



MEMORANDUM

To: Operation Warp Speed (OWS)
Centers for Disease Control and Prevention (CDC)

From: Moderna

Re: Transport of Moderna COVID-19 Vaccine in Exceptional Circumstances

Dear Dr. Jeanne Santoli,

On December 2, 2020, CDC and OWS requested information regarding transport of the Moderna COVID-19 Vaccine under certain circumstances in which frozen state transport is not feasible. You have specifically asked whether the Moderna COVID-19 Vaccine can be transported in the liquid state at 2-8°C. We understand that your request is intended to relate only to exceptional scenarios, where frozen state transport cannot be accomplished.

The Moderna COVID-19 Vaccine should be shipped in the frozen state at -25°C to -15°C (-13°F to 5°F) and should not be shipped or stored below -40°C (-40°F). This is the preferred mode of shipment, which we expect to be reflected in the Emergency Use Authorization (EUA) Prescribing Information (PI) that the U.S. Food and Drug Administration (FDA or the Agency) will authorize if the Agency issues an EUA. The working draft of the EUA PI includes the following information regarding storage temperatures for the Moderna COVID-19 Vaccine:

Store frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unopened vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

We do not yet know whether this language will be modified in the final version of the PI. The product is designed to be maintained at the temperatures described above, for the time periods noted above, and we do not recommend deviating from the parameters reflected in the FDA-authorized labeling.

The vaccine generally should be shipped and transported frozen, with cold chain maintained between -25° to -15°C (-13° to 5°F). We understand that the U.S. government has determined that there may be circumstances in which vaccine must be transported but frozen state transport is not feasible. Below, we have provided the requested information. **Please note, however, that this information may not be consistent with the FDA-authorized labeling for the product or with FDA's views of the stability of the product at certain temperatures.**

- The vaccine should be shipped in the frozen state at -25°C to -15°C (-13°F to 5°F).
- The vaccine should not be shipped or stored below -40°C (-40°F).
- The long-term storage condition for the vaccine is $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ (i.e., -25° to -15°C (-13°F to 5°F)).
- Once a vial of the drug product has been thawed, it may be kept at 2°C to 8°C (36°F to 46°F) for up to 30 days.
- Unopened vials may be stored between 8°C and 25°C (46°F to 77°F) for up to 12 hours, after which the product must be discarded.
- Once thawed, the product cannot be refrozen.
- Opened vials should never be transported.

As noted above, the vaccine generally should be transported in the frozen state. We understand that, in the event that frozen state transport resources are not feasible, ability to transport the thawed vaccine at 2°C to 8°C may be required. We therefore have provided guidance below, and we may update this guidance as further data from ongoing studies becomes available.

General precautions for liquid state (2°C to 8°C) transport of Moderna COVID-19 Vaccine

- (1) The Moderna COVID-19 Vaccine drug product, when in the liquid state, is susceptible to interfacial stresses.
 - a. The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.
 - b. The transport container should be labeled prominently with “Fragile: Handle with Care, Do Not Drop” cautionary statements.
 - c. The transport containers must be secured (strapped/braced) when being transported to prevent unnecessary movement.
 - d. The Moderna COVID-19 Vaccine drug product must be protected from being dropped.
- (2) The Moderna COVID-19 Vaccine drug product, when in the liquid state, should always be transported in insulated containers that are qualified to maintain the load at 2°C to 8°C for at least the duration of the intended transport.
 - a. Examples of such containers include molded EPS foam shippers, or hard plastic vacuum insulated shippers (e.g., Credo).

- b. The transport container should be labeled prominently with cautionary statements pertaining to temperature control.
- (3) Care must be taken to ensure that the thawed vaccine drug product does not re-freeze in transit.
- a. Take measure to ensure that the thawed vaccine does not come into contact with any frozen-packs added to maintain temperature.
 - b. The transport container should be labeled prominently with cautionary statements pertaining to prevention of re-freezing.
- (4) The Moderna COVID-19 Vaccine drug product should be transported in the carton configuration wherever possible.
- a. The carton should be placed with dunnage (padding material) inside the container to minimize product/carton movement during transport.
 - b. If transport must be conducted at the vial level, the vial should be placed in insulation and bubble wrap or similar padding to protect the product.
 - c. Containers, cartons, and vials of the Moderna COVID-19 Vaccine drug product must be protected from being dropped.
- (5) After completion of transport, Moderna COVID-19 Vaccine drug product should be inspected, inventoried, and immediately be placed into a refrigerator qualified to maintain the product at 2°C to 8°C.
- (6) Any set of cartons/vials should not be subjected to repeat instances of transport. If a carton/vial has been on a transfer once, it should not be sent out again and instead used locally, even if the vial has not been in transit for the maximum allowable period. This is a precautionary measure since it will be difficult to keep track of the transportation time “used up” for any specific vial.

Scenario Planning. We understand that the government would like to be prepared for transport scenarios that vary in nature and time. As noted above, we recommend transporting, storing, and handling the vaccine according to the instructions contained in the FDA-authorized PI. Because you have requested information regarding particular scenarios, we have responded to your inquiries below.

Scenario 1: Short Duration Transport on a Medical, Commercial or University Campus-Like Setting

Transport in a qualified container, as defined above, may be carried out using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked, no running). Follow the general precautions described above. Such transport may be conducted for up to one (1) hour. If cumulative time for this local transport (walked/pushcart) will exceed one (1) hour, user should transport in frozen state at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ (i.e., -25° to -15°C (-13°F to 5°F)).

Scenario 2: Medium and Long Duration Ground Transport

Transport in qualified container, as defined above, may be carried out using a car, van, or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Such transport may be conducted for up to twelve (12) hours.

Scenario 3: Medium and Long Duration Ground Plus Air Transport

Transport in qualified container, as defined above, may be carried out using a combination of ground transportation (car, van, or truck on paved, smooth gravel, or smooth dirt roads) for up to nine (9) hours plus a flight for up to three (3) hours. Total travel should not exceed twelve (12) hours.