A. Formulations
- Adult ≥12 yo (Do Not Dilute) Grey Cap Grey Label Border
- Pediatric 5 yo<-12 yo (Do Not Dilute) Blue Cap Blue Label Border
- Infant 6 mo<-5 yo (Dilute Prior to use) Maroon Cap Maroon Label Border

B. Shipping:
- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed at 2°C to 8°C.
- Single-dose preloaded syringes or punctured and diluted vials of vaccine may be transported in exceptional circumstances.
- Vials should be upright during transport, and tightly packed to reduce jostling of the vials.
- Validated containers must be used for transport.
- Temperature must be monitored continuously during transportation and documented

B. Storage:
-60°C to -90°C, Ultra-Low Temperature (ULT) Shipper (frozen):
- Carton may arrive packaged in thermal packing designed for temporary storage. The shipper can be used for temporary frozen storage for up to 30 days.
- If using the Pfizer-provided shipper upon receipt and after opening, dry ice should be replenished within 24 hours (maximum of 20-23 kg of dry ice pellets; recommended sizes: 9-16 mm). If transferring into a provincially/federally provided shipper, follow guidelines for dry ice replenishment to prepare shipper to store the vaccine.
- With every re-icing, shipper can maintain ULT storage for 5 days with 2 openings per day of 3 minutes or less, i.e. dry ice must be replenished every five days. **NOTE:** Additional openings of shipper will require more frequent dry ice replenishment (see resource link below).
- Temperature monitoring must be continually conducted while vaccine is stored in thermal shipper.

-60°C to -90°C, Ultra-Low Temperature (ULT) Freezer (frozen):
- Can be stored at ULT until the written expiry date printed on the vial/carton.
2°C to 8°C Refrigerator (thawed):
- Adult/Pediatric: Thawed vaccine can be stored for up to 10 weeks (70 days).
- Infant: Thawed and undiluted vaccine can be stored for up to 10 weeks (70 days).
- Once placed in 2°C to 8°C environment, the carton should be updated with the expiry information.

2°C to 25°C Room Temperature (thawed):
- Adult/Pediatric: Vials may be stored for up to 12 hours at temperatures up to 25°C prior to first puncture.
- Adult/Pediatric: Vials may be stored for up to 12 hours at temperatures up to 25°C after first puncture.
- Infant: Vials may be stored for up to 12 hours at temperatures up to 25°C prior to dilution.
- Infant: Vials may be stored for up to 12 hours at temperatures up to 25°C after dilution.
- Thawed vials can be handled in room light conditions.

D. Thawing:

<table>
<thead>
<tr>
<th>Environment</th>
<th>Adult ≥ 12 yo (Do Not Dilute) Grey Cap Grey Label Border</th>
<th>Pediatric 5 yo-&lt;12 yo (Do Not Dilute) Blue Cap Blue Label Border</th>
<th>Infant 6 mo-&lt;5 yo (Dilute Prior to use) Maroon Cap Maroon Label Border</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thawed at 2°C-8°C</td>
<td>6 hours</td>
<td>6 hours</td>
<td>2 hours</td>
</tr>
<tr>
<td>Thawed at room temp (up to 25°C)</td>
<td>30 minutes</td>
<td>30 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Handling Frozen Vials
- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to 5 minutes.
- If a carton is at room temperature for close to, but not over 5 minutes, place back in ULT freezer for 2 hours before it can be removed again.
- If a carton is at room temperature for over 5 minutes, consider it to be thawing and do not place back in freezer. Vials must be stored and moved into a refrigerated (2°C-8°C) container.
- Individual vials removed from a carton and left at room temperature should not be returned to frozen or refrigerated storage and must be thawed for use.

Thawed vaccine cannot be refrozen.

E. Use
- Vials may be stored for up to 12 hours at temperatures up to 25°C pre and post first puncture for a total of up to 24 hours
F. Vaccine Stability

<table>
<thead>
<tr>
<th>ULT</th>
<th>2°C to 8°C</th>
<th>Room temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>-90°C to -60°C for 30 days (replenish dry ice q 5 days)</td>
<td>10 weeks (70 days)</td>
<td>Vials may be stored for up to 12 hours at temperatures up to 25°C pre and post first puncture for a total of up to 24 hours</td>
</tr>
<tr>
<td>-90°C to -60°C Can be stored until written expiry</td>
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<td></td>
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</table>

[Diagram of vaccine storage conditions]
G. Helpful Resources

While specific links have been identified below, it is highly recommended that health authorities and sites familiarize themselves with the resources provided by Pfizer at [www.cvdvaccine.ca](http://www.cvdvaccine.ca)

- Pfizer Product Monograph
- Pfizer COVID Vaccine Resources
- Pfizer Dry Ice Safety Data Sheet
- Pfizer Vaccine Shipping And Handling Guidelines
- Pfizer instructions on dry ice replenishment

Any questions or requests for revision of this document should be sent to IBCOC_Operations@phsa.ca
### List of Amendments

<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Description</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 11, 2023</td>
<td>A, B, C, D, E, F, G</td>
<td>SOP developed based on product monograph and information provided by Pfizer</td>
<td>Calvin Kaila</td>
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