Vaccine Provider's Name: _____

Pfizer-BioNTech COVID-19 Vaccine EXAMPLE Competency Exam

***Refer to* the EUA Fact Sheet for Healthcare Providers (updated 8/23/2021) *for questions 1-23*:**

1. **According to the Emergency Use Authorization (EUA), the Pfizer-BioNTech 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. **Thawing UNDILUTED vials in the REFRIGERATOR can be stored for up to _____ and may take up to _____to thaw for a carton of vials at temperatures of 2°C to 8°C.**
   a. 4 days; 1 to 2 hours **b.** 31 days (1 month); 2 to 3 hours **c.** 6 days; 4 to 5 hours **d.** 7 days; 5 to 6 hours

3. **For immediate use, thawing undiluted vials for 30 minutes at ROOM TEMPERATURE (up to 25°C) must then be diluted within _____.**
   a. 2 hours **b.** 6 hours **c.** 2 days **d.** 6 days

4. **Before AND after diluting the vial, you should:**
   a. GENTLY invert vaccine vial 10 times **b.** Shake the vial vigorously **c.** Swirl the vial

5. **The appropriate diluent to use is:**
   a. 1.8mL of 0.9% Sodium Chloride Injection **b.** 2.1mL of 0.9% Sodium Chloride Injection
   c. 1.8mL of Bacteriostatic Sodium Chloride Injection **d.** 2.1mL of Sterile Water

6. **After diluting the vial, store vials of vaccine between_____ while protecting from light and using within_____ from the time of dilution.**
   a. -80°C to -60°C; 2 hours **b.** -80°C to -60°C; 6 hours **c.** 2°C to 25°C; 2 hours **d.** 2°C to 25°C; 6 hours

7. **The vaccine is a _____ primary series with the 2nd dose ideally given on day _____.**
   a. 2-dose; 21 **b.** 2-dose; 28 **c.** 3-dose; 14 **d.** 1-dose; 21

8. **How should the vaccine be administered?**
   a. Intramuscularly; 0.3mL per dose **b.** Intramuscularly; 0.5mL per dose
   c. Subcutaneously; 0.3mL per dose **d.** Subcutaneously; 0.5mL per dose

9. **True/False** If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume (i.e., do NOT pool excess vaccine from multiple vials).

10. **True/False** Six (6) doses are expected from each vial. Anything less should be reported as "wastage".

11. **True/False** It is appropriate to interchange this vaccine with other COVID-19 vaccines to finish the series.

12. **True/False** After properly diluting the vaccine, immediately record date and time on vaccine vial.

13. **True/False** After adding the diluent of 1.8mL of 0.9% Sodium Chloride to the vial, equalize pressure by withdrawing 1.8mL of air into the empty diluent syringe before removing the needle.

14. **True/False** Before drawing up a dose of the vaccine, vigorously shake the vial to properly mix the product.

15. **True/False** The diluted vaccine should appear as a fully clear liquid without particulate matter.

16. **True/False** Dry ice, when stored in a tightly closed container, can build pressure and potentially explode.

17. **True/False** Ultracold shipping containers containing dry ice should be opened in a small, enclosed space to encourage stability of the product.

18. **True/False** Unopened vials with expiry date of Aug 2021 – Feb 2022 may remain in use for 3 months beyond the printed date if maintained in proper storage conditions of-90°C to -60°C.

19. **True/False** Unopened vials may be stored at -25°C to -15°C for up to two weeks (track total time); vials may then be returned ONE TIME back to recommended storage condition of -90°C to -60°C.

20. **True/False** Transporting thawed vials at 2°C to 8°C is not supported under the EUA.

21. **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 www.cvdvaccine.com to obtain the Fact Sheet.
    - **c.** Any of the above are correct.
    - **d.** None of the above are correct; providing the Fact Sheet is NOT Required.

22. **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 and children.
    - **d.** Case of COVID-19 that result in hospitalization or death.
    - **e.** All of the above are correct.

23. **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 24-30 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 (updated 8/25/2021):

24. **True/False** Patients considered moderately to severely immunocompromised per CDC should be offered an additional dose (i.e., 3rd dose) of mRNA vaccine at least 28 days after completing the series.

25. **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.

26. **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.

27. **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.

28. **What is the minimum interval for the second dose of the vaccine to be consider as "valid"?**
    a. 14 days **b.** 17 days **c.** 21 days **d.** 28 days

29. **It is recommended to space the COVID vaccine from any other vaccine by at least:**
    a. 7 days **b.** 14 days **c.** 21 days **d.** Minimum spacing is no longer recommended

30. **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 any cause unrelated to COVID vaccine components.
    - **c.** History of immediate/severe allergic reaction to polyethylene glycol (PEG).
    - **d.** Both (a) and (b) are correct.
    - **e.** All of the above are correct.

Vaccine Provider's Printed Name Signature Date