. <ul style="list-style-type: none"> ➤ Tracking and recording the total transport time is required. Keep the records on file in the event of needing to further transport the vaccine. <ul style="list-style-type: none"> ○ Utilize a transport time tracking form to document total transport time from the time of pick-up of the vaccine until the time of delivery at point of administration site. A sample tracking form is included in Appendix A. ○ Develop a site process to identify the vials that have been transported and the cumulative transport time. ● Special precautions must be taken during vaccine transport to prevent excessive movement, jostling and vibrations. <ul style="list-style-type: none"> ➤ The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc. ➤ Container must be secured (strapped/braced) when being transported to prevent unnecessary movement. ➤ Travel distance should be as short as possible. ➤ Ground transport should be conducted on paved or smooth gravel/dirt roads. Forest or gravel roads are generally not suitable for transporting this vaccine. ● Upon arrival to storage site, immediately place the vaccine in a temperature monitored refrigerator between 2°C and 8°C. DO NOT REFREEZE. ● Immediately analyze the temperature monitoring device for a cold chain excursion outside of 2°C to 8°C. ● If a cold chain excursion occurred, follow the Ministry of Health's cold chain management work standard COVID-19 Vaccine Storage & Handling & Cold Chain Break Procedures.pdf. NOTE: The data logger reading following transportation in a thawing state (i.e. vaccine removed from the freezer and placed directly into the container/cooler) may show a temperature lower than 2°C initially with gradual stabilization between 2°C to 8°C. This would be an expected reading and does not need to be considered a cold chain excursion. When using a min/max thermometer, any temperature excursion under 2°C must be reported since this device does not distinguish the time of temperature readings.
5.	<p>Vaccine Packing Considerations</p> <ul style="list-style-type: none"> ● Vaccine packing should occur quickly where the vaccines are taken directly from the freezer/fridge and immediately placed into the shipping container/cooler. ● Pick vaccine with the shortest expiry date (if applicable). ● If vaccine vials are separated from a full box (10 vials), refer to #6.

6.	<p>Packing Vaccines from Original Packaging</p> <p>NOTE: Please also refer to the Ministry of Health work standard <i>Repacking Vaccines from Original Packaging</i> on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Documents/WS-Repacking-of-vaccines-from-original-packaging.pdf</p> <ul style="list-style-type: none"> • It is a Health Canada requirement that a licensed healthcare professional (e.g., registered pharmacist, registered nurse) oversee the packing of vaccines into new packages (e.g., cardboard boxes, opaque or amber bags) from their original packages (written communication from Health Canada to the Ministry of Health, 2020-11-13). • Vaccine must be placed into a package that will protect the vaccine from light (e.g. opaque or amber bag). • Remove the exact or rounded up vaccine doses from their original package and place them directly into the new package under the required frozen storage conditions. • Securely seal the new package. • Place a label stating the vaccine name, number of vial/syringe units and corresponding doses, and a reference to the product monograph onto the new packaging. (COVID-19 vaccine specific labels are posted on the Saskatchewan COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx). • The package containing the vial(s) should be placed in insulation or bubble wrap or similar padding to protect the product. <p>NOTE: Ensure padding material is conditioned to 2°C to 8°C prior to placing in container/cooler with vaccine.</p> • The newly prepared package(s) are stored under the required storage conditions until they are ready to be shipped.
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References:

CDC (2023). *Vaccine Storage and Handling Toolkit*. [Vaccine Storage and Handling Toolkit-Updated with COVID-19 Vaccine Storage and Handling Information, Addendum April 12, 2022 \(cdc.gov\)](#)

Appendix A- Sample Transport Time Tracking Form

Moderna Spikevax® COVID-19 Vaccine Transport Time Tracking Form		
Pick-up Date:		
Number of Vials:		
Lot Number(s):		
Transport Start Time	Transport Stop Time ²	Cumulative Transport Time ³

¹Document time vehicle begins transport.

²Document time vehicle stops at a destination (includes stops to drop off other products, overnight stops, etc.)

³ Document the total time from transport start time and stop time columns.