

## Introduction to Vaccine Development

This brochure addresses the development of mRNA-based COVID vaccines. Examples of this type of vaccine include the ones developed by Moderna and Pfizer-BioNTech.

COVID-19 vaccines are misunderstood by many to have been developed too quickly. This thought can be understood, considering the short amount of time a vaccine becomes available within months of a new organism. Unlike most medications, vaccine technologies can easily be adapted to include different organisms.

The vaccine technologies found in the current COVID-19 vaccines existed long before 2020 and COVID-19. They were developed to help deliver protection against a wide variety of other diseases and were already being studied in humans for other novel and rare infections.

These vaccine technologies have a unique advantage over other types of vaccine delivery systems: they can be produced quickly and in large numbers. When the COVID-19 pandemic began, scientists turned to these technologies to see if they could deliver much needed immunity. This helped decrease the time needed to produce and study the vaccine.

## Why is the monovalent primary series vaccine necessary?

The monovalent primary series of vaccination is required before receiving a booster dose against COVID-19. Even though the primary series only consists of one strain of the virus, it provides the body the appropriate immunity against the original strain of COVID-19.

The booster containing two strains of the virus improves protection against the virus by adding on to the primary series. Those with a primary series and booster in their system, allows for improved protection against the present strains of COVID-19 found today.

## A Shot for Alabama Support



For help with COVID-19 vaccine questions, concerns, and assistance with vaccine scheduling, you can contact the Shot for Alabama Call Center:

**334-844-2018**



For More Information on COVID-19 Vaccines and Resources, please visit our webpage:

**<https://aub.ie/shot4alabama/>**



A Shot for Alabama is a collaboration between the Harrison College of Pharmacy and the Alabama Cooperative Extension System



**AUBURN UNIVERSITY**  
Harrison College of Pharmacy



# mRNA COVID VACCINE DEVELOPMENT

## VACCINE TESTING



# A SHOT FOR ALABAMA

A white outline of the state of Alabama, positioned to the right of the text 'FOR ALABAMA'.

# The mRNA COVID -19 Vaccines: A History

**Early 1970s** Scientists discovered that mRNA can be used to express proteins

**1989** mRNA 1st promoted as a therapeutic option

**Early 1990s** Scientists prove mRNA can work in human cells

**1993** Scientists show mRNA vaccine for the flu can produce an immune response

**2000s** Scientists develop simplified method for producing mRNA vaccines  
Human studies of mRNA vaccines begin - early studies focus on use in cancer

**2010s** Increased development of mRNA vaccines against infectious diseases

Human studies conducted for mRNA vaccines for infectious diseases  
**2017** Studies show vaccine produces immune response and is safe. mRNA vaccine production simplified - requires DNA sequence of virus

In January, DNA sequence for SARS-CoV-2 (the virus that causes COVID-19) discovered by scientists

**2020** Scientists use this information to produce COVID-19 vaccine  
COVID-19 mRNA vaccines studies in thousands of people

## FDA Priority

Because of the priority given to the pandemic, the time it took for the FDA to review all the COVID-19 vaccine information was shorter than the average medication or drug. That does not mean that they spent less time reviewing it; it just took them less time to start reviewing it and then less time to have a meeting to discuss the information.

When a company submits paperwork to the FDA for drug or vaccine approval, it can take a VERY long time before the review occurs. There is a lot of paperwork, and it takes a long time to go through everything.

- The FDA prioritized the COVID-19 vaccines. They placed their applications for approval to the front of the line of drugs and vaccines waiting for review and discussion. This helped shorten the wait for vaccine availability.

- The FDA has advisory committees that consist of experts in certain areas. The committee members are healthcare professionals that do not work for the government or the FDA. They are mostly practicing and caring for real patients out in communities across the United States. When a new drug or vaccine is submitted for consideration, these committees independently review all the submitted information in depth.
- The FDA dedicated advisory committee meetings to each individual COVID-19 vaccine and were able to schedule the meetings independent of the regularly occurring committee meeting. Committee members took their responsibilities seriously and scrutinized all the information before voting to recommend COVID-19 vaccine approval.

## What We Knew About MRNA Vaccines 10 Years Ago

After the Swine Flu Pandemic in 2009-10, scientists realized that we needed to have a vaccine that would be 1) safe, and 2) easy to mass produce in case of a future pandemic. A decade before COVID-19, scientists were studying the potential for different vaccine technologies to be used in just this type of setting.

### Quick and easy to make

Diverse products can be made using the same established production process.

### Production is flexible

General production process is the same - it just requires knowledge of the protein.

### Any protein can be used

mRNA can express any protein - the vaccine can be encoded to produce antibodies against any organism that can use this method.

### Limited in what it contains

mRNA only contains what information is needed to tell the body what protein to make - nothing more.

### Does NOT get into the DNA

mRNA does not cross the envelope of the area that contains our DNA. Since it stays outside that area, it does not interact with or get into our DNA. This is an advantage of mRNA.

### Does not replicate

mRNA does not actually contain the organism and is not able to replicate in the body. Because of that, it cannot cause the infection.

### Decays within a few days

mRNA has a short lifespan. It lasts long enough to tell the body what proteins to make to develop immunity - and then it is removed from the body.

### It is safe to use in humans

Human testing of the technology started over a decade ago. It was found safe in short term studies and no long-term problems have been reported.