A. Formulations
- Orange Cap 10 mcg/0.2ml – intended population: 5 years to <12 years (monovalent and bivalent)
- Maroon Cap 3 mcg/0.2ml – intended population: 6 months to <5 years (monovalent)

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 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

C. 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):
- Monovalent: Can be stored at ULT for 18 months after manufacturing date printed on the vial/carton.
- Bivalent: Can be stored at ULT for 12 months after manufacturing date printed on the vial/carton.
2°C to 8°C Refrigerator (thawed):
- 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):
- Vials may be stored for up to 24 hours at temperatures up to 25°C, with no more than 12 hours from the time of dilution (first puncture). After dilution the vials should be stored at 2°C to 25°C
- Thawed vials can be handled in room light conditions.

D. Thawing:

Regular Use (2°C to 8°C Refrigerator)
- A carton of 10 vials of Orange Cap (5 years to <12 years) may take up to 4 hours to thaw.
- A carton of 10 vials of Maroon Cap (6 months to <5 years) may take up to 2 hours to thaw
- Product needs to reach room temperature prior to dilution.  

Immediate Use
- Thaw at room temperature (up to 25°C) for 30 minutes.
- Product needs to reach room temperature before dilution.  

Handling Frozen Vials
- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to 5 minutes
- If at room temperature for close to, but not over 5 (full carton) minutes, place back in ULT freezer for 2 hours before they can be removed again.
- If 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 24 hours at temperatures up to 25°C with no more than 12 hours from the time of dilution (first puncture).
- Vials and cartons may state that vials be discarded 6 hours after dilution. This information is incorrect, and has been updated to 12 hours.

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1 It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
## 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 24 hours at temperatures up to 25°C with no more than 12 hours from the time of dilution (first puncture)</td>
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<tr>
<td>-90°C to -60°C Monovalent: 18 months from manufacturer date</td>
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<td></td>
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<tr>
<td>Bivalent:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 months from</td>
<td></td>
</tr>
<tr>
<td></td>
<td>manufacturer date</td>
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</tbody>
</table>
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

- Pfizer Monovalent Product Monograph
- Pfizer Bivalent 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>
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<tbody>
<tr>
<td>November 24, 2021</td>
<td>A, B, C, D, E, F</td>
<td>SOP developed based on product monograph and information provided by Pfizer</td>
<td>Calvin Kaila</td>
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<tr>
<td>November 26, 2021</td>
<td>A</td>
<td>Added hyperlink to preloaded syringes</td>
<td>Calvin Kaila</td>
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<tr>
<td>December 15, 2021</td>
<td>B, D, E</td>
<td>Information on storage at room temperature updated</td>
<td>Calvin Kaila</td>
</tr>
<tr>
<td>January 31, 2022</td>
<td>B, E</td>
<td>Shelf life extension from 6 to 9 months at ULT updated</td>
<td>Calvin Kaila</td>
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<tr>
<td>May 3, 2022</td>
<td>B, E</td>
<td>Shelf life extension from 9 to 12 months at ULT updated</td>
<td>Calvin Kaila</td>
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<tr>
<td>Sept 22, 2022</td>
<td>Title, A,B,C,D,E,F,G</td>
<td>Inclusion of Maroon Cap information</td>
<td>Calvin Kaila</td>
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<tr>
<td>Dec 13 2022</td>
<td>Title, G</td>
<td>Bivalent information added</td>
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<tr>
<td>Jan 11 2023</td>
<td>C,F</td>
<td>Expiry information updated</td>
<td>Calvin Kaila</td>
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