

COVID-19 Vaccination Program Procedures

Management of Moderna SPIKEVAX bivalent Original/Omicron (elasomeran/imelasomeran) COVID-19 Vaccine from a standard temperature (-20°C) freezers to refrigerator

Last updated: 3 November 2022

Purpose

This procedure describes the process of receiving frozen Moderna SPIKEVAX bivalent Original/Omicron (elasomeran/imelasomeran) COVID-19 Vaccine (*Moderna Bivalent*) cartons and vials, transferring them to a freezer (-25°C to -15°C) or to a refrigerator (+2°C to +8°C), and ensuring subsequent appropriate transport, storage and handling.

Scope

Transferring frozen Moderna SPIKEVAX bivalent Original/Omicron (elasomeran/imelasomeran) COVID-19 Vaccine cartons and vials from delivery to the freezer (-25°C to -15°C) or to a refrigerator (+2°C to +8°C).

Requirements:

The freezer/refrigerator's 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/refrigerator must also have an audible alarm.

The freezer/refrigerator'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/refrigerator is accessed). 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](https://www.tollstreamdirect.com/NSWH/user.asp) (<https://www.tollstreamdirect.com/NSWH/user.asp>) to record this.

Local procedures must be in place to respond to cold chain breaches and power failures, including reporting temperatures outside -15°C to -50°C range (for freezer) or +2°C to +8°C range (for refrigerator) immediately to senior executive and also to the Australian Government Vaccine Operations Centre (VOC) on 1800 318 208 using the NSW Health COVID-19 vaccine cold chain breaches reporting form.

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

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 Moderna Bivalent vaccine must be appropriately trained (i.e. have undertaken the Australian Government COVID-19 training program and the Health Education and Training module in Vaccine Storage and Cold chain management).

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 managing and storing the Moderna Bivalent vaccine.

Procedure

Receiving vaccine delivery

- The Moderna Bivalent vaccine will arrive frozen, between -50°C and -15°C.
- Each box contains 10 multi-dose vials and each multidose vial contains 5 doses of 0.5mL.
- Store vaccine in a freezer or refrigerator- see below for each storage unit.
- Examine the shipment for signs of damage.
- Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine)
- Check the TagAlert temperature monitoring device by pressing the blue “start and stop” button.
 - Left arrow points to a green checkmark: The vaccine is ready to use. Store the vaccine at proper temperatures immediately (frozen at -25°C and -15°C).
 - Right arrow points to a red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label **DO NOT USE!** Contact the Australian Government Vaccine Operations Centre (VOC) on 1800 318 208 using the NSW Health COVID-19 vaccine cold chain breaches reporting form for advice.
- The expiry date can be found on the packaging.

Storage in a Freezer

Unopened vials may be stored in the freezer between -25°C and -15°C (and can be stored from -50°C to -15°C).

- Store in the original packaging
- Protect from light
- Do **NOT** store with dry ice, or below -50°C.
- The vaccines should be transferred between the transportation and freezer storage as quickly as possible.

Unopened thawed vaccine vials may be stored in the refrigerator between +2°C and +8°C for up to 30 days.

- Do **NOT** refreeze thawed vaccine
- Thawed vaccine can be handled in room light. It should however be protected from light when stored in the refrigerator.
- Monitor how long the vaccine has been in the refrigerator using a ‘Fridge temperature bag expiry label (appendix 1A)’ or via an electronic system
 - Remove the box from frozen storage
 - Complete the information on the storage label.
 - Attach it to the carton holding the vaccine vials.
 - Once labeled, place vaccine in the refrigerator.
- The unopened vaccine may be stored at +8°C to +25°C up to 24 hours after removal from refrigerated conditions

Thawing

The thawing process in a refrigerator (+2°C to +8°C) takes 2 hours and 30 minutes or 1 hour at room temperature (+15°C to +25°C).

Transportation of vials

If vials are transported frozen specialised equipment and couriers are required to ensure that the vaccines do not thaw.

Available data supports transportation of one or more thawed vials for up to 12 hours at +2°C to +8°C. Vials may be transported using a temperature monitored container protected from light. Once thawed and transported at +2°C to +8°C, vials must NOT be refrozen and should be stored at +2°C to +8°C until use.

If the vials are removed from a freezer and transported refrigerated at +2°C to +8°C, the vaccines should be labelled with the date and time they are removed from the freezer. The 30 days until expiry commences at this time.

Appendix 1

1. A. Fridge temperature bag expiry label

(to be used when vaccine is removed from freezer and placed in a fridge)

SPIKEVAX BIVALENT ORIGINAL/OMICRON (elasomeran/IMELASOMERAN) Moderna COVID-19 VACCINE

Fridge Temperature Bag/Container Expiry Label
Unpierced vial can be stored at 2-8°C for up to 30 days

Removed from -20°C freezer:

DD / MM / YY at HH : MM

Batch No:

Discard after:

DD / MM / YY at HH : MM

Signed: _____

Checked: _____

NH700907 181022