

# Management of COVID-19 Pfizer (COMIRNATY™) vaccine from freezer to refrigerator

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## Purpose

This procedure describes the process of unpacking frozen COVID-19 Pfizer (COMIRNATY™) vaccine vials and trays and transferring them from a freezer (whether Ultra-Low Temperature or standard freezer) into a refrigerator to thaw.

## Scope

Transferring COVID-19 Pfizer (COMIRNATY™) from the freezer to a refrigerator.

## Responsibility

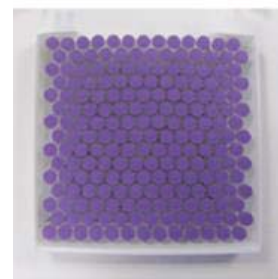
When working in pairs, it is the responsibility of both people to continue to observe all local COVID-19 measures. Staff following this procedure are responsible for adhering to the appropriate time frames for thawing, managing and storing the COVID-19 Pfizer (COMIRNATY™) vaccine.

## Vials



- 2mL type 1 glass preservative free
- A single dose of COMIRNATY™ is 0.3mL once diluted and drawn up
- 5 doses per vial using standard stock needles and syringes
- 6 doses per vial using low dead space needles and syringes (when available)

## Trays



- Single tray holds 195 vials
- 975 doses using standard stock needles and syringes
- 1,170 doses using low dead space needles and syringes (when available)

## Procedure

1. Complete one Pfizer thaw label for each vial tray detailing
  - Time and date removed from the ULT freezer, ULT shipper or standard freezer
  - Time and date of thawed expiry i.e. 1 month (31 days) from removal from ULT freezer, ULT shipper or standard freezer Batch number
  - Signature of person completing the label

2. A second person check is required to verify
  - The time and date removed from the freezer for thawing
  - The thawed expiry date
  - The batch number
  - That there are the same number of completed Pfizer thaw labels as there are vial trays
  - Initial the labels to confirm the information is correct.
3. Attach one Pfizer thaw label to each of the vial trays, ensuring not to cover any original labels on the carton. It may be necessary to use tweezers or ask the other person to peel the label off its backing if this cannot be done while wearing gauntlets.
4. Transfer the vial trays into the refrigerator in a timely manner to reduce the duration of exposure at room temperature (see 'Removing vial trays from ULT environment' diagram below).
5. Managing the thawed concentrate vaccine vials (prior to dilution):
  - Based on current stability studies, a tray of 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, whereas a smaller number of vials may thaw in less time.
  - Thawed concentrate vials may be stored in the refrigerator for up to 1 month (31 days)
  - Concentrate vials may be at room temperature for a maximum of TWO hours prior to dilution
  - If less than a full tray of vials is repacked and thawed for redistribution, the hub will need to provide a smaller packaging unit that is transported via reputable courier or a temperature control vehicle (TCV).
  - Repacking should be done in a 2° to 8°C environment whenever possible. Otherwise, time at room temp should be tracked and minimised to stay within the two-hour allowance for room temperature for thawed vials.
  - If using 2° to 8°C for transportation, there needs to be a process to ensure that the 12 hours available for transportation at 2° to 8°C is not exceeded.
  - The 12 hours available for transportation should be included as part of the total allowable 1 month (31 days) at 2° to 8°C.

## Removing vial trays from ULT environment



### Closed-lid, 195 Vial (Full) Trays

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (<math><-60^{\circ}\text{C}</math>) may be at temperatures up to 25°C for up to 5 minutes for transfer between ultra-low-temperature environments (eg between the shipper and the ULT freezer). After vial trays are returned to ultra-low temperature frozen storage following temperature exposure up to 25°C, they must remain in ultra-low temperature frozen storage for at least 2 hours before they can be removed again. Closed-lid vial trays containing 195 vials removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 3 minutes.
- Do NOT refreeze thawed vaccine.



### Open-lid, and/or Less Than 195 Vial Trays

- Open lid vial trays, or vials containing less than 195 vials removed from ultra-low temperature frozen storage/shipper (<math><-60^{\circ}\text{C}</math>) may be at room temperature (<math><25^{\circ}\text{C}</math>) for up to 3 minutes for transfer between ultra-low temperature environments or to remove vials for thawing or use.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 1 minute before being returned to the standard freezer.
- Individual vials- once an individual vial is removed from a vial tray at room temperature, it should not be returned to frozen storage. It should be thawed for use.