

	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, First Nations and Inuit Health Branch Staff 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: 2023-07-24	Date Approved:

Work Standard Summary: This work standard outlines the guidelines for transportation of Moderna Spikevax™ Bivalent BA.4/5 0.1mg/mL Blue Cap/Grey Label) in a frozen or thawed/thawing state, as well as specific vaccine packing considerations.

Saskatchewan Health Authority work standards on the transportation of COVID-19 vaccine can be accessed on their [Vaccine Storage and Handling-COVID-19](#) website and include:

- [Packing and Temperature Monitoring of Vaccine work standard](#)
- [Documentation and Reconciliation Process when Transporting Pfizer BioNTech and Moderna COVID-19 Vials work standard](#)

Essential Tasks:	
1.	Transportation Recommendations <ul style="list-style-type: none"> Moderna's recommendation is to transport their COVID-19 mRNA vaccines in a frozen state but will 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. <ul style="list-style-type: none"> ➤ mRNA vaccines are subject to additional precautions when transported in a thawed state compared to usual vaccines to maintain their stability and integrity, and therefore their effectiveness. The mRNA strands in the vaccine degrade easily and are protected by small spheres of miniature lipids to ensure stability. Once thawed, these spheres can shatter if there is too much impact within the vaccine vial during transportation. Open Vial Transport: In exceptional circumstances Moderna Spikevax™ Bivalent BA.4/5 (0.1mg/ml Blue Cap/Grey Label) may be transported in an open vial as outlined in Task #4 of this work standard. The exceptional circumstance criteria has been applied out of an abundance of caution due to the potential risk to the vaccine integrity with excessive vibrations/shaking/jostling. Refer to <i>COVID-19 Vaccine Storage and Handling and Cold Chain Break Procedures work standard Appendix A</i> found on the COVID-19 Immunization Manual webpage for a summary of Moderna Spikevax™ vaccine stability.

Essential Tasks:	
	<ul style="list-style-type: none"> For additional information on vaccine storage and handling, refer to: <ul style="list-style-type: none"> ➤ The Ministry of Health's <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
2.	<p>Prior to Redistributing the Vaccine</p> <ul style="list-style-type: none"> Confirm the number of vaccine doses that are required at the receiving site. <ul style="list-style-type: none"> ➤ For receiving sites that will store vaccine in a refrigerator - if delivery includes second doses, ensure all doses are planned to be administered within 30 days (this period begins once vaccine is removed from freezer). Ensure the receiving site has the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature. <ul style="list-style-type: none"> ➤ If transporting the vaccine in a frozen state, the site requires a temperature monitored freezer or refrigerator. ➤ If transporting the vaccine in a thawed state, the site requires a temperature monitored refrigerator. Ensure the receiving site has the appropriate ancillary supplies and education/information materials to support vaccine storage and administration. Ensure each receiving site has patient vaccine handouts including vaccine fact sheets, vaccine screening questions, after care sheets, wallet cards and the I Got My COVID-19 Vaccine stickers. Communicate clearly with each receiving site on exact time of vaccine delivery to ensure their readiness.
3.	<p>Guidelines for Transporting Moderna Spikevax™ in a Frozen State</p> <ul style="list-style-type: none"> Transport vaccine between -50°C to -15°C in the original carton/box. DO NOT use dry ice. Vaccine must be shipped in a validated shipping container (i.e. intended to transport frozen vaccine or drugs), such as a Credo Cube™. <ul style="list-style-type: none"> ➤ Assemble and condition the shipping container according to manufacturer instructions. ➤ Maximum transport time is based on the model and type of shipping container. ➤ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze Vaccine Immediately on Arrival). ➤ Label the shipping container with a cautionary statement pertaining to fragility (e.g. "Fragile: Handle With Care, Do Not Drop"). ➤ 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 #6. Upon arrival at the destination, the frozen vaccine is immediately placed 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 30 days in the refrigerator between 2°C to 8°C. It is important to record the date and time the vaccine is placed in the refrigerator.

Essential Tasks:	
	<ul style="list-style-type: none"> Immediately analyze the data logger for cold chain excursion outside of -50°C to -15°C. <ul style="list-style-type: none"> ➤ If a cold chain excursion occurred, follow the Ministry of Health's <i>COVID-19 Vaccine Storage and Handling and Cold Chain Break Procedures work standard</i>. ➤ Allow vaccine to thaw prior to administration. Follow the thawing and administration instructions outlined in: <ul style="list-style-type: none"> ▪ The Ministry of Health's <i>COVID-19 Vaccine Storage and Handling and Cold Chain Break Procedures work standard</i> found on the COVID-19 Immunization Manual webpage. <p>The Saskatchewan Immunization Manual, Chapter 9: Management of Biological Products https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf</p>
4.	<p>Guidelines for Transporting Moderna Spikevax™ in a Thawed State (+2 °C to +8°C)</p> <p>NOTE: The 30-day stability timeline in a thawed state begins once Moderna vaccine is removed from the freezer. DO NOT REFREEZE THAWED VACCINE.</p> <p>Open Vial Transport: Transportation of open/punctured vials 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.</p> <ul style="list-style-type: none"> ➤ Open/punctured vials must be stored at the appropriate temperature 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. <ul style="list-style-type: none"> 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 (container/cooler bag typically used to transport vaccine at 2° C to 8° C may be used). 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. <p>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 vaccine.</p> <ul style="list-style-type: none"> ➤ Place vials in an upright position. ➤ Take measures, including use of bubble wrap or similar material, 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 dunnage (padding material) 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 #6.

Essential Tasks:

- Add a temperature monitoring device to the centre of the cooler.
 - 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.**
- DO NOT USE DRY ICE.
- See #5 below for additional vaccine packing information.
- **Cumulative transport time¹ must be less than 12 hours.** In addition, the 12 hours is subtracted from the 30 day stability timeline between 2° C to 8° C.
- Tracking and recording the total transport time is required. Keep the records on file in the event of needing to further transport the vaccine.
 - Utilize a transport time tracking form to document total transport time¹ 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. For example, mark the vial label with a red sticker and write the total transport time on the sticker. When additional transportation is required, only transport vaccine that has transportation time tracked and documented.
- Special precautions must be taken during vaccine transport to **prevent excessive movement, “jostling”, and vibrations**.
 - 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 *COVID-19 Vaccine Storage and Handling and Cold Chain Break Procedures work standard*.
 - **NOTE:** The data logger reading following transportation in a thawing state (i.e. vaccine removed from the ultra-low temperature 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.

Essential Tasks:	
	<ul style="list-style-type: none"> Prior to administering, ensure vaccine is fully thawed if vaccine was frozen at the beginning of transport. Follow the thawing and administration instructions outlined in: <ul style="list-style-type: none"> ➤ The Ministry of Health's <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
5.	Vaccine Packing Considerations <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.	Packing Vaccines from Original Packaging <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. NOTE: Ensure dunnage material (e.g. bubble wrap) is conditioned to 2° C to 8° C prior to placing in container/cooler with vaccine. The newly prepared package(s) are stored under the required storage conditions until they are ready to be shipped.

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 ¹	Transport Stop Time ²	Cumulative Transport Time ³

¹Document time vehicle begins transport.

² Document 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.