Removing Vials to Thaw: Pfizer-BioNTech COVID-19 Vaccine

Removing from Thermal Shipping Container or Ultra-Low-Temperature Freezer

- If less than a full tray is needed, remove the number of vials needed from the tray and return the tray to frozen storage in ≤3 minutes
- Vials should be transferred into a secondary container for safe transportation
- Protective gloves allowing manual dexterity should be worn while handling frozen vials

Transferring Frozen Vials Immediately to a Refrigerator (2 to 8 °C or 35 to 46 °F)

- An entire 195 vial tray will take about 3 hours to thaw in a refrigerator; a smaller number of vials may thaw more quickly
- Vials needed for more immediate use can be thawed at room temperature (30 minutes)
- Vials thawed at room temperature form condensation on the outside of the vial. Thawing in a secondary container is recommended
- Do not re-freeze thawed vials
- Storing Undiluted Vials

<table>
<thead>
<tr>
<th>Condition</th>
<th>Storage Time</th>
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</thead>
<tbody>
<tr>
<td>Refrigerator (2 to 8 °C or 35 to 46 °F)</td>
<td>up to 120 hours (5 days)</td>
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<tr>
<td>Room Temperature (up to 25 °C or 77 °F)</td>
<td>no more than 2 hours or transferred to a refrigerator</td>
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</table>

In-Use Stability

Vials Before Dilution

- Undiluted vials may be held at room temperature for up to 2 hours before dilution
  - Includes time for thawing and/or to come to room temperature

Vials After Dilution

- After dilution, vials may be stored at Room Temperature or in the refrigerator (2 to 25 °C or 35-77 °F)
- Diluted vaccine must be used within 6 hours from the time of dilution
- Any vaccine remaining in vials must be discarded after 6 hours

*Temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site's Standard Operating Procedures.
Supplies Required to Prepare

Supplies Needed per Vial

- 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL)
- 1 diluent syringe/needle (3 mL or 5mL syringe/21G needle)
- 5 dosing syringes/needles (1 mL syringe/IM injection needle)
- Other materials such as alcohol swabs, gloves, PPE
Dose Preparation of Pfizer-BioNTech COVID-19 Vaccine

**Syringe and Needle Specifications**

**For Diluent Withdrawal and Mixing With Pfizer-BioNTech COVID-19 Vaccine**
- ONE 3 mL syringe (optimal size) or 5 mL syringe to withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP from each diluent vial
- ONE 21 gauge or narrower needle should be used to withdraw the diluent

**For Vaccine Administration (Intramuscular Injection)**
- FIVE 1 mL syringes for each vaccine vial
  - 1 syringe for each 0.3 mL dose/patient
- FIVE 23- or 25-gauge needles for intramuscular injection for each vaccine vial
  - Needle Lengths appropriate for varied body sizes – 5/8”, 1”, 1 1/2”

*Do not prepare all 5 syringes at once

• Ancillary supply kits have been purchased by the US Government and will be distributed from McKesson at the direction of the US Government

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Dose Preparation of Pfizer-BioNTech COVID-19 Vaccine

**Diluent Specifications**

- Each thawed vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP
  - Bacteriostatic saline or other diluents must not be used
- Optimal diluent vial size is 2 mL (0.9% Sodium Chloride Injection, USP), however depending on the manufacturer stock availability, larger size diluent vials can be used

**IMPORTANT:** Regardless of the volume of the diluent vial, it must be used for ONE TIME dilution (after 1.8 mL withdrawal, the remaining diluent must be discarded)

- 2 mL saline vial is preferred to reduce diluent wastage, risk of over-dilution, and infection risk associated with excess diluent reuse
- US Government has purchased 2 mL vials of 0.9% Sodium Chloride, USP, which will be distributed in coordination with the US Government