

COVID-19 Pfizer Vaccine

Shipping, Storage, Thawing and Use Guidelines

A. Shipping:

- Ideally, vaccine will be shipped frozen between -60°C to -90°C or -15°C to -25°C. Any hours used for transport at -15°C to -25°C count against the 2-week limit for storage at -15°C to -25°C.
- Vaccine may be shipped thawed at 2°C to 8°C in exceptional circumstances; maximum of 12 cumulative hours in transport allowable. Any hours used for transport at 2°C to 8°C count against the 31-day (1 month) limit for storage 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.
- Refer to the [Pfizer Transportation Decision Guide](#) if unsure whether to ship vaccine frozen or thawed.

B. Storage:

-60°C to -90°C, Ultra-Low Temperature (ULT) **Shipper** (frozen):

- Trays come 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 20-23kg 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 -80°C, Ultra-Low Temperature (ULT) **Freezer** (frozen):

- Can be stored at ULT until the expiry date printed on the label.

-15°C to -25°C Freezer (frozen):

- Can be stored and transported at -15°C to -25°C for up to two weeks.
- Any hours used for transport at -15°C to -25°C count against the 2-week limit for storage at -15°C to -25°C.
- May be returned **one time** to the recommended storage condition of -60°C to -80°C. Total cumulative time the vials at stored at -15°C to -25°C should tracked and should not exceed 2 weeks.

2°C to 8°C Refrigerator (thawed):

- Thawed and undiluted vaccine can be stored for up to 31 days (1 month).
- Can be transported at 2°C-8°C for a cumulative 12 hours, Any hours used for transport at 2°C to 8°C count against the 1-month limit for storage at 2°C to 8°C.

2°C to 25°C Room Temperature (thawed):

- Undiluted vials may be kept at room temperature for no more than 2 hours.
- Thawed vials can be handled in room light conditions.

C. Thawing:

Regular Use

- Approximately 2-3 hours in the refrigerator to thaw a full tray. Fewer vials will take less time to thaw.
- Product needs to reach room temperature prior to dilution.¹

Immediate Use

- Thaw at room temperature for 30 minutes.
- Product needs to reach room temperature before dilution.¹

Handling Frozen Vials

- Closed-lid vial trays, or vial trays containing 195 vials removed from frozen storage may be at room temperature for up to **5 minutes**
- Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage may be at room temperature for up to **3 minutes**.
- If at room temperature for close to, but not over, 3 (partial/open trays) or 5 (full/closed trays) minutes, place back in ULT freezer for **2 hours** before packing.
- If tray is at room temperature for over 3/5 minutes (partial/full, see above), consider it to be thawing and **do not place back in freezer**. Vials must be stored and moved in a refrigerated (2°C-8°C) container.
- Vial trays returned to frozen storage following room temperature exposure, must remain in frozen storage for at least **2 hours** before they can be removed again.
- Individual vials removed from a vial tray and left at room temperature should not be returned to frozen or refrigerated storage and must be thawed for use.

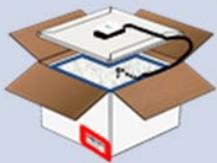
Thawed vaccine cannot be refrozen.

D. Use

- Vaccine must be diluted within 2 hours after it reaches room temperature.
- Vaccine must be used within 6 hours of dilution.

¹ It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.

E. Vaccine Stability

ULT	2°C to 8°C	Room temperature
 <p>-90°C to -60°C for 30 days (replenish dry ice q 5 days)</p>	 <p>31 days (1 month)</p>	 <p>Up to 25°C: Must be diluted within 2 hours</p>
 <p>-80°C to -60°C for 6 months</p>	 <p>12 cumulative hours (comes out of 31-day total. Risk assumed by redistributor).</p>	 <p>2°C to 25°C: Discard unused vaccine within 6 hours after dilution</p>
 <p>-80°C to -60°C: No impact on shelf life (risk assumed by redistributor)</p>	<p>+</p> 	<p>+</p> 

Note: Total amount of time at room temperature is up to 8 hours (2 hours max undiluted + 6 hours max diluted).

Pfizer can also be stored frozen at -15°C to -25°C for up to two weeks. See *Section B: Storage* for details.

F. 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 Product Monograph](#)
- [Pfizer COVID Vaccine Resources](#)
- [Pfizer Product Storage and Dry Ice](#)
- [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

Date	Section	Description	Author
March 25, 2021	A, B	Clarification that vaccine may be stored at -60°C to -90°C in a ULT thermal shipper and at -60°C to -80°C in a ULT freezer.	Keren Massey
May 3, 2021	A	Update to guidance on shipping frozen at -25°C to -15°C.	Keren Massey
May 19, 2021	A	Link added to Pfizer Transport Decision Guide.	Keren Massey
May 19, 2021	A, B, C	Update to stability information at 2°C to 8°C.	Keren Massey
May 19, 2021	E	Section added.	Keren Massey
May 19, 2021	F	Updated and expanded.	Keren Massey
July 21, 2021	B	Minor revision to guidance on storage times at ULT. Clarification that thawed and undiluted vaccine may be stored at 2°C to 8°C for one month. Section added on storage at room temperature. Updated info on dry ice replenishment (shipper can be open for up to 3 minutes).	Keren Massey
July 21, 2021	C	Update to time to thaw for regular use.	Keren Massey
August 12, 2021	C	Additional guidance that It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.	Keren Massey