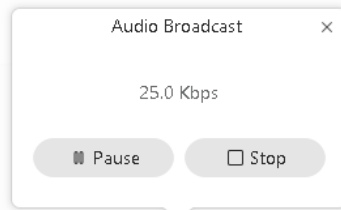


Removing Vials to Thaw: Pfizer-BioNTech COVID-19 Vaccine

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

Refrigerator (2 to 8 °C or 35 to 46 °F)	up to 120 hours (5 days)
Room Temperature (up to 25°C or 77°F)	no more than 2 hours or transferred to a refrigerator

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 Standard Operating Procedures.

Preparation of Pfizer-BioNTech COVID-19 Vaccine



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

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