Vaccinator Provider's Name:	
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Janssen COVID-19 Vaccine EXAMPLE Competency Exam

fer t	to the EUA Fact Sheet for Healthcare Providers (updated 8/27/2021) for questions 1-15:				
1.	According to the Emergency Use Authorization (EUA), the Janssen COVID-19 vaccine can be used in the following individuals:				
	a. 6 months & older b. 12 years & older c. 16 years & older d. 18 years & older				
2.	Unpunctured multidose vials should be protected from light and stored at: a80°C to -60°C b60°C to -20°C c25°C to -15°C d. 2°C to 8°C				
3.	Alternatively, unpunctured vials may be stored between 9°C to 25°C for up to: a. 2 hours b. 4 hours c. 6 hours d. 12 hours				
4.	The vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C. If the vaccine is still frozen upon receipt, thaw at a. 26°C to 35°C b. 2°C to 8°C c15°C to 1°C d80°C to -60°C				
5.	Alternatively, the vaccine can be thawed at ROOM TEMP (up to 25°C). It can take approximately to thaw an individual vial, or it can take approximately to thaw a carton of 10 vials. a. 30 minutes; 1 hour; 4 hours c. 2 hours; 3 hours d. 3 hours; 4 hours				
	 a. Frozen temp (-25°C); 6 hours b. Refrigerated temp (2°C to 8°C); 6 hours c. Room temp (up to 25°C); 2 hours d. Both (b) and (c) are correct 7. The vaccine is a series with the 2nd dose ideally given on day 				
7.	a. 2-dose; 21 b. 2-dose; 28 c. 3-dose; 14 d. 1-dose; (No 2nd dose recommended)				
8.	8. How should the vaccine be administered? a. Intramuscularly; 0.3mL per dose c. Subcutaneously; 0.3mL per dose d. Subcutaneously; 0.5mL per dose				
9.	9. True/False After the first dose is withdrawn, record the date and time immediately on the vial label.				
10. True/False This vaccine must be diluted prior to administration.					
11. True/False Before drawing up a dose of the vaccine, vigorously shake the vial to properly mix the product.					
12. True/False Unpunctured vaccine vials can safely be stored in the freezer at your facility.					
 13. Regarding the "Fact Sheet for Recipients and Caregivers", the vaccination provider MUST: a. Provide a copy of the Fact Sheet. b. Direct the recipient/caregiver to the website https://www.janssencovid19vaccine.com to obtain the Fact Sheet. c. Any of the above are correct. d. None of the above; providing the Fact Sheet is NOT Required. 					
 14. The vaccination provider is responsible for mandatory reporting of the following that occur post-administration of this vaccine to the Vaccine Adverse Event Reporting System (VAERS): a. Vaccine administration errors, even if no adverse event occurred. b. Serious adverse events (life-threatening, death, hospitalization, etc.). c. Cases of Multisystem Inflammatory Syndrome (MIS) in adults. 					
	d. Case of COVID-19 that result in hospitalization or death.e. All of the above are correct.				

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- 15. The vaccination provider must communicate to the recipient/caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to vaccine administration, including:
 - **a.** FDA has authorized the emergency use of the vaccine, which is not a fully licensed vaccine.
 - **b.** The recipient or caregiver has the option to accept or refuse the vaccine.
 - **c.** The significant known/potential risks and benefits of the vaccine, and the extent to which such risks and benefits are unknown.
 - d. Information about the available alternative vaccines and the risk and benefits of those alternatives.
 - e. All of the above are correct.

Answers to questions 16-24 can be found on the CDC website regarding Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the U.S. by clicking here.

- **16. True/False** Patients considered moderately to severely immunocompromised per CDC should be offered an additional dose (i.e., 2nd dose) of the Janssen vaccine > 28 days after receiving an initial dose.
- **17. True/False** Patients who are immunocompromised, pregnant, breast-feeding, or have history of a resolved COVID-19 infection can generally be offered this COVID vaccine.
- **18. True/False** Patients who are currently on home isolation with suspected or confirmed COVID should come to the clinic to get vaccinated during their quarantine period.
- 19. True/False Patients need only one dose of this vaccine to be considered fully immunized against COVID-19.
- **20. True/False** Women aged 18-49 years of age can receive any FDA-authorized COVID vaccine; however, they should be informed of a rare but increase risk of thrombosis with thrombocytopenia syndrome (TTS) after receiving this vaccine.
- **21. True/False** An unvaccinated patient just completed home isolation protocol due to resolved COVID-19 infection. However, the patient must wait at least 90 days before receiving the vaccine.
- **22. True/False** If the first dose of mRNA COVID vaccine was given but the patient is unable to complete the series with the same or different mRNA vaccine, a single-dose of Janssen's COVID vaccine may be given at a minimum interval of 28 days.
- 23. A patient arrives to your clinic to get vaccinated. You only have the Janssen COVID vaccine available. The patient has heard that other COVID vaccines are more effective & wonders if vaccination should be delayed until your clinic has another product available. Given the current data so far, what is the best response?
 - **a.** All three COVID-19 vaccines authorized for use in the United States and are shown to be safe and very effective in preventing severe COVID-19 disease.
 - **b.** Comparative effectiveness is not known since no head-to-head trials exist among the available COVID-19 vaccines. If no contraindications exist, the patient should get this vaccine today.
 - **c.** Trials were large for this vaccine, resulting in high-quality data among very diverse populations, including areas where variants of the COVID virus were present.
 - **d.** Since this is a single-dose vaccine, full protection occurs sooner (at least 14 days post-vaccination).
 - e. All of the above statements are correct.
- 24. Which of the following patients need to be observed for at least 30 minutes post-vaccination (versus the standard 15 minutes) to monitor for the occurrence of immediate adverse reactions?
 - **a.** History of immediate allergic reaction to other vaccines unrelated to COVID vaccine components.
 - **b.** History of anaphylaxis due to <u>any</u> cause unrelated to COVID vaccine components.
 - **c.** History of immediate/severe allergic reaction to polysorbate.
 - **d.** Both (a) and (b) are correct.
 - e. All of the above are correct.

Vaccine Provider's Printed Name	Signature	Date	
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