

COVID-19 Vaccine Moderna Excursion Table

Intended Storage Condition: FROZEN -25°C to -15°C (-13°F to 5°F)

| Intended Storage Condition | Excursion Scenario | Recommended Action | Shelf Life Expiration/Usable range |
|--|---|--|---|
| Frozen (-25°C to -15°C) (-13°F to 5°F) | Below -40°C (-40°F) | DO NOT USE. Quarantine vials and contact manufacturer. | Contact Manufacturer |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -40°C to < -25°C (-40°F to < -13°F) Less than 24 hours | Move to -25°C to -15°C (-13°F to 5°F) storage (if > 24 hours, contact manufacturer) | Through published Expiry Date |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -25°C to -15°C (-13°F to 5°F) (Recommended Storage Temperature Range) | None - This is the Recommended Storage Temperature | Through published Expiry Date |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | > -15°C to < -2°C (5°F to < 28°F) Less than 24 hours | Move to -25°C to -15°C (-13°F to 5°F) storage (if > 24 hours, contact manufacturer) | Through published Expiry Date |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -2°C to < 8°C (28°F to < 46°F) | If vials can be visually confirmed still frozen , move back to Recommended Storage Temperature -25°C to -15°C, (-13°F to 5°F) | Through published Expiry Date |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -2°C to < 8°C (28°F to < 46°F) Less than 60 minutes | If vials cannot be visually observed , and excursion is < 60 minutes: Return to -25°C to -15°C (-13°F to 5°F) storage. | Through published Expiry Date |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -2°C to < 8°C (28°F to < 46°F) More than 60 minutes | If vials cannot be visually observed , and excursion is > 60 minutes, contact manufacturer for further guidance | Contact Manufacturer |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | -2°C to < 8°C (28°F to < 46°F) More than 30 days | If vials can be visually observed and are confirmed thawed , DISCARD following local procedures for medical waste disposal | DO NOT USE |
| Frozen (-25°C to -15°C) (-13°F to 5°F) | 8°C to < 30°C (46°F to < 86°F) Ambient Room Temperature (ART) | Do not refreeze vials. Move vials to refrigerated condition (-2C to 8C) as soon as possible. Vials are permitted a cumulative 12-hour excursion above 8°C (46°F). | Use within 12 hours cumulative. Track and record time at ambient room temperature for individual vials. |

The COVID-19 Vaccine Moderna multiple-dose, preservative-free vials are to be stored frozen between -25°C to -15°C (-13°F to +5°F). Do not store on dry ice. Clinical judgment should be exercised when deciding to administer vaccine that has incurred excursion conditions.¹

To **contact manufacturer**, please email the details of your excursion to 'excursions@modernatx.com'

Effective March 2021

Intended Storage Condition: Refrigerated 2°C to 8°C (36°F to 46°F)

| Intended Storage Condition | Excursion Scenario | Recommended Action | Shelf Life Expiration/Usable range |
|--|--|---|--|
| Liquid 2°C to 8°C (36°F to 46°F) | -40°C to -2°C (-40°F to 28°F) | Return vials to 2°C to 8°C (36°F to 46°F) location. | Use within 30 days of original storage at original 2°C to 8°C (36°C to 46°C) period. THIS EXCURSION IS ONLY ALLOWED ONCE. If a vial freezes a second time, DISCARD following local procedures for disposal of medical waste. |
| Liquid 2°C to 8°C (36°F to 46°F) for up to 30 days | -2°C to 8°C (28°F to 46°F) (recommended storage temperature range) | None - This is the Recommended Storage Temperature | Use within 30 days of storage at 2°C to 8°C (36°F to 46°F). |
| Liquid (2°C to 8°C) (36°F to 46°F) | >8°C to ≤ 30°C (46°F to < 86°F) Ambient Room Temperature (ART) | Vials are permitted a cumulative 12-hour excursion in this range. The 12-hr countdown starts as soon as the vial is removed from the refrigerator. Countdown stops as soon as the vial is returned to the fridge. Vial time at ambient room temperature must be tracked by user. | Once 12 hours in this temperature range has elapsed, any remaining material should be discarded. |
| Liquid (2°C to 8°C) (36°F to 46°F) | Above 30°C (86°F); Temp exceeding ART | DISCARD following local procedures for medical waste disposal | DO NOT USE |

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|--|---|
| | Recommended Temperature and Time Parameter |
| | Allowable Excursion: Action Required |
| | Excursion Outside of Allowable Parameters: Do Not Use |
| | Contact Manufacturer |

The COVID-19 Vaccine Moderna multiple-dose, preservative-free vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Clinical judgment should be exercised when deciding to administer vaccine that has incurred excursion conditions.

To **contact manufacturer**, please email the details of your excursion to 'excursions@modernatx.com'

COVID-19 Vaccine Moderna has been granted a Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency. The European Medicines Agency will review new information on this medicinal product as it becomes available and the SmPC will be updated as necessary.

1. Moderna, Inc. COVID-19 Vaccine Summary of Product Characteristics Including Patient Information Leaflet. Moderna, Inc., Cambridge, MA, USA: January 06, 2021. <https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna#authorisation-details-section>