

AHL COVID-19 EDUCATIONAL WORKSHOP

YES, WE CAN BEAT COVID-19!



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TUSKEGEE MUNICIPAL COMPLEX

OBJECTIVES



- Recap basic COVID-19 information
- Define antigen, antibody, virus, and vaccines
- Provide clinical trials data for Moderna, Pfizer and Johnson and Johnson
- Provide illustrations of how the vaccines work
- Discuss testing options
- Dispel key myths

INTRODUCTION



- COVID19, aka, Coronavirus, SARS CoV-2
- Science overdrive □ information overload
 - Sequence
 - Testing
 - Vaccines
 - Treatment
 - Confusing led to myths

DEFINITIONS



- Virus - microscopic infectious agent that replicates only inside the living cells of an organism. Viruses infect all life forms, from animals and plants to microorganisms.
- Antigen – Any substance that causes the body to make an immune response against that substance. Antigens include toxins, chemicals, bacteria, viruses, or other substances that come from outside the body that when recognized as non-self by the immune system will trigger an immune response.
- Antibody - a blood protein produced in response to and counteracting a specific antigen by the immune system in response to an infection. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood. They are an important part of the body's defense system as they work to destroy disease-causing organisms (such as viruses or bacteria) and block them from infecting human cells.
- Vaccine - A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.

TYPES OF COVID-19 VACCINES



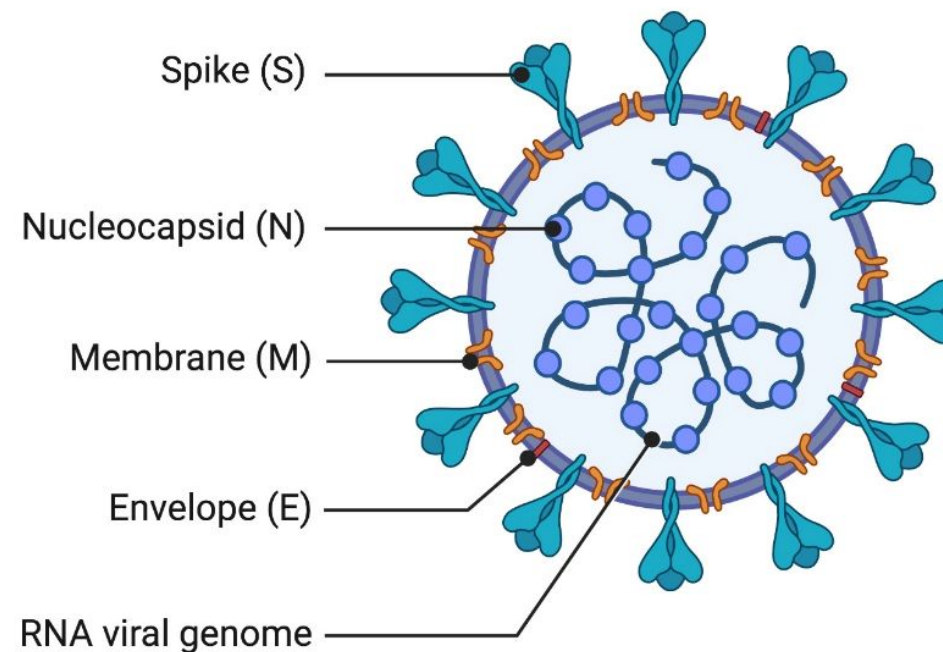
- **mRNA-** messenger RNA molecules carry the genetic information needed to make proteins. Unlike live-attenuated or viral-vectored vaccines, mRNA is non-infectious and poses no concern for DNA integration—mainly because it cannot enter the nucleus which contains DNA. mRNA is made through a cell-independent process and does not require inactivation; thus, it poses no safety concerns due to contamination with toxic agents. mRNA is rapidly degraded in the body, and cells don't readily take up foreign mRNA.
- Viral vector vaccines use a modified version of a virus that is different from the virus being targeted to deliver important instructions to our cells. The modified version of the virus is called a vector virus. COVID-19 vector virus is **not** the virus that causes COVID-19, but a different, harmless virus. It enters the muscle cells and uses the cells' machinery to produce **a harmless piece** of what is called a spike protein. The spike protein is found on the surface of the virus that causes COVID-19. The genetic material delivered by the viral vector does not integrate into a person's DNA.



ORF1ab, **the largest gene**, contains overlapping open reading frames that encode polyproteins PP1ab and PP1a. The polyproteins are cleaved to yield 16 nonstructural proteins, NSP1-16.

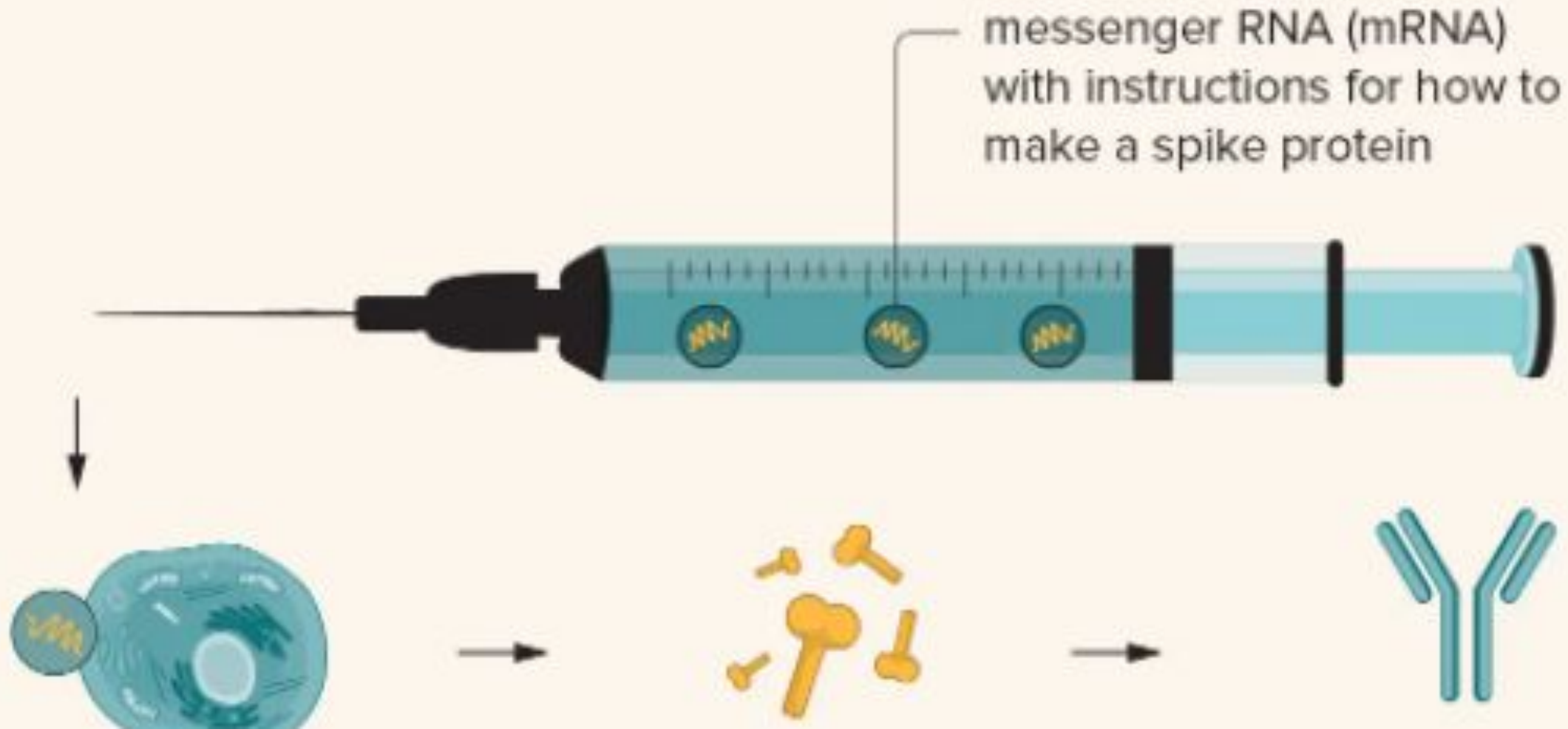
ORF1ab gene is the most specific and the N gene is most sensitive.

Coronavirus Structure



PFIZER AND MODERNA

The Pfizer-BioNTech and Moderna vaccines use mRNA to teach the immune system to prevent infection from the coronavirus.

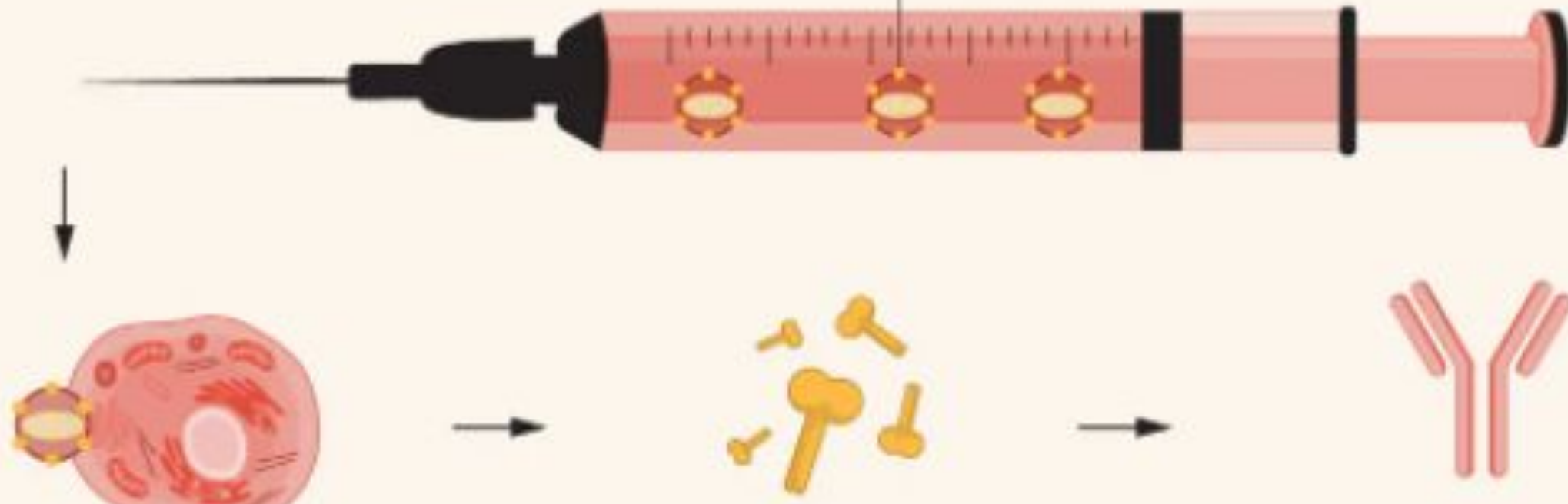


JOHNSON & JOHNSON

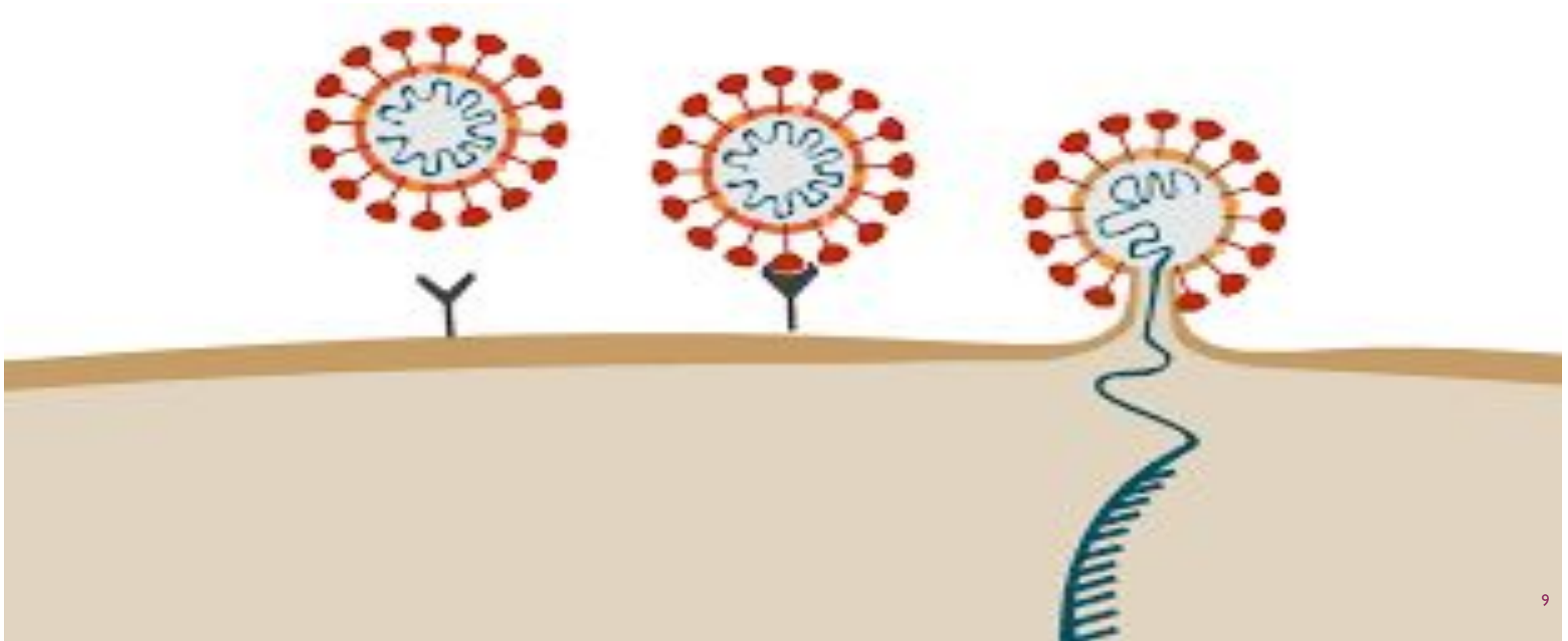
The J&J vaccine teaches the immune system to attack the protein that causes the coronavirus to infect other cells.



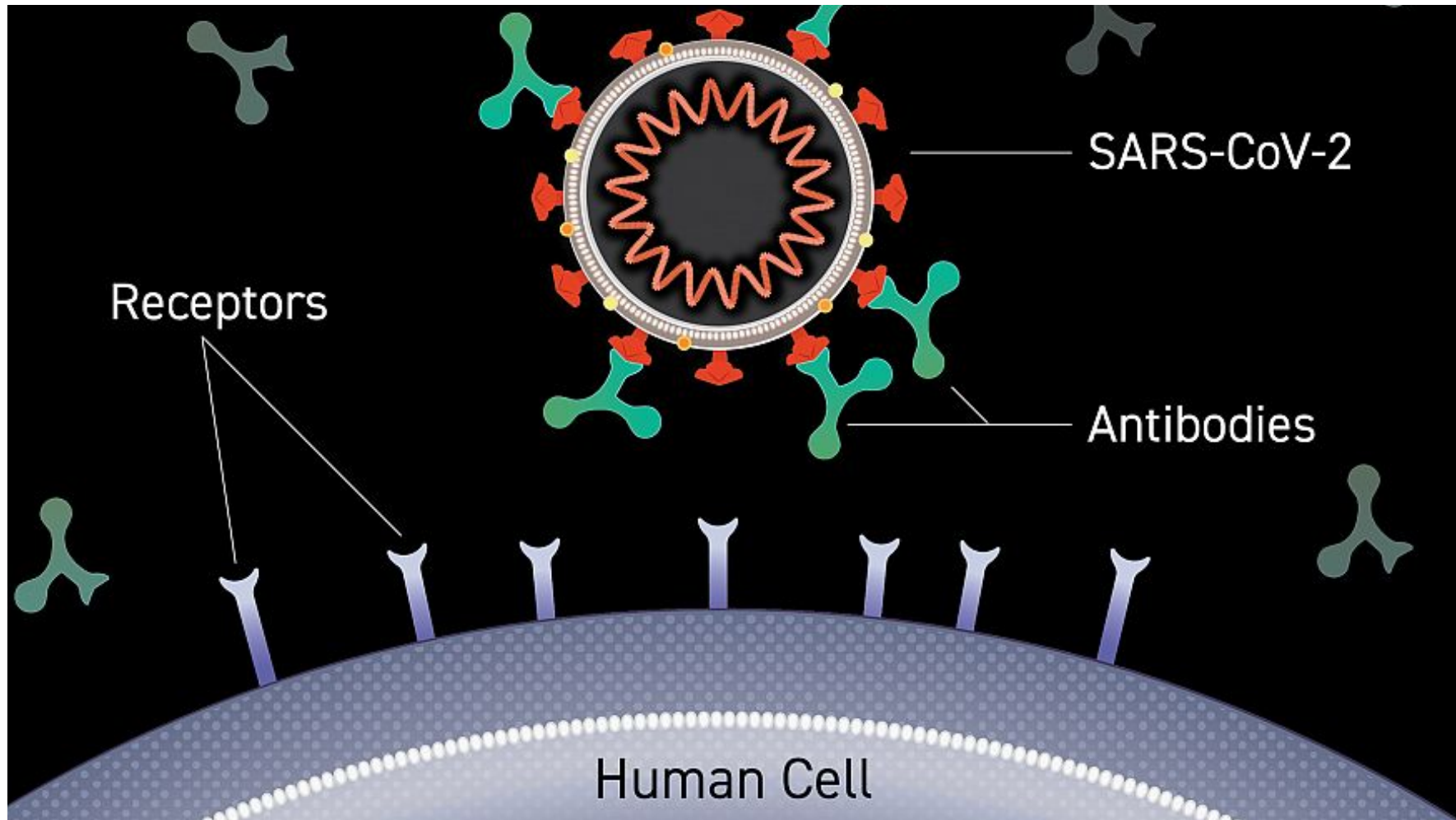
cold virus with instructions for how to make a spike protein



COVID-19 ENTERS THE HUMAN CELL



ANTIBODIES BLOCK COVID-19 VIRUS FROM ENTERING THE HUMAN CELL



MODERNA



- In phase 1 clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.
- About 25% of trial participants were 65 years of age and older. About 21% were Hispanic or Latino and 10% were Black.
- In the phase 3 clinical trial of the Moderna vaccine, 30,420 people participated. In this trial, each participant got either two doses of the vaccine or two doses of a placebo spaced 28 days (4 weeks) apart.
- Researchers evaluated vaccine efficacy 14 days after the second dose of the vaccine. At this point, vaccine efficacy was found to be 94.1 percent.
- According to the CDC, as of February 7, 2022, more than 205 million doses of Moderna COVID-19 Vaccine have been administered in the US, and over 74 million people have received the primary series.
- The vaccine is made in the US.
- The vaccine does not contain any preservatives, antibiotics, or products of human or animal origin. Also, the vial stoppers are not made with natural rubber latex.
- The vaccine has been shown to prevent COVID-19. The duration of protection against COVID-19 is currently unknown.

PFIZER



- 46,331 participants from 151 clinical trial sites around the world
- 30% US, 42% Worldwide 49.17% male, 50.9 female
 - 6% Asian
 - 10% Black
 - 13% Hispanic/Latinx
 - 1.3% Native American
- In the phase 3 clinical trial of the Pfizer-BioNTech vaccine, each participant received two doses of the vaccine or two doses of a placebo spaced 21 days (3 weeks) apart.
- Researchers assessed vaccine efficacy 7 days after the second dose of the vaccine. At this time, it was found that vaccine efficacy was 95 percent.

JOHNSON AND JOHNSON



- There were 43,783 participants from eight countries across North America (44%), Central and South America (41%), and Africa (15%).
- More than one-third (34%) of participants were over the age of 60, and 45% were female.
- In the United States, 74% of participants were White/Caucasian, 15% were Hispanic/Latino, and 13% were Black/African American.
- Researchers evaluated vaccine efficacy 14 days after the single dose of the vaccine was given. The results also broke down efficacy by COVID-19 severity and location.
- Overall, J&J vaccine efficacy was found to be 74.4 percent.

DIAGNOSTIC AND ANTIBODY TESTS



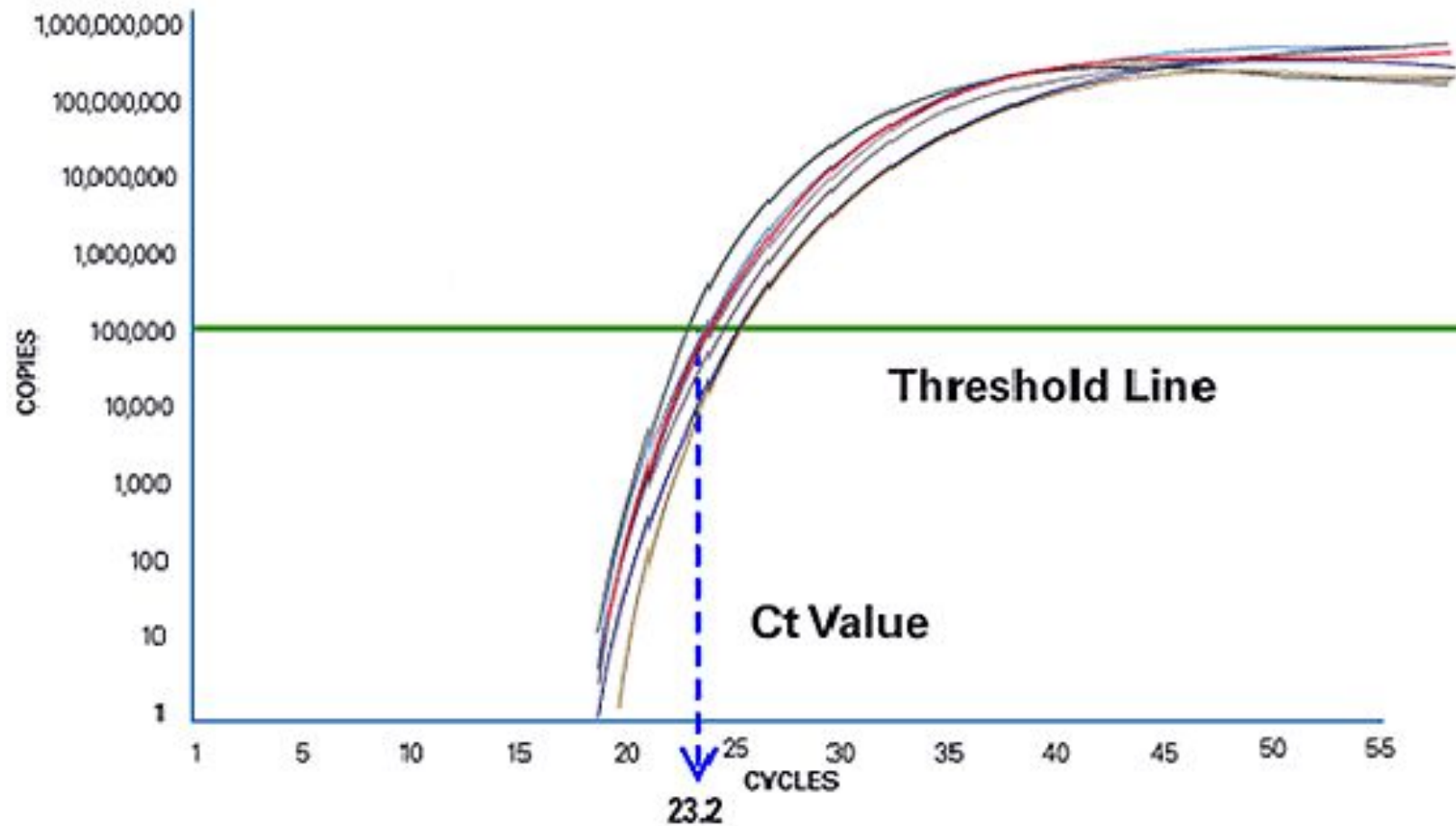
	Molecular Test	Antigen Tests	Antibody
Test	Diagnostic, nucleic acid amplification	Immunoassay	Serological test
Sample	Nasal, nasopharyngeal, saliva	Nasal or nasopharyngeal swab	Capillary or venous blood
Time Frame	15 minutes to 3 hours	12 to 30 minutes	30 minutes
Results	Confirmatory, highly accurate,	Screening, confirm negative tests with PCR	Sometimes a second test is needed for accurate results
Diagnoses	Active infection	Active infection	Past infection or immunization
Limitations	Sample, collection method, storage, transport, viral load	Sample, collection method, storage, transport, viral load	Not diagnostic, based on the immune response

CYCLE THRESHOLD (C_t) VALUE



- To improve the test's ability to detect virus, a RT-PCR test creates many copies of the same genetic material from the virus in a process called amplification.
- The cycle threshold (C_t value) is the point at which a reaction reaches a fluorescent intensity above background levels. The C_t value indicates when the nucleic acid target is detectable in the amplification process.
- There is a correlation between the C_t value and the amount of viral genetic material that was present in the specimen. Low C_t values (under 30) indicates a large amount of virus in the sample.

THE PCR CYCLE AT WHICH THE SAMPLE REACHES A FLUORESCENT INTENSITY ABOVE BACKGROUND IS THE CYCLE THRESHOLD OR C_t .



UNDERSTANDING RESULTS

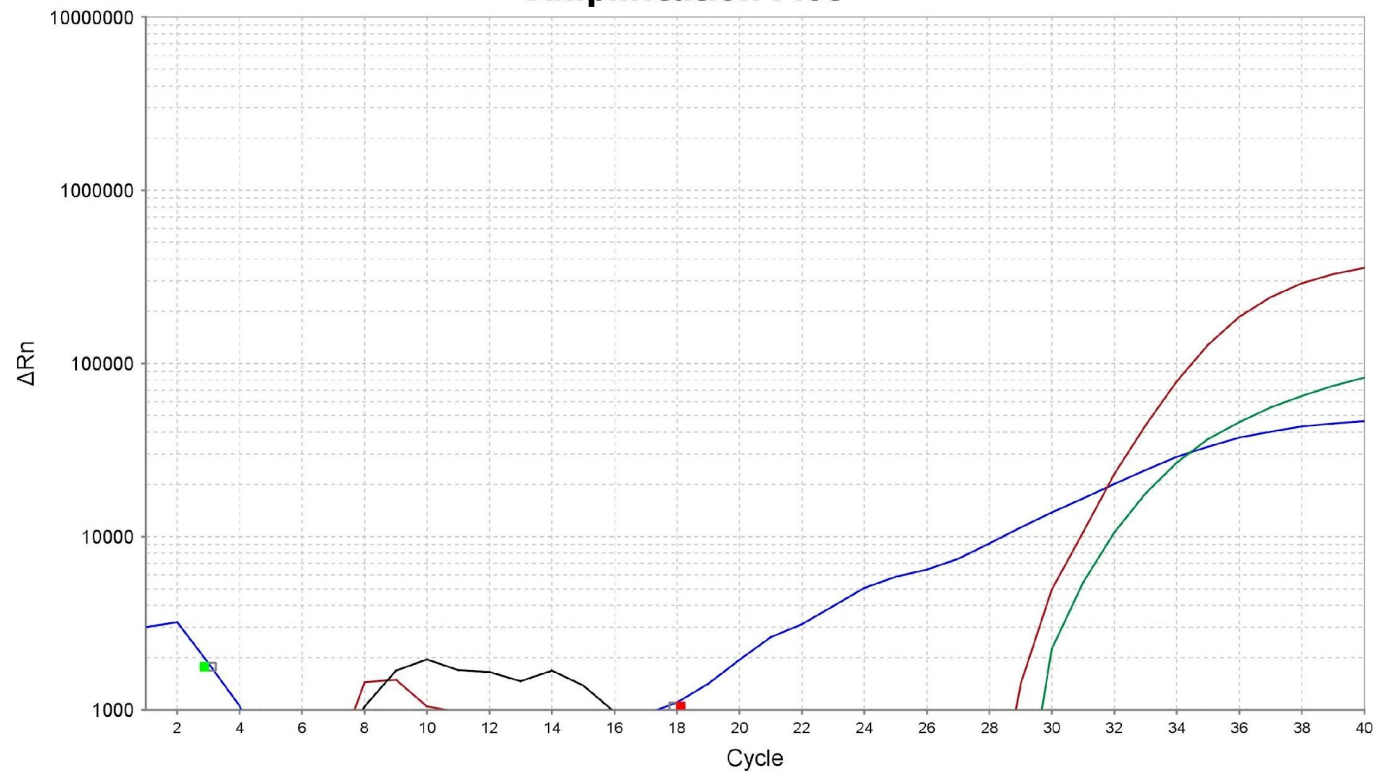


- S gene, N gene, ORF1ab
- Positive – two of the three SARS-CoV-2 targets were amplified
- Negative – none of the three SARS-CoV-2 targets were amplified
- Inconclusive – one of the SARS-CoV-2 targets were amplified, repeat or request a new sample
- No test is perfect or 100% accurate.
- If you take a number of tests you may get different results.
- This can be due to multiple reasons such as the amount of virus in your respiratory tract at the time of sample collection or how the sample was collected.
- Also, each PCR method tests for different targets and uses different C_t levels, therefore, you cannot compare the results from different labs.

POSITIVE RESULT



Amplification Plot



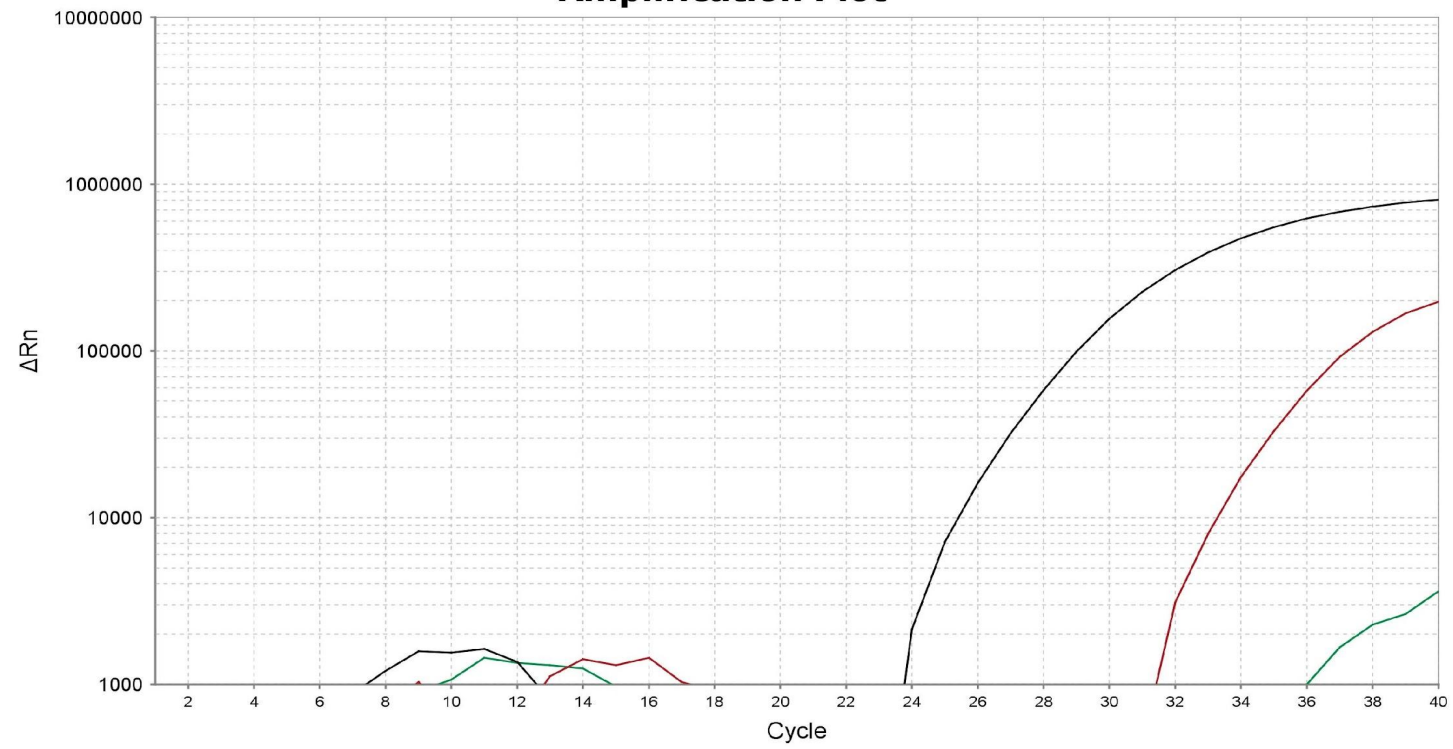
■ MS2 ■ ORF1ab ■ N gene ■ S gene



INCONCLUSIVE RESULT



Amplification Plot



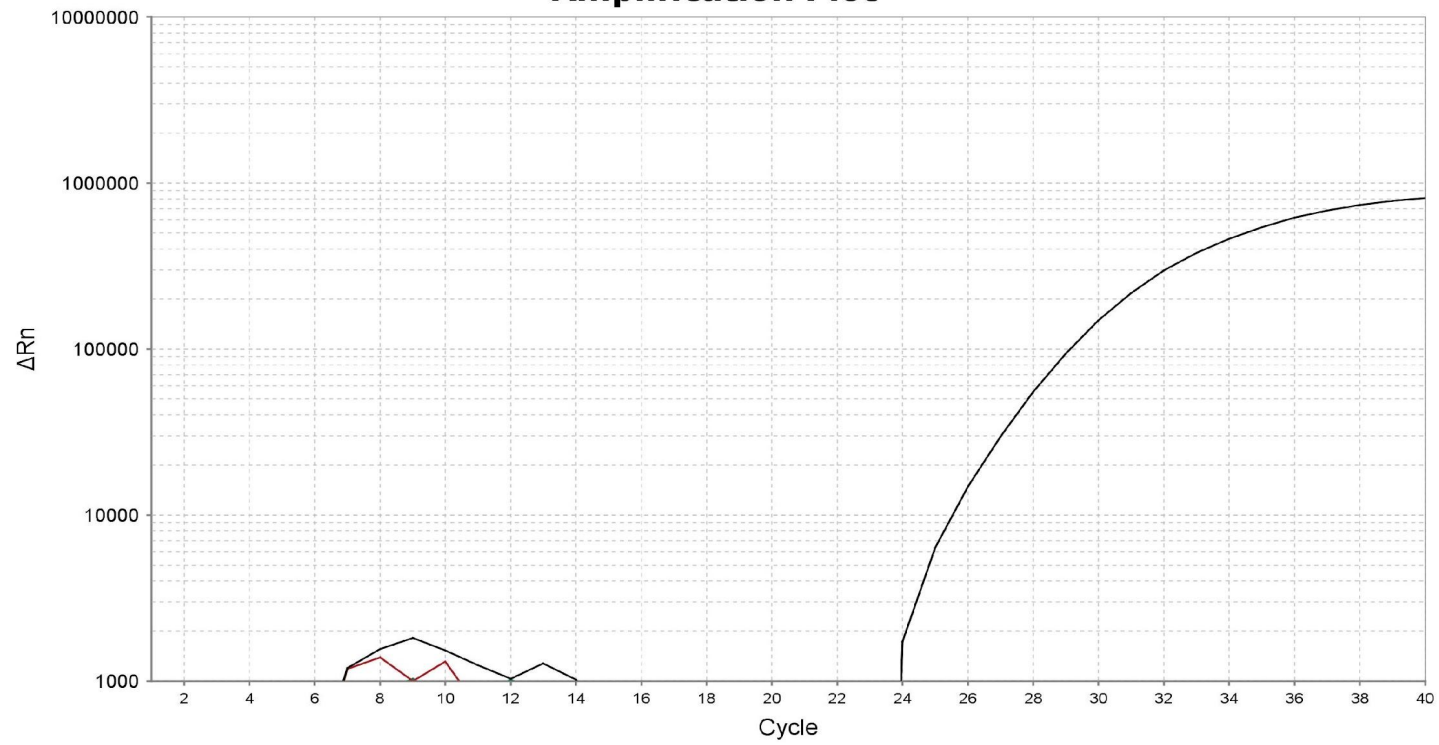
■ MS2 ■ ORF1ab ■ N gene ■ S gene



NEGATIVE RESULT



Amplification Plot



■ MS2 ■ ORF1ab ■ N gene ■ S gene



COMPARISON OF MOLECULAR DIAGNOSTICS FOR COVID-19 WITH FDA-EUA APPROVAL



Manufacturer	Test	SARS CoV-2 Biomarkers	Time to Results	Sensitivity/Specificity
CDC	2019-nCoV Real-Time RT-PCR Diagnostic Panel	N1, N2, RP	~80 min for 1 sample	100% (13/13) 100% (104/104)
QIAGEN	QIAstat-Dx/Respiratory SARS-CoV-2 Panel	ORF1b, E	~1 h for 1 sample	100%(30/30) 100% (30/30)
PerkinElmer	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	ORF1ab, N	~2h for 96 samples	100% (20/20) 100% (20/20) 100% (94/94)
Thermo Fisher Scientific	Taqpath COVID-19	ORF1ab, S, N	3 h for 94 samples	100% (60/60) 100% (60/60)
Roche	Cobas SARS CoV-2	ORF1a/b, E	3 h for 96 samples	100% (50/50) 100% (100/100)
Abbott Molecular	Alinity m SARS-CoV-2 Assay	RdRp, N	~ 2 h for 24 samples	100% (40/40) 96.5% (55/57)

MYTHS



- **MYTH: The ingredients in COVID-19 vaccines are dangerous.**
- **FACT:** Nearly all the ingredients in COVID-19 vaccines are also ingredients in many foods – fats, sugars, and salts.

- **MYTH: The natural immunity I get from being sick with COVID-19 is better than the immunity I get from COVID-19 vaccination.**
- **FACT:** Getting a COVID-19 vaccination is a safer and more dependable way to build immunity to COVID-19 than getting sick with COVID-19.

- **MYTH: COVID-19 vaccines cause variants.**
- **FACT:** COVID-19 vaccines do not create or cause variants of the virus that causes COVID-19. Instead, COVID-19 vaccines can help prevent new variants from emerging.

- **MYTH: COVID-19 vaccines can alter my DNA.**
- **FACT:** COVID-19 vaccines do not change or interact with your DNA in any way.

MYTHS



- **MYTH: All events reported to the Vaccine Adverse Event Reporting System (VAERS) are caused by vaccination.**
- **FACT:** Anyone can report events to VAERS, even if it is not clear whether a vaccine caused the problem. Because of this, VAERS data alone cannot determine if the reported adverse event was caused by a COVID-19 vaccination.

- **MYTH: The mRNA vaccine is not considered a vaccine.**
- **FACT:** mRNA vaccines, such as Pfizer-BioNTech and Moderna, work differently than other types of vaccines, but they still trigger an immune response inside your body.

- **MYTH: COVID-19 vaccines authorized for use in the United States shed or release their components.**
- **FACT:** Vaccine shedding is the release or discharge of any of the vaccine components in or outside of the body and can only occur when a vaccine contains a live weakened version of the virus.

MYTHS



- **MYTH: A COVID-19 vaccine can make me sick with COVID-19.**
- **FACT:** Because none of the authorized COVID-19 vaccines in the United States contain the live virus that causes COVID-19, the vaccine cannot make you sick with COVID-19.

- **MYTH: COVID 19 will affect my fertility**
- **FACT:** Currently no evidence shows that any vaccines, including COVID-19 vaccines, cause fertility problems (problems trying to get pregnant) in women or men.

- **MYTH: Being around someone who has been vaccinated will affect my menstrual cycle**
- **FACT:** Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine.

- **MYTH: Getting the COVID 19 vaccine will cause me to test positive for the viral test.**
- **FACT:** None of the authorized and recommended COVID-19 vaccines can cause you to test positive on viral tests, which are used to see if you have a current infection.

MYTHS



- **MYTH: Receiving a COVID-19 vaccine can make you magnetic.**

FACT: Receiving a COVID-19 vaccine will not make you magnetic, including at the site of vaccination which is usually your arm.

- **MYTH: COVID-19 vaccines contain microchips.**

FACT: COVID-19 vaccines do not contain microchips. Vaccines are developed to fight against disease and are not administered to track your movement.



Adam Maida / The Atlantic

TUSKEGEE HEALTH DISPARITIES DIAGNOSTIC CENTER AND COVID-19 TESTING LAB



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