

COVID-19 Vaccine Storage and Handling Updates and Review Q & A 6-3-21

Do we still need to have hourly checks of the refrigerator temperature? Temperatures must be checked twice a day unless transporting (see guidance for transporting below). Staff must check and record the current temperature and min/max temperature at the beginning of each workday. Recording the min/max temperature at the beginning of the workday helps with determining if any excursions have occurred since the last temperature check. They also must check and record temperatures at the end of each clinic day. It is recommended to check temperatures 30 minutes prior to leaving the clinic. This will help give you time to respond if there is an excursion.

Monitoring requirements may vary if you are using the manufacturer-provided shipping container for storage; review the product specific information provided in the toolkit.

When recording include:

- Minimum/maximum temperature
- Date/Time
- Name of person checking and recording temperature
- Actions taken if a temperature excursion occurred

When Transporting Vaccine: Record the time and temperatures at the start, during, and end of transport - if longer than 1 hour, document hourly. If device displays min/max temperatures, review and record information.

Temperature records must be kept for a minimum of three years, or longer if required by your jurisdiction.

Resources:

[Vaccine Storage and Handling Toolkit-March 2021 \(cdc.gov\)](#)

Refrigerator Temperature Logs Fahrenheit & Celsius

[refrigerator-storage-logger-fahrenheit.pdf \(cdc.gov\)](#)

[refrigerator-storage-logger-celsius.pdf \(cdc.gov\)](#)

Ultra-Cold Vaccine Storage Temperature Log Fahrenheit & Celsius

[temp-log-ultra-cold-storage-fahrenheit.pdf \(cdc.gov\)](#)

[temp-log-ultra-cold-storage-celsius.pdf \(cdc.gov\)](#)

Transport Temperature Log

[You Call The Shots: Temperature Log when Transporting Vaccine at Refrigerated Temperatures \(cdc.gov\)](#)

Does Pfizer need to be kept in the fridge after punctured? It can be but does not need to be. **After puncture**, Pfizer vaccine needs to be kept between 2°C to 25°C (36°F to 77°F) for up to 6 hours. So, it can be kept at room temperature as long as you are not exceeding 77°F. Discard any unused vaccine after 6 hours.

Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).

Resources:

[Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary \(cdc.gov\)](#)

[COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals \(cdc.gov\)](#)

[Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary-May 20, 2021 \(cdc.gov\)](#)

Why can it only be kept in the freezer for a shorter time than refrigerator? Assuming you're referring to Pfizer, which can be kept at any three of the following temperatures if unpunctured: -80°C and -60°C (-112°F and -76°F) until the expiration date; -25°C and -15°C (-13°F and 5°F) for up to 2 weeks; and 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days). These temperature parameters and timeframes are based on how the vaccine was studied and the available data that the manufacturer has to support these parameters. As more data becomes available, these temperature recommendations can change (e.g., when Pfizer changed refrigerated storage from up to 120 hours (5 days) to up to 1 month (31 days)).

Can you transport to other sites pre-drawn to minimize waste? Routine transportation of vaccines to different facilities is not generally recommended, however, there are times when this is necessary. CDC recommends transporting COVID-19 vaccine in vials and always with a continuous temperature monitoring device to ensure adherence to authorized storage times and temperatures. There may be instances when the only option is to transport vaccine in a predrawn syringe. CDC refers to the U.S. Pharmacopeia (USP) guidance for transporting predrawn vaccine in syringes on page 11 of the *USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners*. The complete document provides detailed guidance on COVID-19 vaccine transport and is available for download from this site: www.usp.org/covid-19/vaccine-handling-toolkit.

With Pfizer vaccine, the 2-week freezer temps -25°C and -15°C (-13°F and 5°F), can it be stored in freezer that runs a bit colder at -16°F? No, it must be kept within these parameters. This is a narrower temperature range than what we are used to with routine vaccines. Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. CDC provides guidance on how to handle temperature excursions in their [Vaccine Storage and Handling Toolkit-March 2021 \(cdc.gov\)](#).

Vials stored in the **freezer** can be returned **one time** to ultra-cold temperature storage. Once returned, the 2-week time frame is suspended.

Resources:

[Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary \(cdc.gov\)](#)

[COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals \(cdc.gov\)](#)

Can unpunctured vaccine be returned to refrigeration after being at room temperature? If so, does the time period when it returns to room temperature start over or is it cumulative? Please see below the answer to this question for each authorized vaccine.

Pfizer: *Per Pfizer (response as of 6/9/21)* — unpunctured vials cannot be kept at room temperature [up to 25°C (77°F)] for more than 2 hours (including thaw time). If you do not exceed the 2 hours at room temperature, you can return the vaccine to the refrigerator. The storage times for each temperature range are total allowable times, and must be tracked cumulatively (as an example, a vial held for 30 minutes at room temperature may be returned to the refrigerator, but the 30 minutes must count against the allowed 2 hours at room temperature).

Moderna: *Per Moderna (response as of 4/27/21)* — one should refrain from mixing and matching temperature. So, for example, **unpunctured** refrigerated vials can be stored in the refrigerator for 30 days at 2 to 8°C, and the **unpunctured** vial can be stored at 8 to 25°C for a total of 24 hours. If it is kept at refrigerated temperatures, it can be stored under those conditions for 30 days, if the vial is thawed and at room temperature then it really should stay at room temperature and needs to be used within 24 hours. (do not mix and match temperatures). The 24-hour countdown starts as soon as the vial is removed from the refrigerator and **DOES NOT** stop if the vial is returned to the refrigerator, there is no “pause”.

Janssen: *Per Janssen (response as of 6/9/21)* — unpunctured vials may be stored between 9°C and 25°C (47°F and 77°F) for up to 12 hours. If you do not exceed the 12 hours at room temperature, you can return the vaccine to the refrigerator. The storage times at room temperature are total allowable times, and must be tracked cumulatively (as an example, a vial held for 1 hour at room temperature may be returned to the refrigerator, but the 1 hour must count against the allowed 12 hours at room temperature).

For clinics that are not open 24/7, is remote temperature monitoring or excursion alerting required? I realize remote monitoring would be preferred. CDC requires a specific type of temperature monitoring device called a “digital data logger” (DDL) to monitor COVID-19 vaccines. A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a “temperature excursion”). DDLs using a buffered temperature probe provide the most accurate way to measure actual vaccine temperatures. Always use DDLs with a current and valid Certificate of Calibration Testing. Note that not all DDLs can measure ultra-cold temperatures. Many manufacturers use pure propylene glycol (freezing point -59°C) or a glycol mixture with a warmer freezing point in their probes. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe, or a probe designed specifically for ultra-cold temperatures with the DDL.

Remote temperature monitoring is not required. However, it could be beneficial in helping to reduce the risk of losing vaccine(s), especially if your clinic is closed for multiple days at a time. Some options out there offer text message alerts, phone calls, and apps where you can see the current status.

Resources:

[COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations \(cdc.gov\)](https://www.cdc.gov/vaccines/imz/downloads/pdf/19-covid-19-ops-guidance-jurisdiction-operations-2021.pdf)

[Vaccine Storage and Handling Toolkit-March 2021 \(cdc.gov\)](https://www.cdc.gov/vaccines/imz/downloads/pdf/19-covid-19-vaccine-storage-handling-toolkit-march-2021.pdf)