Name: _____**KEY**_____ **Date:** _____

Directions: Match the following vocabulary words.

1. ___**D**___ **messenger RNA**
2. ___**C**___ **Vaccine Engineering**
3. ___**F**___ **Adenovirus-Based Vaccine**
4. ___**A**___ **Vaccine**
5. ___**G**___ **Adjuvants**
6. ___**B**___ **Antigen**
7. ___**H**___ **Antibody**
8. ___**E**___ **Immunogenicity**

A. Product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease

B. Molecules capable of stimulating an immune response, with each having distinct surface features (or epitopes) resulting in specific responses

C. Approach to discover novel antigens, epitopes, and adjuvants that can stimulate and manipulate the immune system, as well as their targeted delivery, for the prevention and treatment of important diseases such as cancer and infectious diseases

D. Vaccine method that instructs immune cells to make copies of the COVID-19 spike protein, acting as if the cells have been infected with the coronavirus

E. A therapy's tendency to trigger an unwanted immune response against themselves

F. Vaccine method that uses non-enveloped, double-stranded DNA viruses

G. Components capable of enhancing and/or shaping antigen-specific immune responses

H. (also known as immunoglobulins) Y-shaped proteins that have the ability to recognize and bind to antigens

Directions: Label following steps from (1-6) in the order of the general vaccine development process as given by the CDC.

9. ___**3**___ **Clinical development (3 Phase Process)**

10. ___**2**___ **Pre-clinical stage**

11. ___**5**___ **Manufacturing**

12. ___**6**___ **Quality control**

13. ___**4**___ **Regulatory review and approval**

14. ___**1**___ **Exploratory stage**

Directions: Multiple Choice - Circle the choice that best answers the question.

15. What does the preclinical stage involve?
    a. Tissue-culture or cell-culture systems
    b. Small groups of adults
    c. Animal testing
    d. Basic laboratory research
    e. a, c
    f. a, c, d
    g. All of the above

The allocation of the vaccine should shift depending on the...
    a. Supply
    b. Demand
    c. Vaccine characteristics
    d. Disease epidemiology
    e. All of the above
    f. None of the above

16. During the COVID-19 pandemic, who did the CDC say critical populations included?
    a. All adults
    b. Adults with high-risk medical conditions
    c. Non-healthcare essential workers
    d. People 85 years of age and older
    e. Children under 16
    f. b, c
    g. b, d, e
    h. All of the above

17. Which is/are NOT a characteristic of engineered nanoparticles?
    a. Stabilizes vaccines
    b. Cannot double as an adjuvant
    c. Regulates the route of entry into antigen presenting cells
    d. a, c
    e. a,b
    f. None of the above

18. Regulatory Review and Approval includes which of the following?
    a. Manufacturing facility undergoes a pre-approval inspection
    b. Presentation to a non-expert audience
    c. Biologics License Application (BLA)
    d. Product License Application (PLA)
    e. b, c
    f. b, c, d
    g. All of the above

Directions: Answer the following questions in 1-2 sentences.

19. What is the main goal(s) of quality control?

Check the consistency in the production of vaccine

- Each batch of the product is of the same quality and specifications of the batch that has been tested
- Each batch is shown to be safe and efficacious in research

20. Name THREE sources of funding.

National Institutes of Health (NIH):

- multi-PI grants
- PPG
- NCRR
- RFAs
- Contracts (IEDB)

Pharmaceutical Industry:

- Research contracts
- Licensing

Biotech Industry:

- Funding for IP
- Startups
- Angel investors
- Venture capitalist companies

21. What are TWO risks of the SARS/COVID-19 Vaccine?

The SARS/COVID-19 Vaccine comes with the potential issues of:

- Antibody-dependent enhancement (ADE), in which a vaccine may actually worsen the consequences of the disease rather than protect
- Those most at risk are over 60, but resistance to vaccination begins as early as 30
- May reduce the *chance* of getting the disease (and its symptoms) but not prevent infection
- New variants being less susceptible

22. Why might allocation disparities occur?

- There are different circumstances and situations
- Federal, states, and local health departments as well as medical centers have each developed different allocation formulas, based on a variety of ethical and political considerations
- Some areas may have greater numbers of a certain population, such as there being more elderly than educators