

Management of COVID-19 Pfizer (COMIRNATY™) vaccine – use of standard temperature (-20°C) freezers

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Purpose

This Procedure describes the use of standard dedicated pharmaceutical (-20°C) freezers to store the COVID-19 Pfizer (COMIRNATY™) vaccine for up to two weeks.

Scope

Use of standard dedicated pharmaceutical (-20°C) freezers for storage of COMIRNATY™ for up to two weeks.

Requirements

The freezer must be plugged into an uninterrupted power supply and must be continually data logged with back to base alarm to individual/s that are available to respond immediately 24 hours a day. The data logging report must be downloaded and reviewed at least weekly. The freezer must also have an audible alarm.

The freezer's current/minimum/maximum temperatures must be visualised and manually recorded four times a day, twice in the morning and twice in the afternoon/evening, including at the beginning and end of the shift (in addition to recording each time the freezer is accessed). These temperatures must be recorded. A staff member must be allocated for each shift to undertake this duty. A Freezer temperature monitoring chart is available to order from Stream Solutions to record this: <https://www.tollstreamdirect.com/NSWH/user.asp>

Local procedures must be in place to respond to cold chain breaches and power failures, including reporting temperatures outside -15 to -25°C range immediately to senior executive and also to the State Health Emergency Operations Centre (SHEOC) on 9859 5690.

Vaccines must not be discarded until advice is received from the SHEOC.

Cold chain breaches resulting in vaccine wastage or recall, and revaccination of patients must be reported in the NSW Health Incident Management System (IMS+) to facilitate investigation, resolution and minimise the risk of future incidents.

All staff involved in the handling, preparation and administration of the COVID-19 Pfizer (COMIRNATY™) vaccine must be appropriately trained (undertake the Australian Government COVID-19 training program and the Health Education and Training module in Vaccine Storage and Cold chain management (also available via NSW Health - Immunisation programs).

Procedure

Frozen Vials Prior to Use

After removing from the thermal shipper or an ultra-low temperature freezer, vials may be stored at -25°C to -15°C for up to 2 weeks. The freezer must be dedicated to pharmaceutical use only. It must be temperature monitored and alarmed.

Vials must be kept frozen and protected from light until ready to use.

Vials stored at -25°C to -15°C for up to 2 weeks may be returned **ONCE** to the recommended ultra-low storage condition of -90°C to -60°C. The time at -25°C to -15°C must be clearly labelled on the storage box for the vials. Do not refreeze any thawed vials.

Total cumulative time the vials are stored at -25°C to -15°C must be tracked and must not exceed 2 weeks.

Storage of the vials between -90°C to -60°C is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C, vials may be transported at -25°C to -15°C using a temperature monitored container protected from light. Any hours used for transport at -25°C to -15°C count against the 2-week limit for storage at -25°C to -15°C and this time **MUST** be clearly labelled on the storage box (such that cumulative time at -25°C to -15°C is documented)

Frozen vials transported at -25°C to -15°C may be returned **ONCE** to the recommended ultra-low storage condition of -90°C to -60°C (this must be recorded on the vial storage box).

Removing vial trays from ULT environment



Closed-lid, 195 Vial (Full) Trays

- Closed lid vial trays containing 195 vials removed from storage (<-60°C) may be at room temperature (<+25°C) for up to **5 minutes** for transfer between the ultra-low temperature freezer to a standard freezer.
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be moved again.



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

- Open lid vial trays, or vials containing less than 195 vials removed from frozen storage (<-60°C) may be at room temperature (<+25°C) for up to 3 minutes for transfer between ultra- low temperature environments or to move to a standard freezer or to remove vials for thawing or use
- **Do not re-freeze thawed (+2-+5°C) vials.**