	<b>Name of Activity:</b> Vaccine Storage and Handling and Cold Chain Break Procedure for Pfizer and Moderna COVID-19 Vaccines	
	<b>Role Performing Activity:</b> Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch Staff Ministry of Health	
<b>WORK STANDARD</b>	<b>Location:</b>	<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> 2020-01-19

**Work Standard Summary:** Pfizer and Moderna COVID-19 vaccines have very 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 a COVID-19 vaccine 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 Appendix A for Temperature Stability Summary Table.**

Essential Tasks:	
1.	<p><b>Arrival of Vaccine</b></p> <p><b>Pfizer COVID-19</b> vaccine will arrive 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>Moderna COVID-19</b> vaccine will arrive in frozen containers.</p> <p>Refer to the Ministry of Health’s Procedure for Receiving COVID-19 Vaccines, Diluent, and Dry Ice work standard.</p>
2.	<p><b>Storage of Vaccine</b></p> <p><b><u>Pfizer COVID – 19 Vaccine</u></b></p> <p>Upon receipt of the vaccine, stop the data logger included in the thermal container (as per Pfizer instructions) and remove the vial cartons immediately from the thermal container and store in the ultra-low temperature (ULT) freezer between -80°C to -60°C. The ULT freezer is to be equipped with a compatible data logger.</p> <p>Vials must be kept frozen between -80°C to -60°C and protected from light, in the original cartons, until ready to use.</p> <p>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).</p> <p>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.</p> <p>The thermal container maintains a temperature range of -90°C to -60°C. Storage in the thermal container at this temperature is <b>not</b> considered a temperature excursion. Insert a new data logger to monitor the temperature.</p>

### Essential Tasks:

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

If a ULT freezer or thermal shipper is not available the vaccine can be stored in the refrigerator between +2°C to +8°C for up to five days (120 hours) prior to first use.

#### **Moderna COVID-19 Vaccine**

Upon delivery, remove the cartons of vaccine immediately from the shipping container and store in a regular freezer between -25°C and -15°C. Do not store on dry ice or below -40° C.

Store in the original carton to protect from light.

If a regular freezer is not available the vaccine can be stored in the refrigerator between +2°C to +8°C for up to 30 days prior to first use.

### 3. **Thawed Vials**

#### **Pfizer COVID-19 Vaccine**

##### **Prior to dilution:**

- Frozen vials may be thawed and stored in the refrigerator at +2°C to +8°C. A carton of 195 vials may take up to two to three hours to thaw in the refrigerator. Mark the date and time on the vials that they were removed from the freezer to the refrigerator.
- Undiluted and un-punctured thawed vials may be stored in the refrigerator between +2°C and +8°C for up to five days (120 hours).
- Frozen vials may also be thawed at room temperature (up to 25°C) and kept at room temperature for no more than two hours before mixing with diluent. Mark the date and time on the vials that they were removed from the refrigerator to room temperature.

##### **After dilution of thawed vial with normal saline:**

- Must be stored between +2°C to +25°C. Mark the date and time of dilution on the vials.
- Must be used within six hours from time of dilution. Any discarded vaccine is considered wastage and must be reported to the Ministry of Health using the Product Wastage Report Form.

**NOTE:** Vials kept in thawed state beyond the guidelines above must be discarded. The wastage must be reported to the Ministry of Health using the Vaccine Wastage Report Form

Thawed vials can be handled in room light conditions.

**Do not refreeze thawed vials, whether or not they are diluted.**

#### **Moderna COVID-19 Vaccine**

Thaw each vial before use.

- Thaw in refrigerated conditions between +2°C to +8°C for two hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between +15°C to +25°C for one hour.

Once thawed, the vaccine may be stored in the refrigerator at +2°C to +8°C for up to 30 days prior to first use.

Un-punctured vials may be stored between +2°C and +25°C for up to 12 hours.

**Do not refreeze thawed vials.**

<b>Essential Tasks:</b>	
	Once the vial is punctured it can be stored at room temperature or refrigerated, but must be discarded after six hours. The wastage must be reported to the Ministry of Health using the Product Wastage Report Form.
4.	<p><b>Process for Temperature Excursion</b></p> <p><b><u>Pfizer COVID-19 Vaccine</u></b></p> <p>For frozen vaccine, a temperature excursion colder than -80°C or warmer than -60°C constitutes a cold chain break (for thermal shipper storage cold chain excursion is colder than -90°C or warmer than -60°C). 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.</p> <p>For thawed undiluted vaccine a temperature excursion under +2°C for any length of time or over +8°C for two hours undiluted 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. <b>Do not assume the vaccine is to be wasted.</b></p> <p>Vials thawed 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 two hours at room temperature limit.</p> <p>Complete a cold chain break report form (Appendix A), print a temperature log reading from the data logger if applicable and fax both to the Ministry of Health at 306-787-3237 immediately.</p> <p><b><u>Moderna COVID-19 Vaccine</u></b></p> <p>For frozen vaccine, a temperature excursion colder than -25°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. <b>Do not assume the vaccine is to be wasted.</b></p> <p>For thawed vaccine, a temperature excursion under +2°C for any length of time or over +8°C for more than 12 hours constitutes a cold chain break. Track the duration of time the vaccine is stored at over +8°C so the total time does not exceed 12 hours. 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.</p> <p>Complete a cold chain break report form (Appendix A), print the temperature log reading from the data logger if applicable and fax to the Ministry of Health at 306-787-3237 immediately.</p>
5.	The Ministry of Health will contact the National Operating Centre regarding the stability and viability of the vaccine.
6.	When recommendations are received from the manufacturer, the Ministry of Health will advise regarding viability of the vaccine.

## Appendix A

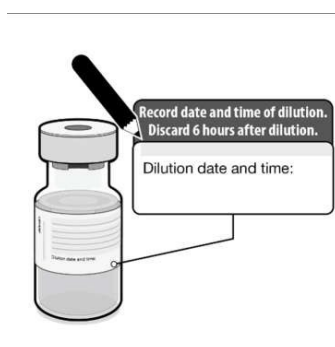
**Table 1: Pfizer/BioNTech Vaccine Storage and Stability Requirements**

Frozen Vials		Thawed Vials	
ULT Freezer	Thermal Shipper	Undiluted	Diluted
<ul style="list-style-type: none"> <li>-80°C to -60°C until ready to use for up to expiry date.</li> <li>Store in original carton.</li> <li>Protect from light.</li> </ul>	<ul style="list-style-type: none"> <li>-90°C to -60°C</li> <li>Replenish with dry ice within 24 hours initially and then every five days for up to 30 days.</li> </ul>	<ul style="list-style-type: none"> <li>Thaw at room temperature for 30 minutes.</li> <li>Can thaw in refrigerator for about three hours for a tray.</li> <li>Can stay at room temperature up to 25°C for two hours before mixing with diluent.</li> <li>Can be stored in refrigerator at +2°C to +8°C for five days (120 hours).</li> <li><b>Do not refreeze</b></li> </ul>	<ul style="list-style-type: none"> <li>Use within six hours.</li> <li>Avoid direct sunlight.</li> <li><b>Do not refreeze.</b></li> </ul>

**NOTE:** Vials must be marked with date and time to track vaccine stability in the following situations:

- When vial is moved from freezer to the fridge
- When the vial is moved from the fridge to room temperature undiluted
- When diluted at room temperature

There is a label on the vial for this purpose. See picture below.



**Table 1: Moderna Vaccine Storage and Stability Requirements**

Frozen Vials	Thawed Vials	
Freezer	Refrigerated	Room Temperature
<ul style="list-style-type: none"> <li>• -25°C to -15°C for up until expiry date.</li> <li>• Store in original carton</li> <li>• Protect from light</li> </ul>	<ul style="list-style-type: none"> <li>• Thaw in refrigerator between +2° C and +8° C for two hours and 30 minutes. After thawing let stand at room temperature for 15 minutes before administering.</li> <li>• If un-punctured can be stored between +2° C to +8° C for up to 30 days.</li> <li>• Protect from light.</li> <li>• <b>Do not refreeze.</b></li> </ul>	<ul style="list-style-type: none"> <li>• Can thaw at room temperature between 15° C and 25° C for one hour.</li> <li>• If un-punctured can be at room temperature up to 25° C for up to 12 hours.</li> <li>• Once punctured, can be stored for up to six hours, then discard.</li> <li>• Protect from light</li> <li>• <b>Do not refreeze.</b></li> </ul>

**NOTE:** Vials must be marked with date and time to track vaccine stability in the following situations:

- When vial is moved from freezer to the fridge
- When the vial is moved from the fridge to room temperature
- When vial is first punctured