

	<b>Name of Activity:</b> Vaccine Storage & Handling & Cold Chain Break Procedures for mRNA COVID-19 Vaccines (Pfizer Comirnaty® and Moderna Spikevax®)		
	<b>Role Performing Activity:</b> Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch, Ministry of Health		
<b>WORK STANDARD</b>	<b>Location:</b> COVID-19 Immunization Manual	<b>Department:</b> Population Health Branch	
	<b>Document Owner:</b> Vaccine Management Team	<b>Region/Organization where this Work Standard originated:</b> Ministry of Health Population Health Branch	
	<b>Date Prepared:</b> 2020-12-10	<b>Last Revision:</b> 2024-09-20	<b>Date Approved:</b> 2020-12-10

**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><b>Arrival of Vaccine from the National Operations Centre or the Manufacturer</b></p> <p><b>A. <u>Pfizer BioNTech Comirnaty® COVID-19</u></b> Vaccines will arrive ultra-frozen in thermal containers with dry ice. Follow required Occupational Health and Safety dry ice storage and handling procedures, including proper Personal Protective Equipment (PPE) use and dry ice disposal. Pfizer has dry ice Safety Data Sheets and other dry ice safe handling resources on their website: <a href="https://www.cvdvaccine.ca/resources">https://www.cvdvaccine.ca/resources</a></p> <p><b>B. <u>Moderna Spikevax® COVID-19</u></b> vaccines will arrive in frozen containers between -50 °C to -15°C.</p> <p>Refer to the Ministry of Health’s <a href="#">Procedure for Receiving COVID-19 Vaccines, Diluent, and Dry Ice</a> work standard found on the <a href="#">COVID-19 Immunization Manual website</a>.</p>
2.	<p><b>Arrival of Vaccine from the Roy Romanow Provincial Lab (RRPL)</b></p> <p><b><u>All COVID Vaccines</u></b> Default vaccine transport temperatures from RRPL to vaccine holding points are outlined in the <a href="#">Routine and Urgent COVID-19 Vaccine Requests—via Panorama Inventory Module</a> work standard found on the <a href="#">COVID-19 Immunization Manual website</a></p> <p><b><u>Pfizer BioNTech Comirnaty® COVID-19</u></b> When vaccine is transported from RRPL to the vaccine holding point in an ultralow 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>

3.	<p><b>Storage of Vaccine</b></p> <p><b>A. Pfizer Comirnaty® 12+ (0.3ml [30mcg] Gray Cap/Label)</b></p> <ul style="list-style-type: none"> <li>• Store in an ULT freezer between -90°C to -60°C until the expiry date.</li> <li>• <b>Do not store at -25°C to -15°C.</b></li> <li>• If an ULT freezer is not available, the thermal container in which the Pfizer COVID-19 vaccine arrives may be used as temporary storage when consistently replenished to the top of the container with dry ice (refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage).</li> <li>• The dry ice must be replenished within 24 hours after delivery and then up to five additional times, five days apart for a total of 30 days.</li> <li>• If a ULT freezer is not available, the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for <b>up to 10 weeks</b> prior to first puncture. To assist with tracking, mark the date and time of discard on the vial.</li> <li>• <b>Do not refreeze thawed vials.</b></li> <li>• During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.</li> </ul> <p><b>B. Moderna Spikevax® (0.1mg/ml Royal Blue Cap/Coral Blue Label)</b></p> <ul style="list-style-type: none"> <li>• Store in a temperature monitored freezer between -50°C to -15°C. Do not store on dry ice.</li> <li>• Store in the original carton to protect from light.</li> <li>• If a temperature monitored freezer is not available, the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for up to <b>50 days</b> prior to first use.</li> <li>• <b>Do not refreeze thawed vials.</b></li> </ul>
4.	<p><b>Thawed Vials</b></p> <p><b>A. Pfizer Comirnaty® 12+ (0.3ml [30mcg] Gray Cap/Label)</b></p> <p><b>Prior to use:</b></p> <ul style="list-style-type: none"> <li>• Frozen vials may be thawed and stored in the refrigerator at +2°C to +8°C.</li> <li>• A carton of 10 vials may take up to 6 hours to thaw in the refrigerator.</li> <li>• <b>Do not refreeze thawed vials.</b></li> <li>• Un-punctured vials may be stored in the refrigerator between +2°C and +8°C for <b>up to 10 weeks</b>. To assist with tracking, <b>write the fridge expiry date on the vial.</b></li> <li>• Frozen vials may also be thawed at room temperature (up to +25°C). <ul style="list-style-type: none"> <li>○ Vial(s) take 30 minutes to thaw at room temperature.</li> <li>○ Un-punctured vials may be stored at room temperature for up to 12 hours prior to use.</li> <li>○ 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. <b>Mark the date and time of discard on the vial.</b></li> <li>○ Thawed vials can be handled in room light conditions.</li> </ul> </li> </ul> <p><b>Punctured vials:</b></p> <ul style="list-style-type: none"> <li>• Vials may be stored at +2°C to +25°C. <ul style="list-style-type: none"> <li>○ Vials must be discarded 12 hours after first puncture. <b>Mark the date and time of puncture on the vial.</b></li> </ul> </li> </ul>

	<p><b>Moderna Spikevax® (0.1mg/ml Royal Blue Cap/Coral Blue Label)</b></p> <p><b>Prior to use:</b></p> <ul style="list-style-type: none"> <li>• Thaw each vial before use.</li> <li>• Thaw in refrigerated conditions between <b>+2°C to +8°C for 2 hours</b>. Let each vial stand at room temperature for 15 minutes before administering.</li> <li>• Alternatively, thaw at room temperature between <b>+15°C to +25°C for 45 minutes</b>.</li> <li>• Once thawed, the vaccine may be stored in the refrigerator at <b>+2°C to +8°C for up to 50 days</b> prior to first use. To assist with tracking, <b>write the fridge expiry date on the vial</b>.</li> </ul> <p><b>Un-punctured vials:</b></p> <p>May be stored between +8°C and +25°C for up to 12 hours.</p> <ul style="list-style-type: none"> <li>• 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, <b>write the fridge expiry date on the vial</b>.</li> <li>• <b>NOTE:</b> Vaccine not used within this timeline is considered a cold chain excursion and must be reported to the Ministry of Health as outlined in #4 below.</li> </ul> <p><b>Punctured vials:</b></p> <p>Once the vial has been entered (needle-punctured) it can be stored at:</p> <ul style="list-style-type: none"> <li>• Room temperature or refrigerated but must be discarded after 12 hours, or</li> <li>• Refrigerated, but must be discarded after 24 hours. <ul style="list-style-type: none"> <li>○ <b>The duration of time an un-punctured vial is stored at room temperature is counted against the 12 hour stability period after puncture.</b> After the 12 hour period, punctured vials must be discarded. <b>Mark the date and time of discard on the vial.</b></li> <li>○ Any discarded vaccine is considered wastage and must be reported to the Ministry of Health using the <a href="#">Product Wastage Report Form</a>.</li> <li>○ <b>Do not refreeze thawed vials.</b></li> </ul> </li> </ul>
5.	<p><b>Process for Temperature Excursion</b></p> <p><b>Pfizer Comirnaty® 12+ (3ml [30 mcg] Gray Cap/Label)</b></p> <p><u>For frozen vaccine:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• <b>Do not assume the vaccine is to be wasted.</b></li> </ul> <p><u>For thawed vaccine storage in the fridge:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• <b>Do not assume the vaccine is to be wasted.</b></li> </ul> <p><u>For thawed vaccine stored at room temperature:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• <b>Do not assume the vaccine is to be wasted.</b></li> <li>• Complete a cold chain break report form (<b>Appendix D</b>), print a temperature log reading from the data logger if applicable and fax both to the Ministry of Health at 306-787-3237 immediately.</li> </ul>

	<p><b>Moderna Spikevax® (0.1mg/ml Royal Blue Cap/Coral Blue Label)</b></p> <ul style="list-style-type: none"> <li>• <b>For frozen vaccine</b>, 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.</li> <li>• <b>Do not assume the vaccine is to be wasted.</b></li> <li>• <b>For opened or unopened, thawed vaccine</b>, 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.</li> <li>• <b>Do not assume the vaccine is to be wasted.</b></li> <li>• Complete a cold chain break report form (<b>Appendix D</b>), print the temperature log reading from the data logger if applicable and fax to the <b>Ministry of Health at 306-787-3237</b> immediately.</li> </ul>
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](#)

Appendix A1



Appendix A2



## Appendix D- Cold Chain Break Report Form

A fillable PDF is available on the COVID-19 Immunization Manual website:

<https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx>



For COVID-19 vaccines: fax form to the Ministry of Health at 306-787-3237  
 For publicly funded vaccines: fax the form to the regional immunization supervisor.  
 Pharmacists: fax form to the Ministry of Health at 306-787-3237

**Complete for all publicly funded products. Do not assume that vaccines must be wasted.**

Ensure report is completed in full. If pertinent information is missing, report will be returned for completion.

Section 1	Date of Break: (www-mm-dd) _____ Date of Report: (www-mm-dd) _____ Reporter Name: _____
	Telephone Number: _____ Fax Number: _____ Reporter Email Address: _____
	Organization (SHA Network, FNJ, AHA, Pharmacy) _____ Location (Community) _____ Facility Name _____
Section 2	Facility type: <input type="checkbox"/> Public Health <input type="checkbox"/> Pharmacy <input type="checkbox"/> Physician office <input type="checkbox"/> Primary Health Care <input type="checkbox"/> Long-Term Care <input type="checkbox"/> Acute Care <input type="checkbox"/> Employee Health Are products Quarantined & Labeled DO NOT USE and stored on cold chain? <input type="checkbox"/> Yes <input type="checkbox"/> No (attach explanation if no)
	<b>Check box for type of break and complete corresponding information:</b> <input type="checkbox"/> Vaccine left out of fridge/freezer: <input type="checkbox"/> in cooler with cold packs <input type="checkbox"/> in cooler with no cold packs <input type="checkbox"/> in package on counter <input type="checkbox"/> out of package on counter Vaccine returned to storage within required temperature range on: (date) _____ at (time) _____ Maximum length of time outside required temperature range: _____ Room temperature at time of break: _____ °C on (date) _____ at (time) _____
	<input type="checkbox"/> Fridge/freezer temperature excursion: Fridge/freezer temperature when break identified _____ °C on (date) _____ at (time) _____ Max. temp recorded during break interval _____ °C Min. temp recorded during break interval _____ °C Vaccine returned to storage within required temperature range on (date) _____ at (time) _____ Maximum length of time outside required temperature range: _____ Last fridge temperature record before the break _____ °C on (date) _____ at (time) _____ Room temperature before the break _____ °C on (date) _____ at (time) _____ Is temperature log being submitted? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, indicate why: _____
	Refrigerator/freezer type: <input type="checkbox"/> Lab Fridge <input type="checkbox"/> Biological Fridge <input type="checkbox"/> Domestic Fridge <input type="checkbox"/> Bar Fridge <input type="checkbox"/> ULT Freezer <input type="checkbox"/> Freezer <input type="checkbox"/> Thermal Shipper <input type="checkbox"/> Other _____ Date last serviced: _____ Thermometer/Monitor Type (Not Brand Name): <input type="checkbox"/> Digital Min/Max <input type="checkbox"/> Smart Button/Data Logger <input type="checkbox"/> Warm/Cold Mark <input type="checkbox"/> Chart/Wheel Recorder <input type="checkbox"/> Not Monitored <input type="checkbox"/> Other _____
	<input type="checkbox"/> Break during transportation Transportation category: <input type="checkbox"/> from RRPL to a facility <input type="checkbox"/> from a wholesaler to a pharmacy <input type="checkbox"/> from a facility to a facility Vehicle type (e.g. car/courier) _____ Time delivery received: _____ Time when unpacked: _____ Was there a data logger included in the cooler/container? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, is it being sent back to RRPL (or if COVID-19 vaccine, to the manufacturer)? <input type="checkbox"/> Yes <input type="checkbox"/> No Was there a warm/cold marker in cooler? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, was it activated? <input type="checkbox"/> Yes <input type="checkbox"/> No Reading: _____
	Description of break: _____ _____ _____
	Cause of cold chain break: <input type="checkbox"/> Human error <input type="checkbox"/> Power outage <input type="checkbox"/> Backup generator failed <input type="checkbox"/> Thermometer malfunction <input type="checkbox"/> Refrigerator malfunction <input type="checkbox"/> Other: _____
	Corrective action details and additional comments: _____ _____ _____
	Were any affected products administered to clients? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, indicate the date the local Medical Health Officer was notified: _____ If yes, identify these products with an asterisk* on page 2 or use a separate page if necessary.
	Section 3



Once completed, fax as per instructions on page 1.

Ensure report is completed in full. If pertinent information is missing, report will be returned.

Go to <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> for further instructions.

Vaccine Brand or Abbreviation	Manufacturer Name	# of Doses	Lot Number	Expiry date	Open multi-dose vial?	Previous cold chain break?	SK Health USE ONLY	
							Viable	Discard
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		

Ministry of Health reviewer: \_\_\_\_\_ Date: \_\_\_\_\_