

Beyond use date in vial or syringe for COVID-19 Vaccines

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Practice settings may benefit from certain operational efficiencies that support a separation of the vaccine preparation steps from vaccine administration to the patient. For example, this may occur when a practice setting prepares and pre-draws the vaccine into syringes or prepares the vaccine in vials in one area and then transports the pre-drawn syringes or vials to a different site for administration. It is critical to use pre-drawn syringes with the earliest discard time first to avoid waste. If pre-drawn syringes are used, consider the following manufacturer-released information supporting stability of vaccine in vials and in pre-drawn syringes.

Pfizer-BioNTech COVID-19 Vaccine



Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in polycarbonate and polypropylene syringes with stainless steel needles for 6 hours at 2°C to 25°C (36°F to 77°F) after the source vial is diluted.



Microbiological risk was assessed through a microbiological challenge study which showed that microbiological growth has a greater potential to occur after 6 hours. The hold time of 6 hours, from the time the source vial is diluted, is not specifically tied to a preparation environment and can be applied to doses prepared outside of ISO Class 5 environment (PEC).



Keep out of direct sunlight.

Moderna COVID-19 Vaccine



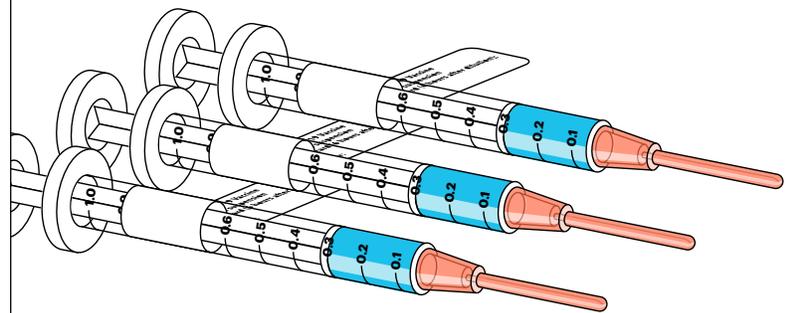
According to the Chemistry, Manufacturing and Control (CMC) department at Moderna, pre-drawn syringes can be either stored in the refrigerator or ambient room temperature at 2°C to 25°C (36°F to 77°F) provided they are administered within 12 hours of the first time the source vial is punctured.



Per Moderna, common disposable syringes made of polypropylene or polycarbonate are suitable for use.



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Janssen Ad26 COVID-19 Vaccine

Janssen is a subsidiary of Johnson & Johnson



According to Janssen Biotech, Inc. based on data on file, pre-drawn syringes can be stored:

- ▶ In the refrigerator at 2°C to 8°C (36°F to 46°F) provided they are administered within 6 hours of the first time the source vial is punctured.
- ▶ In ambient room temperature up to 25°C (77°F) provided they are administered within 2 hours of the first time the source vial is punctured.



Per Janssen Biotech, Inc., common disposable syringes made of polypropylene or polycarbonate are suitable for use.



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Table 1
Beyond-Use Date of COVID-19 Vaccine

	Pfizer-BioNTech COVID-19 Vaccine ¹ <i>from point of dilution</i>		Moderna COVID-19 Vaccine ² <i>from point of initial vial puncture</i>		Janssen Ad26 COVID-19 Vaccine ³ <i>from point of initial vial puncture</i>	
	Temperature	Maximum allowable storage time	Temperature	Maximum allowable storage time	Temperature	Maximum allowable storage time**
Diluted or punctured vial beyond-use date*	6 hours when held at refrigerated to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	12 hours when held at refrigerated to ambient room temperature at 2°C to 25°C (36°F to 77°F)	12 hours	6 hours when held at refrigerated temperature at 2°C to 8°C (36°F to 46°F)	6 hours
					2 hours when held at ambient room temperature up to 25°C (77°F)	
Pre-drawn syringe beyond-use date*	6 hours when held at refrigerated to ambient room temperature at 2°C to 25°C (36°F to 77°F)	6 hours	12 hours when held at refrigerated to ambient room temperature at 2°C to 25°C (36°F to 77°F)	12 hours	6 hours when held at refrigerated temperature at 2°C to 8°C (36°F to 46°F)	6 hours
					2 hours when held at ambient room temperature up to 25°C (77°F)	

* Based on stability information provided by the manufacturers.

**No data is available at this time regarding the cumulative temperature ranges and duration (e.g., kept in refrigerator for 2 hours, then at room temperature for 1 hour, back in the fridge for 2 hours, then at room temperature for 1 hour). It is preferred to choose one storage condition after first puncture. Any excursions should be reviewed with [Janssen's interactive tool](#).

This document is for informational purposes only and is intended to address operational considerations for COVID-19 vaccine preparation during the COVID-19 pandemic. This does not reflect the USP Healthcare Safety and Quality Expert Committee's opinions on future revisions to official text of the USP-NF. Parties relying on the information in this document bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements. USP is actively monitoring the evolving situation and will update this document accordingly.

¹ <https://www.cvdvaccine-us.com>

² <https://www.modernatx.com/covid19vaccine-eua/>

³ <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>