



# COVID-19 Testing

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# COVID-19 Tests

## The many types of tests available are causing considerable confusion

- Unfortunately, this novel coronavirus is indeed novel
- COVID-19 is a new disease
- Every test has a different accuracy level and no test is 100% accurate
- Tests are not widely available
- It takes a long time between the test and the results – sometimes as long as a week, making the test meaningless



# Types of COVID-19 Tests

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include **Molecular Tests / PCR (Polymerase Chain Reaction)** and **Antigen Tests**
- **Serology/Antibody Tests:** Tests that detect antibodies (e.g., IgM, IgG) to the SARS-CoV-2 virus. Serology/antibody tests *cannot* be used to diagnose a current infection, but they are a **useful tool for public health**. With these tests, the true case fatality rate of COVID-19 can be determined from the true prevalence of SARS-COV-2 infection, as well as the effects of mitigation strategies. Sound decisions may be made about:
  - PPE resource allocation
  - Mitigation efforts
  - Vaccine procurement and prioritization

# Molecular Test

*(also called PCR test, viral RNA test, nucleic acid test)*

- **What it does:** Diagnoses people who are currently sick with COVID-19
- **How it works:** This test uses a sample of mucus typically taken from a person's nose or throat. The test also works on saliva. It looks for the genetic material of the coronavirus. The test uses a technology called PCR, which greatly amplifies the viral genetic material if it is present. That material is detectable when a person is actively infected

- As of October 11, 2020, Emergency Use Authorization (EUA) by FDA:
  - 182 Molecular PCR tests
  - 35 Lab based PCR tests

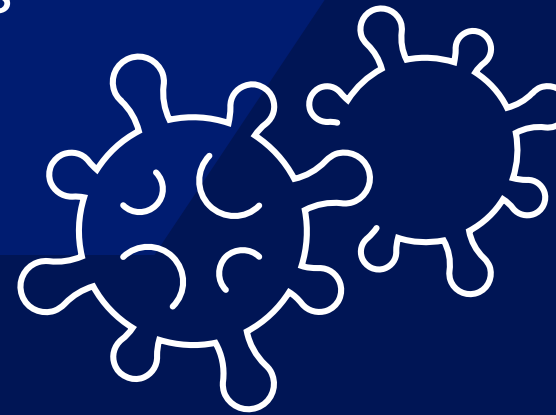




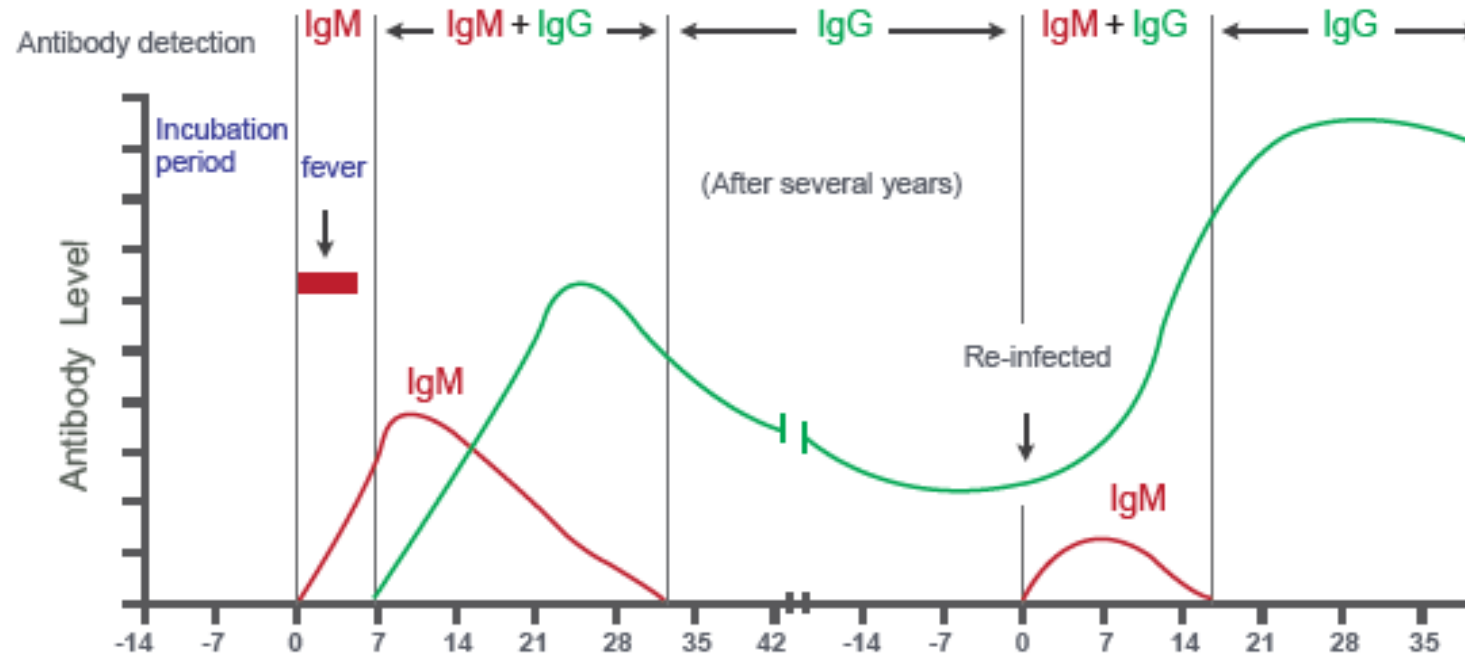
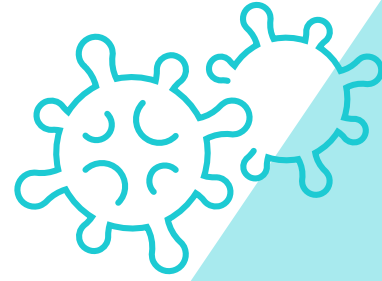
# Antibody Test

- **What it does:** Antibody tests identify people who have previously been infected with the coronavirus. They do not show whether a person is currently infected. This is primarily a good way to track the spread of the coronavirus through a population.
- **How it works:** This is a blood test. It looks for antibodies to the coronavirus. Your body produces antibodies in response to an infectious agent such as a virus. These antibodies generally arise after four days to more than a week after infection, so they are not used to diagnose current disease.

- As of October 11, 2020, Emergency Use Authorization (EUA) by FDA:
  - 55 Antibody (Serology) tests

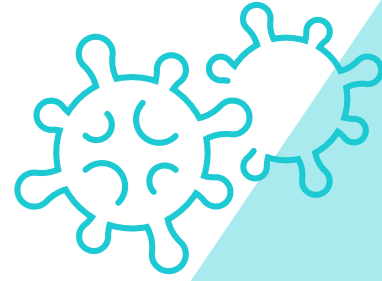


# More on Antibody Test



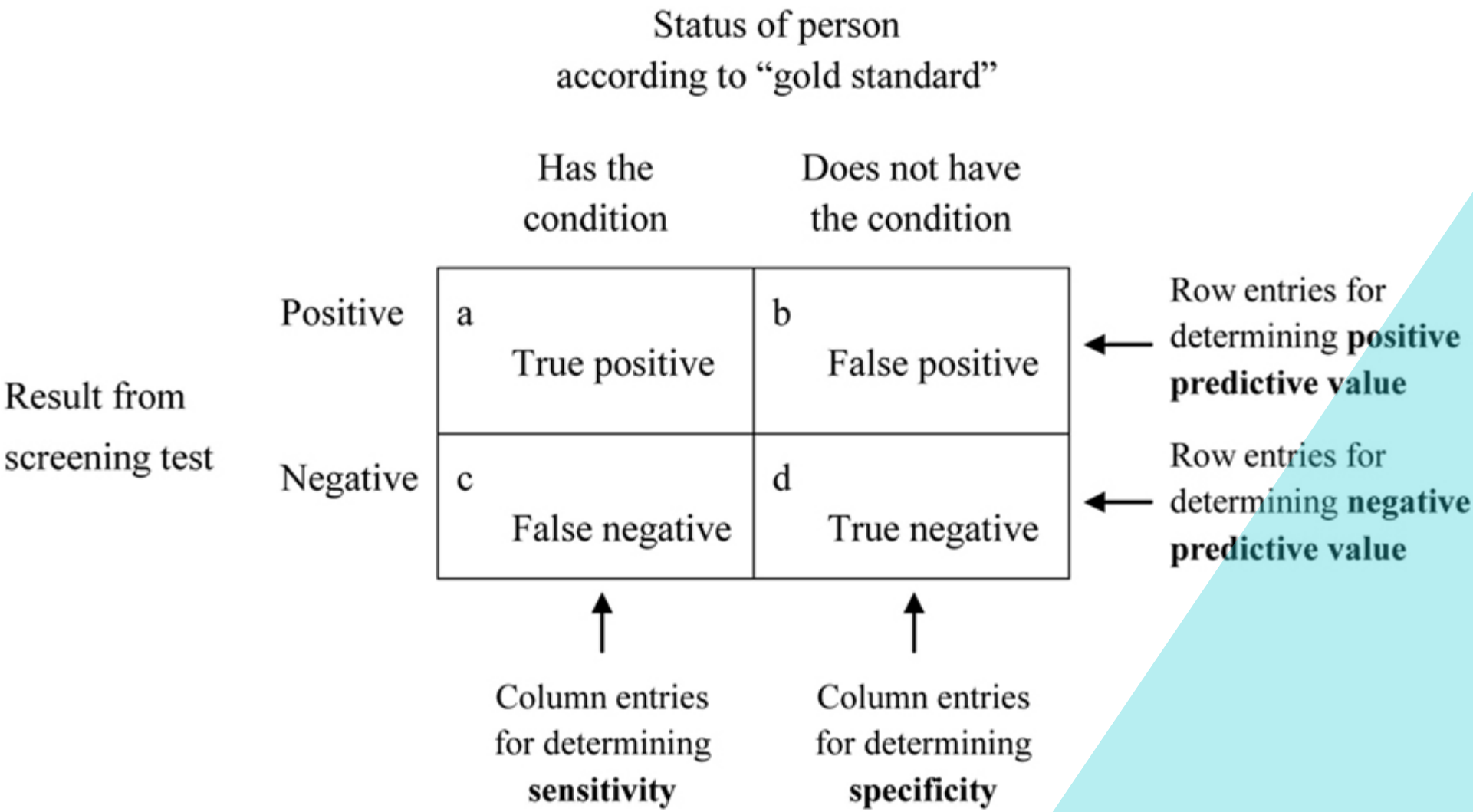
- A positive test result shows you may have antibodies from an infection with the virus that causes COVID-19. However, there is a chance that a positive result means you have antibodies from an infection with a different virus from the same family of viruses (called coronaviruses).
- Having antibodies to the virus that causes COVID-19 may provide protection from getting infected with the virus again. But even if it does, we do not know how much protection the antibodies may provide or how long this protection may last.

# Antigen Test



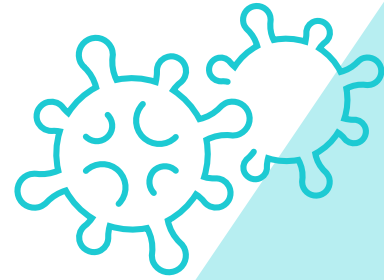
- While PCR tests pick up the coronavirus' genetic material, antigen tests register [surface proteins](#) on the virus. They're easier to spot, making testing quicker and cheaper, and potentially available for at-home use
- The most promising antigen test so far is Abbott's BinaxNOW — a fast, \$5, 15-minute, easy-to-use COVID-19 antigen test that received FDA emergency use authorization on August 26, 2020
- This test delivers results in just 15 minutes with no instrumentation, using proven lateral flow technology with demonstrated **sensitivity of 97.1%** and **specificity of 98.5%** in clinical study
- As of October 11, 2020. Emergency Use Authorization (EUA) by FDA:
  - 6 Antigen tests

# Sensitivity and Specificity



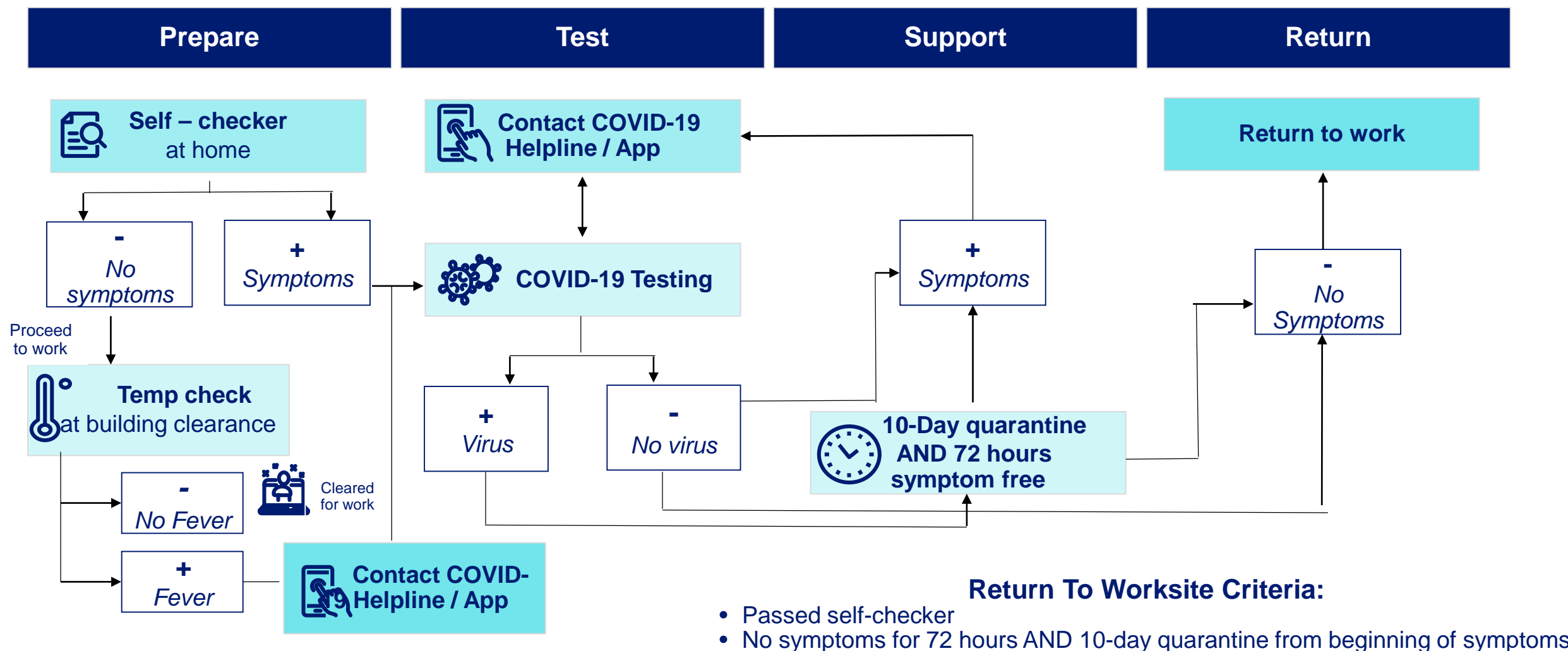


# Accuracy of COVID-19 Tests



- A molecular / PCR test using a deep nasal swab is usually the best option, because it will have fewer false negative results than other diagnostic tests or samples from throat swabs or saliva
- Antigen tests typically have high false negatives – but they are getting better. They are fast and can be mass produced
- Having an antibody test too early can lead to false negative results
- False negative tests provide false reassurance, and could lead to delayed treatment and relaxed restrictions despite being contagious
- All of these tests are new because the virus is new. We will know more in the coming years. Tests will get better and more sensitive and specific

# Screening and testing workflows designed for employee safety



# COVID-19 Testing Costs

Carrier/TPA	Network Labs	Primary Vendor Test	Self-collection Option	Network Discounted Price	Stated Accuracy
<b>Most BCBS Plans</b>	Quest LabCorp	Quest and LabCorp locally.	n/a	<b>\$42.13-\$150.20</b> /test depending on the CPT code.	n/a
<b>United</b>	Quest, LabCorp, etc.	n/a	Yes	Varies.	n/a
<b>Cigna</b>	Unknown	n/a	Yes, for some tests. Pixel by Labcorp costs \$119.test	<b>\$35.91-\$100</b> /test depending on the CPT code.	Varies
<b>Premiera</b>	Quest	n/a	No	Not provided	n/a
<b>Regence</b>	Quest, LabCorp, etc.	n/a	n/a	Paying 100% billed charges	n/a
<b>Anthem</b>	LabCorp, etc.	n/a	Yes for LabCorp.	Negotiated for IN Medicare allowable for OON	Varies

# COVID-19 Test Coverage

- **Group health plans and insurers must provide coverage for, and not charge any cost sharing for, the following services:**
  - Tests that are approved, cleared or authorized by the FDA – includes antibody testing
  - Tests for which the developer has requested, or intends to request, emergency use authorization (EUA)
  - The administration of such tests
  - Items and services furnished to individuals during provider office visits (whether in-person or via telehealth), urgent care visits, and emergency room visits that result in an order for, or the administration of, the test described above
- **Return-to-Work testing is *not* required to be covered**

# COVID-19 Testing Frauds

**CORONAVIRUS**

## A Doctor Went to His Own Employer for a COVID-19 Antibody Test. It Cost \$10,984.

Physicians Premier ER charged Dr. Zachary Sussman's insurance \$10,984 for his COVID-19 antibody test even though Sussman worked for the chain and knows the testing materials only cost about \$8. Even more surprising: The insurer paid in full.

by Marshall Allen, Sept. 5, 5 a.m. CDT

FDA Issues Warnings to Fraudulent COVID-19 Test Manufacturers

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FBI Warns of Potential Fraud in Antibody Testing for COVID-19

June 26, 2020

The Federal Bureau of Investigation is warning the public about potential fraud schemes related to antibody tests for COVID-19.

Scammers are marketing fraudulent and/or unapproved COVID-19 antibody tests, potentially providing false results. In addition, fraudsters are seeking to obtain individuals' personal

**The plan does not have to pay the out of network charges at face price – that rule only applies to the test. The plan has to pay the facility bill, but can negotiate at an in-network rate**



# COVID-19 Vaccines

# COVID-19 Vaccine Tracker

**Preclinical Testing:** Scientists test a new vaccine on cells and then give it to animals such as mice or monkeys to see if it produces an immune response.

**Phase 1:** Scientists give the vaccine to a small number of people to test safety and dosage as well as to confirm that it stimulates the immune system.

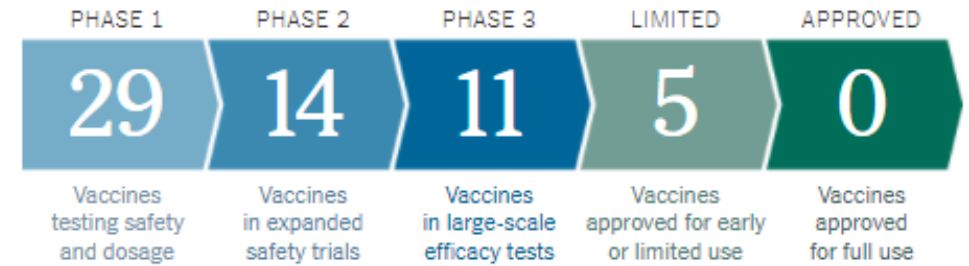
**Phase 2:** Scientists give the vaccine to hundreds of people split into groups, such as children and the elderly, to see if the vaccine acts differently in them. These trials further test the vaccine's safety and ability to stimulate the immune system.

**Phase 3:** Scientists give the vaccine to thousands of people and wait to see how many become infected, compared with volunteers who received a placebo. These trials can determine if the vaccine protects against the coronavirus. In June, the F.D.A. said that a coronavirus vaccine would have to protect at least 50% of vaccinated people to be considered effective. In addition, Phase 3 trials are large enough to reveal evidence of relatively rare side effects that might be missed in earlier studies.

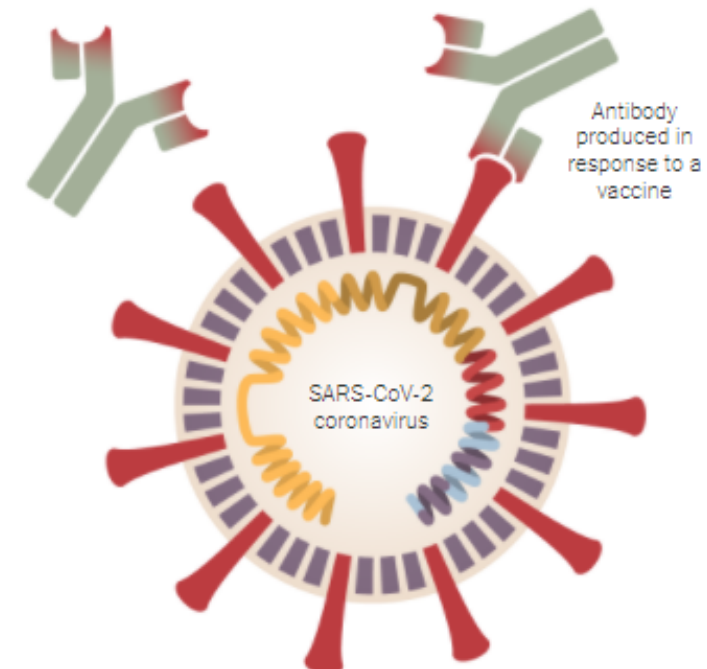
**Early Or Limited Approval:** China and Russia have approved vaccines without waiting for the results of Phase 3 trials. Experts say the rushed process has serious risks.

**Approval:** Regulators in each country review the trial results and decide whether to approve the vaccine or not. During a pandemic, a vaccine may receive emergency use authorization before getting formal approval. Once a vaccine is licensed, researchers continue to monitor people who receive it to make sure it's safe and effective.

Source: NYT Vaccine Tracker as of Oct. 11, 2020



Vaccines typically require years of research and testing before reaching the clinic, but scientists are racing to produce a safe and effective coronavirus vaccine by [next year](#). Researchers are testing **44 vaccines** in clinical trials on humans, and at least 92 preclinical vaccines are [under active investigation](#) in animals.

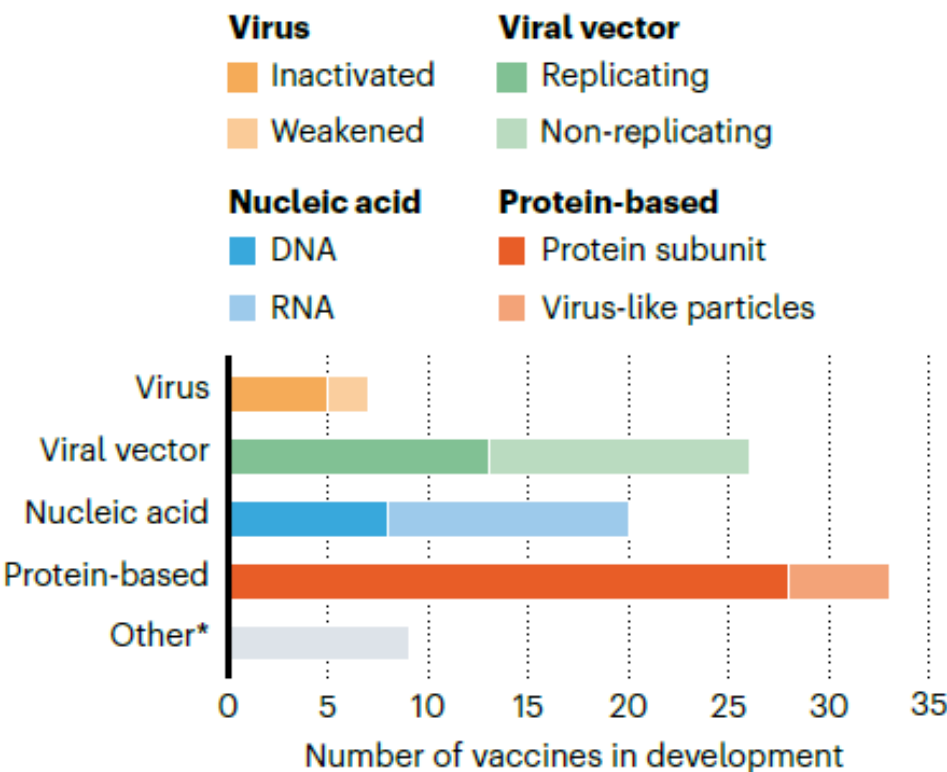


# COVID-19

## *Types of Vaccines*

### AN ARRAY OF VACCINES

All vaccines aim to expose the body to an antigen that won't cause disease, but will provoke an immune response that can block or kill the virus if a person becomes infected. There are at least eight types being tried against the coronavirus, and they rely on different viruses or viral parts.



\* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

# COVID-19 vaccines

## *3 myths and 3 truths*

### Myth #1

We don't need a vaccine; we can rely on "herd immunity."

**Truth #1:** A vaccine is essential for true herd immunity.

### Myth #2

An effective vaccine will soon be broadly available.

**Truth #2:** Widespread availability of a vaccine will take time.

### Myth #3

Once a vaccine is approved, life will soon return to normal.

**Truth #3:** An approved vaccine is no guarantee that life will soon return to normal.

# Thank You!

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