



FDA Authorizes Pfizer-BioNTech to be stored at refrigerated temperatures for up to one month

On May 19th the FDA authorized **undiluted**, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for only up to 5 days. Complete information can be found in the updated EUA located at: <https://www.fda.gov/media/144413/download>

It is important to note, the best practice remains to keep Pfizer-BioNTech COVID-19 Vaccine In ultra-cold storage to prolong the life of the vaccine for as long as possible. Per Pfizer, the Pfizer-BioNTech COVID-19 Vaccine should be stored preferably “in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiry date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.”

Storage Environment	Temperature	Maximum storage time
Ultra-cold environment	-80° to -60° C	Until expiration date
Vaccine Freezer	-25° to -15° C	Up to 2 weeks (note: may be returned <u>one time</u> to ultra-cold environment but cumulative time spent in vaccine freezer should not exceed 2 weeks)
Vaccine Refrigerator	2° to 8° C	Up to one month
Room temperature	8° to 25° C	6 hours after dilution

If the Pfizer vaccine is removed from the ultra-cold environment, it may be put in a vaccine freezer for two weeks and then a vaccine refrigerator for an additional month.

For more information about this update, please see the FDA press release at: <https://www.fda.gov/news-events/press-announcements/fda-brief-fda-authorizes-longer-time-refrigerator-storage-thawed-pfizer-biontech-covid-19-vaccine>

The state is also expecting, beginning June 1st, for Pfizer to make shippers available that hold 450 doses of the Pfizer vaccine. This will give increased access to providers who may not be able to work through 1,170 doses before its expiration and thus the 450-dose shipper may be more appropriate. The state expects both 450 and 1,170 options to be available. The 450-dose shippers will come with an option to select a pediatric ancillary kit (all needles will be 1-inch needles) if preferred.