Vaccinator Provider's Name: _____

Janssen COVID-19 Vaccine EXAMPLE Competency Exam

***Refer to* the EUA Fact Sheet for Healthcare Providers *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:**
   a. -80°C to -60°C **b.** -60°C to -20°C **c.** -25°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 **c.** -15°C to 1°C **d.** -80°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 **b.** 1 hour; 4 hours **c.** 2 hours; 3 hours **d.** 3 hours; 4 hours
6. **After the first dose has been drawn, the vial should be stored at _____and discarded after _____.**
   a. Frozen temp (-25°C to -15°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. **How should the vaccine be administered?**
   a. IM; 0.3mL per dose **b.** IM; 0.5mL per dose **c.** SQ; 0.3mL per dose **d.** SQ; 0.5mL per dose
8. **True/False** The Janssen vaccine is a single-dose primary vaccination.
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 **True/False** After the first dose is withdrawn, record the date and time immediately on the vial label.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: 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
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 16-26 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 completed a Janssen primary series should receive a booster dose ≥ 2 months later.
18. **True/False** Only a Janssen booster can be administered to individuals who initially received Janssen vaccine.
19. **True/False** A patient is considered fully immunized ≥ 2 weeks after receipt of a single dose of Janssen vaccine.
20. **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.
21. **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.
22. **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 increased risk of thrombosis with thrombocytopenia syndrome (TTS) after receiving this vaccine.
23. **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.
24. **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.
25. **In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over Janssen COVID-19 vaccines for primary and booster vaccination due to the risk of serious adverse events. However, Janssen COVID-19 vaccine may still be considered in some patients, including those who:**
    - **a.** Had a severe reaction after an mRNA vaccine dose or who have a severe allergy to an ingredient of Pfizer-BioNTech or Moderna
    - **b.** Would otherwise remain unvaccinated for COVID-19 due to limited access to Pfizer-BioNTech or Moderna vaccines
    - **c.** Want to get the Janssen COVID-19 vaccine despite the safety concerns
    - **d.** All of the above are correct
26. **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 an immediate allergic reaction of any severity to non-COVID-19 vaccines or injectables
    - **b.** History of anaphylaxis due to any cause (unrelated to COVID vaccine components)
    - **c.** History of immediate/severe allergic reaction to polysorbate
    - **d.** Both (a) and (b) are correct – answer (c) would be a contraindication to receiving this COVID vaccine
    - **e.** All of the above are correct

Vaccine Provider's Printed Name Signature Date