

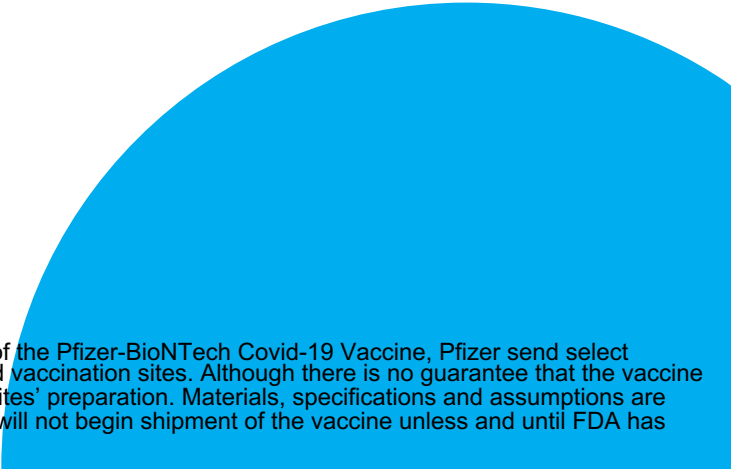


Refrigerator Storage

Current as of December 6, 2020

**Breakthroughs that
change patients' lives**

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.



Change Log

Version	History of Changes
01	Initial version
02	<ul style="list-style-type: none">Updated timing for vial tray exposure at room temperature during transfer from <1 minute to 5 minutes.Updated product thawing times with latest data from stability studies.Updated redistribution information

Refrigerator Usage

Product Refrigeration

Product can be stored at 2 to 8 °C (35.6° to 46.4°F) refrigerator up to 120 hours (5 days).

Product Thawing

Based on current stability studies, a tray of 25 vials or 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, respectively, whereas a fewer number of vials will thaw in less time.

Either: Transfer the frozen vials immediately to a refrigerator at 2 to 8 °C (35.6° to 46.4°F).

Or: Vials needed for immediate use can be thawed at room temperature (30 minutes); room temperature hold time is no more than 2 hours.

Vials thawed at room temperature form condensation on the outside of the vial, so thawing in a secondary container is recommended.

Vials may be stored in the refrigerator prior to dilution for up to 5 days (120 hours).

Vials may be held at room temperature for no more than 2 hours prior to dilution.

Refrigerator Usage

Redistribution in a Refrigerated Container

- If deconsolidating vial trays for redistribution, repacking should be done in a 2° to 8°C environment whenever possible. Otherwise, time at room temp should be tracked and minimized to stay within the 2 hour allowance for room temperature.
- If using 2° to 8°C for transportation, point of delivery (POD) needs to have a process to ensure that the 12 hours available for transportation at 2° to 8°C is not exceeded.
- The 12 hours available for transportation should be included as part of the total allowable 120 hours of product stability at 2° to 8°C.
- Temperature tracking logs/alarms should be put in place for transfer activities, pack-out, deconsolidation and redistribution.
- Vials must be transported un-diluted. Do not transport vials after dilution.

Diluted Product Storage

Diluted product must be used in 6 hours from the time of dilution, stored between 2°C to 25°C (35.6° to 77°F).