

	Name of Activity: Vaccine Storage & Handling & Cold Chain Break Procedures for mRNA COVID-19 Vaccines (Pfizer Comirnaty® and Moderna Spikevax®)		
	Role Performing Activity: Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, Indigenous Services Canada, Ministry of Health		
<h1>WORK STANDARD</h1>	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	
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Work Standard Summary: COVID-19 vaccines have strict storage and handling guidelines. This work standard outlines the storage requirements, the process for identifying and reporting a cold chain break, quarantining the vaccine, and determining the viability of COVID-19 vaccines implicated in a cold chain break. Additional vaccine storage and handling information can be found in the [Saskatchewan Immunization Manual](#), Chapter 9: Management of Biological Products.

See Appendices A1 & A2 for Storage and Handling Summary Tables (found on the [COVID-19 Immunization Manual website](#)).

Essential Tasks:	
1.	<p>Default vaccine transport temperatures from RRPL to vaccine holding points are outlined in the Routine and Urgent COVID-19 Vaccine Requests—via Panorama Inventory Module work standard found on the COVID-19 Immunization Manual website</p> <p>Pfizer BioNTech Comirnaty® COVID-19 When vaccine is transported from RRPL to the vaccine holding point in an ultra low temperature (ULT) portable freezer, staff must retrieve the vaccine from the courier truck (the driver cannot bring the freezer into the building). If maintaining cold chain is a concern, staff may consider moving the portable freezer from the courier truck into the facility themselves (use of a hand dolly needed).</p>
2.	<p>Storage of Vaccine</p> <p>A. Pfizer Comirnaty® 12+ (0.3mL [30mcg] Gray Cap/Label), Multidose Vial</p> <ul style="list-style-type: none"> • Store in an ULT freezer between -90°C to -60°C until the expiry date. • Do not store at -25°C to -15°C. • If a ULT freezer is not available, the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for up to 10 weeks prior to first puncture. To assist with tracking, mark the date and time of discard on the vial. • Once thawed, do not refreeze. • During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

	<p><u>B. Pfizer Comirnaty® 12+ (0.3mL [30mcg] Pre-Filled Syringe)</u></p> <ul style="list-style-type: none"> • Store refrigerated between 2°C to 8°C. • Do not freeze. <p><u>C. Moderna Spikevax® (0.1mg/mL Royal Blue Cap/Coral Blue Label), Multidose Vial and Pre-Filled Syringe</u></p> <ul style="list-style-type: none"> • Store in a temperature monitored freezer between -50°C to -15°C. Do not store in ULT freezer. • Store in the original carton to protect from light. • If a freezer is not available, the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for up to 50 days prior to first use. • Once thawed, do not refreeze.
<p>3.</p>	<p>Thawed Vaccine</p> <p><u>A. Pfizer Comirnaty® 12+ (0.3mL [30mcg] Gray Cap/Label), Multidose Vials</u></p> <p><u>Prior to use:</u></p> <ul style="list-style-type: none"> • Frozen vials may be thawed and stored in the refrigerator at +2°C to +8°C. • A carton of 10 vials may take up to 6 hours to thaw in the refrigerator. • Once thawed, do not refreeze. <p><u>Unpunctured vials:</u></p> <ul style="list-style-type: none"> • Un-punctured vials may be stored in the refrigerator between +2°C and +8°C for up to 10 weeks. To assist with tracking, write the fridge expiry date on the vial. • Frozen vials may be thawed at room temperature (up to +25°C). <ul style="list-style-type: none"> ○ Vial(s) take 30 minutes to thaw at room temperature. ○ Un-punctured vials may be stored at room temperature for up to 12 hours prior to use. ○ Vials thawed or held at room temperature may be returned to the refrigerator for storage if necessary, but total time at room temperature must be tracked to ensure the vial stays within the 12 hours at room temperature limit. Mark the date and time of discard on the vial. ○ Thawed vials can be handled in room light conditions. <p><u>Punctured vials:</u></p> <ul style="list-style-type: none"> • Vials may be stored at +2°C to +25°C. <ul style="list-style-type: none"> ○ Vials must be discarded 12 hours after first puncture. Mark the date and time of puncture on the vial. <p><u>Moderna Spikevax® (0.1mg/mL Royal Blue Cap/Coral Blue Label), Multidose Vials</u></p> <p><u>Prior to use</u></p> <ul style="list-style-type: none"> • Thaw each vial before use. • Thaw in refrigerated conditions between +2°C to +8°C for 2 hours. Let each vial stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between +15°C to +25°C for 45 minutes. • Once thawed, the vaccine may be stored in the refrigerator at +2°C to +8°C for up to 50 days prior to first use. To assist with tracking, write the fridge expiry date on the vial.

Un-punctured vials:

May be stored between +8°C and +25°C for up to 12 hours.

- Track the duration of time the vaccine is stored at over +8°C so the total time does not exceed 12 hours. To assist with tracking, **write the fridge expiry date on the vial.**
- **NOTE:** Vaccine not used within this timeline is considered a cold chain excursion and must be reported to the Ministry of Health as outlined in # below.

Punctured vials:

Once the vial has been entered (needle-punctured) it can be stored at:

- Room temperature or refrigerated but must be discarded after 12 hours, or
- Refrigerated, but must be discarded after 24 hours.
 - **The duration of time an un-punctured vial is stored at room temperature is counted against the 12 hour stability period after puncture.** After the 12 hour period, punctured vials must be discarded. **Mark the date and time of discard on the vial.**
 - Any discarded vaccine is considered wastage and must be reported to the Ministry of Health using the [Product Wastage Report Form](#).
 - **Once thawed, do not refreeze.**

Moderna Spikevax® (50mcg/0.5mL), Single-dose Pre-filled Syringe

Prior to Use:

- Thaw each pre-filled syringe before use.
- In refrigerated conditions between +2°C to +8°C, thaw individual syringes **for 1 hour and 40 minutes** or a carton of 10 syringes **for 2 hours and 40 minutes**. Let each syringe stand at room temperature for 15 minutes before administering.
- Alternatively, if thawing at room temperature between +15°C to +25°C, thaw individual syringes **for 40 minutes** or a carton of 10 syringes **for 1 hour and 20 minutes**.
- Once thawed, the vaccine may be stored in the refrigerator at +2°C to +8°C for up to 50 days prior to use. To assist with tracking, **write the fridge expiry date on the packaging.**
- Pre-filled syringes may be stored at 8°C to 25°C for up to 12 hours after removal from refrigerated conditions.
- **Once thawed, do not refreeze.**

4.

Process for Temperature Excursion

- If a cold chain break occurs (see below), Complete a cold chain break report form, print a temperature log reading from the data logger if applicable and fax both to the Ministry of Health at 306-787-3237 immediately.

Cold Chain Break Report Form A fillable PDF is available in the Saskatchewan Immunization Manual: <https://www.ehealthsask.ca/services/Manuals/Documents/Cold-Chain-Break-Form-fillable.pdf>

Pfizer Comirnaty® 12+ (0.3mL [30 mcg] Gray Cap/Label), Multidose Vial

For frozen vaccine:

- A temperature excursion colder than -90°C or warmer than -60°C constitutes a cold chain break. Immediately quarantine the vaccine by labelling it as being involved in a cold chain break and place it away from other vaccine in the freezer.
- **Do not assume the vaccine is to be wasted.**

4.	<p><u>For thawed vaccine storage in the fridge:</u></p> <ul style="list-style-type: none"> • A temperature excursion under +2°C or over +8°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator between +2°C and +8°C, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. • Do not assume the vaccine is to be wasted. <p><u>For thawed vaccine stored at room temperature:</u></p> <ul style="list-style-type: none"> • Storage longer than 12 hours or over temperature of +25°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator between +2°C and +8°C, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. • Do not assume the vaccine is to be wasted. <p><u>Pfizer Comirnaty® 12+ (0.3mL [30mcg]), Single-dose Pre-filled Syringe</u></p> <ul style="list-style-type: none"> • Must be stored refrigerated between 2°C to 8°C. • A temperature excursion under +2°C or over +8°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator between +2°C and +8°C, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. • Do not assume the vaccine is to be wasted.
	<p><u>Moderna Spikevax® (0.1mg/ml Royal Blue Cap/Coral Blue Label), Multidose Vial and Moderna Spikevax® (50mcg/0.5mL), Single-dose Pre-filled Syringe</u></p> <ul style="list-style-type: none"> • For frozen vaccine, a temperature excursion of colder than -50°C or warmer than -15°C, immediately quarantine the vaccine by labelling it as being involved in a cold chain break and placing it away from other vaccine in the freezer. • Do not assume the vaccine is to be wasted. • For opened or unopened, thawed vaccine, a temperature excursion under +2°C for any length of time or over +8°C for more than 24 hours constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. • Do not assume the vaccine is to be wasted.
6.	Upon receiving notification of the cold chain break, the Ministry of Health will contact the manufacturer regarding the stability and viability of the vaccine.
7.	When recommendations are received from the manufacturer, the Ministry of Health will advise regarding viability of the vaccine.

Found on the [COVID-19 Immunization Manual website](#):

○ **Appendix A1:** Moderna Spikevax® mRNA COVID-19 Vaccine Storage and Handling Summary Table

○ **Appendix A2:** Pfizer Comirnaty® mRNA COVID-19 Vaccine Storage and Handling Summary Table