

	Name of Activity: Transportation of Pfizer Comirnaty® COVID-19 Vaccines	
	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: 2021-01-21	Last Revision: 2025-09-18

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

- Pfizer Comirnaty® 12+ years COVID-19 mRNA vaccine (0.3mL [30mcg] **Grey Cap/Label**), Multidose Vials
- Pfizer Comirnaty® 12+ years COVID-19 mRNA vaccine (0.3mL [30mcg]), Pre-Filled Syringes

IMPORTANT NOTES:

- **Pfizer Comirnaty® vaccine vials cannot be stored or transported between -25°C to -15°C.**
- **Pre-Filled Syringes of Pfizer Comirnaty® COVID-19 vaccine can only be stored and transported between (+2°C to +8°C).**

Essential Tasks:	
1.	Transportation Recommendations <ul style="list-style-type: none"> • Multidose vials (MDV) of Pfizer Comirnaty® COVID-19 vaccine are transported in either an ultra-frozen (-90°C to -60°C) or thawed state (+2°C to +8°C), subject to additional transport precautions outlined in this work standard. • When the required cold chain equipment is not available for ultra-frozen transport, the vaccine can be transported in a thawed or thawing state as outlined in this work standard. • As required, Pfizer COVID-19 open MDVs may be transported as outlined in this work standard. <ul style="list-style-type: none"> ○ Pfizer has stability data from studies using monovalent formulations that shows open vials and syringes transported between 6 and 12 hours has no expected impact on quality. • Pre-Filled Syringes (PFS) of Pfizer Comirnaty® COVID-19 vaccine can only be stored and transported between (+2°C to +8°C). • For additional information on vaccine storage and handling, refer to: <ul style="list-style-type: none"> ○ <i>Vaccine Storage and Handling and Cold Chain Break Procedures for COVID-19 Vaccines work standard</i> and <i>Appendix A</i> on the COVID-19 Immunization Manual website. ○ Saskatchewan Immunization Manual, Chapter 9: Management of Biological Products https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf.
2.	Guidelines for Transporting Pfizer Comirnaty® MDV in an Ultra Frozen State (-90 °C to -60 °C) <ul style="list-style-type: none"> • Only a full tray/carton of vaccine is permitted to be transported in an ultra-frozen state (i.e. do not repackage vaccine and transport individual vials). <ul style="list-style-type: none"> ➢ Pfizer Comirnaty 12+ (Gray Cap/Label) full carton= 10 vials (60 doses). • Transport vaccine between -90°C to -60°C in the original carton/box. • Vaccine must be shipped in a validated shipping container (i.e. intended to transport ultra-frozen vaccine or drugs), such as a portable freezer capable of ultra-frozen temperature. <ul style="list-style-type: none"> ➢ Condition the shipping container according to manufacturer instructions. ➢ Pack vaccine securely to protect the product from damage during transportation.

	<ul style="list-style-type: none"> ➤ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze in a ULT freezer/Refrigerate Vaccine Immediately on Arrival). ➤ A data logger is placed in the middle of the vaccine cartons at the centre of the shipping container and programmed to alert cold chain excursions warmer than -60° C and colder than -90° C. ➤ NOTE: data logger must be compatible for ultra-frozen temperatures. Additional vaccine packing information is outlined in #5. ● Upon arrival at the destination, keep the tray/carton closed and immediately place in a temperature monitored ultra-low temperature freezer between -90°C to -60°C or temperature monitored refrigerator between +2°C to +8°C. NOTE: Pfizer MDV are stable for up to 10 weeks 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 -90°C to -60°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.
3.	<p>Guidelines for Transporting Pfizer Comirnaty® MDV in a Thawed State (+2 °C to +8°C)</p> <ul style="list-style-type: none"> ● NOTE: The stability timeline between 2° C to 8° C begins once Pfizer vaccine is removed from the freezer. Once thawed, DO NOT REFREEZE. A full tray/carton or individual vials are permitted to be transported in a thawed state. <p>Open MDV Transport: Open vials may be transported as required between +2°C to +8°C but vaccine must be utilized within the stability period of 12 hours from the time of first vial puncture.</p> <ul style="list-style-type: none"> ● Transport thawed vaccine at temperature 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 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 saying DO NOT REFREEZE or equivalent must be on the transport container. ➤ A label saying 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 vaccine. ● Place vials in upright position. ● Take measures to ensure thawed vaccine does not contact any frozen or cold packs within the container. ● Transport vaccine in the original carton/box whenever possible. The carton should be surrounded by bubble wrap/paper inside the container to minimize product/carton movement during transport. ● 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. ● Special precautions must be taken during transport to prevent excessive movement of the vaccine.

	<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. ● Closed Vial Transport Time Considerations: <ul style="list-style-type: none"> ➤ There is no limit on the transportation time as long as the product is within the approved stability period and temperature. ● If transporting vaccine in a thawed state by air transport: <ul style="list-style-type: none"> ➤ Vials must be securely packed in a +2°C to +8°C temperature-controlled container appropriate for use on an aircraft. ➤ On unpressurized flights, temperature-controlled containers must maintain +2°C to +8°C even if the outside air temperature is less than 2°C to prevent the vials from refreezing. ● Upon arrival to destination, 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 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: Vaccine Storage & Handling and Cold Chain Break Procedures for COVID-19 Vaccine. <p>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.</p>
4.	<p>Vaccine Packing Considerations</p> <ul style="list-style-type: none"> ● Once an individual vial is removed from a vial tray at room temperature, it cannot be returned to frozen storage and should be thawed for use. ● Vaccine packing should occur quickly where the vaccines are taken directly from the freezer/fridge and immediately placed into the shipping container/cooler. <ul style="list-style-type: none"> ➤ For transport in ultra-frozen state: <ul style="list-style-type: none"> ○ Full cartons/boxes that arrive in ultra-frozen condition are to be kept closed and should not be at room temperature for longer than 5 minutes for transfer between ultra-low temperature environments. Before repacking vials into another thermal shipping container for transport, bring vials back to -90 to -60° C before transferring to new container. ➤ For transport in thawed state: <ul style="list-style-type: none"> ○ Repackaging should be done in a 2-8°C environment whenever possible. ○ When packing vaccine at room temperature, time of exposure should be minimized. ● Pick vaccine with the shortest expiry date (if applicable). ● Fill empty spaces within the shipping container with bubble wrap/paper to prevent shifting in the container/cooler. ● For transport in thawed state only- If vaccine vials are separated from a full carton/box, refer to #6.

5.

Packing Vaccines from Original Packaging

NOTE: Please also refer to the Ministry of Health work standard *Repacking Vaccines from Original Packaging* on the [COVID-19 Immunization Manual](https://www.ehealthsask.ca/services/Manuals/Documents/WS-Repacking-of-vaccines-from-original-packaging.pdf) website:

<https://www.ehealthsask.ca/services/Manuals/Documents/WS-Repacking-of-vaccines-from-original-packaging.pdf>

- 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.
- Remove as much air as possible from the amber bag before sealed to minimize jostling.
- 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 created by the Ministry of Health and posted on the [COVID-19 Immunization Manual](https://www.ehealthsask.ca/services/Manuals/Documents/WS-Repacking-of-vaccines-from-original-packaging.pdf) website).
- The package containing the vial(s) should be placed in insulation or bubble wrap or similar padding to protect the product.
NOTE: Ensure padding is conditioned +2° C to +8° C for thawed transport 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.