

COVID-19 Pfizer Vaccine

Partial Tray ULT Distribution Guidelines

A. Introduction

This document provides information to support redistribution of partial trays of Pfizer vaccine stored at ULT (-60°C to -90°C) and will be updated to reflect best practices identified by health authorities and new information provided by vaccine manufacturers. Guidance on the transportation of partial trays of frozen Pfizer vaccine (-15°C to -25°C) can be found in the [Pfizer Redistribution Guidelines](#).

B. Definitions

Vial: Single, glass vial containing vaccine.

Payload: vial(s) of vaccine.

Pizza Box: Plastic box used by Pfizer to hold 195 vials of vaccine.

Payload Box: Container holding trays of Pfizer vaccine.

Shipper: Thermal packing container, capable of maintaining vaccine in a frozen state during transit.

C. Key Considerations

1. Risk and responsibility associated with secondary distribution of partial trays held by province, health authorities.
2. A validated container must be used to transport vaccine.
3. Temperature must be monitored during transportation and documented.
4. Transfers should be limited to decrease likelihood of temperature excursions and disruption to physical stability of vaccine.
5. Transfers between containers should be completed as quickly as possible.
6. Vaccine should be packed carefully to minimize jostling and kept upright. Vaccine can be used if temporarily knocked over.
7. Package should be handled gently and secured carefully in the vehicle during transport.
8. Diluent should be transported at room temperature.
9. **Vaccine cannot be refrozen once thawed.**

D. Methods of Redistribution of **ULT** Partial Trays

1. Redistribution of **ULT** Pfizer Vaccine (-60°C to -90°C):

Shipping Container:

The thermal shipper belonging to Pfizer can be used for distribution to secondary sites. [Dry ice must be replenished](#) within 24 hours of receipt from the manufacturer/prior to onward movement – whichever happens first.

As the data logger provided by Pfizer must be stopped when the shipment is received at the primary site, a second data logger must be added to monitor the temperature of the shipment during transport to a secondary location. Data loggers can be requested through IBCOC_Operations@phsa.ca.

Alternatively, an ULT thermal shipper provided through the provincial supply chain may be used, also requiring the installation of a new data logger. See Section for guidance on the selection of alternative models of temperature monitoring devices.

Associated Links:

- [Pfizer Storage, Thawing and Use Guideline](#)
- [Thermal Shipper Storage & Dry Ice Replenishment](#)
- [Dry Ice Personal Protective Equipment & Safety Considerations](#)
- [Procurement of Dry Ice - ROUTINE](#)
- [Procurement of Dry Ice – RUSH](#)
- [iMiniPlus Dry Ice Temperature Data Logger Quick Set Up Guide](#)
- [Sensitech TempTale Ultra Set Up Guide](#)
- [Temperature Probe Characteristics](#)

After use, the thermal shipper, including the data logger, must be returned to the supplier to help Pfizer fulfill its commitment to using reusable resources. Detailed instructions on return of materials to Pfizer can be found on pages 14-15 of the Pfizer [Shipping and Handling Guidelines](#).

Additional Considerations for Secondary Distribution of **ULT Vaccine, Partial Tray:**

- Packing:
 - Open-lid vial trays, or vial trays containing less than 195 vials removed from ULT storage may be at room temperature for up to **3 minutes**.
 - If at room temperature for close to, but not over, 3 minutes, place back in ULT freezer for **2 hours** before packing.
 - If tray is at room temperature for **over 3 minutes**, consider it to be thawing and do not place back in ULT environment. Vials must be stored and moved in a refrigerated (2°C to 8°C) environment.

- Vial trays returned to ULT 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 storage and must be thawed for use.
- When shipping at ULT pack out with dry ice; ensure [personal protective equipment](#) and trained personnel are available on the receiving end to safely handle the package.
- Ensure vaccine does not come into contact with dry ice.










E. Packing for redistribution of ULT vaccine (-60°C to -90°C):

1. Ensure data logger is calibrated for shipment and that computers on both ends of the move have been identified for data-logger software installation.
2. Turn data-logger on as per time delay [specific to the model](#).
3. Don dry ice PPE.

Steps 4-10 must take place in under 3 minutes. If these steps take close to, but not beyond, 3 minutes the tray/pizza box must go back into the ULT freezer for 2 hours before being repacked.

4. Pull tray(s)/pizza box from freezer.
5. Place tray(s)/pizza boxes into payload box.
6. Place the data logger into payload box. Close lid. If the payload box does not have a lid, place a piece of cardboard on top.
7. Place the payload box into the ULT shipper.
8. Pour dry ice pellets around the edge of the payload box.
9. Pour a layer of dry ice pellets on top of the payload box.
10. Place lid on shipper.
11. Ensure Class 9 Dry-ice label (UN 1845) on outer packaging.
12. Pack the appropriate number of normal saline diluent vials and any requested paperwork or ancillary supplies with the shipment.
NOTE: This process has not been finalized – pending decision from BCCDC.
13. Ensure regional inventory management processes are followed to track transfer of vaccine to the receiving site.

F. 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>-80°C to -60°C: No impact on shelf life (risk assumed by redistributor)</p>	<p>+</p>  <p>12 <u>cumulative</u> hours (comes out of 31-day total. Risk assumed by redistributor).</p>	<p>+</p>  <p>2°C to 25°C: Discard unused vaccine within 6 hours after dilution</p>

Pfizer can also be stored frozen at -15°C to -25°C for up to two weeks. Time in transit at -15°C to -25°C must be counted against the two week limit. See [Pfizer Shipping, Storage, Thawing and Use Guidelines](#) for more details.

G. Selection of Data Loggers

The [Vaccine Storage and Handling Toolkit](#) (US CDC) has the following information regarding the selection of data loggers (they refer to them as DDL for “digital data logger”). Should health authorities wish to explore their own procurement of data loggers, any models considered should have the following specifications:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended accuracy of +/-0.5°C (+/-1°F) or better
- Logging interval (or reading/recording rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Current and valid *Certificate of Calibration Testing*

H. Procurement of Cold Chain Equipment

All cold-chain equipment coordination and distribution will be handled centrally. This will include:

- All freezers
- All shippers
- All data loggers
- All dry ice PPE

Equipment coordination questions and procurement requests should be directed to IBCOC_Operations@phsa.ca. Health authorities will continue to procure their dry ice directly from the [National Operations Centre](#). In emergency situations, rush orders of dry ice can be procured through a [provincial contract](#).

I. Reporting Requirements

See [Post-arrival Documentation and Reporting Procedures](#) for a summary of critical data elements, and role and responsibilities.

J. Inventory Management

Regular inventory management processes should be followed. Contact regional inventory management teams for advice and guidance.

K. Resources

- [Pfizer Product Monograph](#)
- [Pfizer COVID Vaccine Resources](#)
- [Pfizer Product Storage and Dry Ice](#)
- [Pfizer Dry Ice Replenishment](#)
- [Pfizer Dry Ice Safety Data Sheet](#)

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	All	Document revised to reflect guidance for partial trays of vaccine moved at ULT ONLY.	Keren Massey
May 4, 2021	B, K	Section B added. Section K revised.	Keren Massey
May 19, 2021	F	Update to stability information at 2°C to 8°C.	Keren Massey
May 19, 2021	K	Link to product monograph added.	Keren Massey