

## Coronavirus Disease 2019 Testing Basics

You've probably heard a lot about coronavirus disease 2019 (COVID-19) testing recently. If you think you have COVID-19 and need a test, contact your health care provider, [local pharmacy](#), or [local health department](#) immediately. The FDA has been working around the clock to increase the availability of critical medical products, including tests for SARS-CoV-2, the virus that causes COVID-19, to fight the COVID-19 pandemic. Learn more about the different types of tests and the steps involved.

There are two different types of tests – **diagnostic tests** and **antibody tests**.



A **diagnostic test** can show if you have an active coronavirus infection and should take steps to quarantine or isolate yourself from others. Currently there are two types of diagnostic tests – **molecular tests**, such as RT-PCR tests, that detect the virus's genetic material, and **antigen tests** that detect specific proteins from the virus.



An **antibody test** looks for antibodies that are made by your immune system in response to a threat, such as a specific virus. Antibodies can help fight infections. Antibodies can take several days or weeks to develop after you have an infection and may stay in your blood for several weeks or more after recovery. Because of this, antibody tests should not be used to diagnose COVID-19. At this time researchers do not know if the presence of antibodies means that you are immune to COVID-19 in the future.

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
<b>Also known as...</b>	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Diagnostic test	Serological test, serology blood test, serology test
<b>How the sample is taken...</b>	Nasopharyngeal (the part of the throat behind the nose), nasal or throat swab (most tests) Saliva (a few tests)	Nasal or nasopharyngeal swab (most tests)	Finger stick or blood draw
<b>How long it takes to get results...</b>	Same day (some locations) or up to a week (longer in some locations with many tests)	Some may be very fast (15 – 30 minutes), depending on the test	Same day (many locations) or 1-3 days
<b>Is another test needed...</b>	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate, but false positives can happen, especially in areas where very few people have the virus. Negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
<b>What it shows...</b>	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past
<b>What it can't do...</b>	Show if you ever had COVID-19 or were infected with the virus that causes COVID-19 in the past	Antigen tests are more likely to miss an active COVID-19 infection compared to molecular tests. Your health care provider may order a molecular test if your antigen test shows a negative result but you have symptoms of COVID-19.	Diagnose COVID-19 at the time of the test or show that you do not have COVID-19.

## Diagnostic Tests with Alternative Options

Diagnostic tests are now available with alternative methods and benefits.



- **Rapid, point-of-care** diagnostic tests use a mucus sample from the nose or throat but can be analyzed at the doctor's office or clinic where the sample is collected and results may be available in minutes. These may be molecular or antigen tests.



- **Combination tests** can test for the flu and the coronavirus at the same time. Some can test for many different types of respiratory viruses, including the one that causes COVID-19.



- **At-home collection** tests, available only by prescription from a doctor, allow the patient to collect the sample at home and send it directly to the lab for analysis. Some at-home collection tests have a health care provider oversee the sample collection by video with the patient.



- **Saliva tests** allow a patient to spit into a tube rather than get their nose or throat swabbed. Saliva tests may be more comfortable for some people and may be safer for health care workers who can be farther away during the sample collection.

## Molecular Diagnostic Tests

Many companies and labs have developed tests to diagnose COVID-19 based on detection of the virus's genetic material in a sample from the patient's nose or throat. These steps may change as new technology becomes available, but currently the typical steps in molecular testing are:

1. A doctor, pharmacist, or other health professional orders a COVID-19 test. All currently authorized COVID-19 tests, including those used with a home collection kit, require a prescription or order from a health professional.
2. You or a health care professional use a specialized, swab to collect mucus from your nose or throat.
3. You or a health care professional put the swab in a sterile container and seal it for transport to a lab.
4. During the shipping process, most molecular test swabs must be kept within a certain temperature range so that the test will be accurate. The sample must arrive at the lab within 72 hours.

5. A lab technician mixes liquids with the swab to extract the genetic material of any virus that may be on the swab.
6. The lab technician uses special reagents, called primers and probes, and a high-tech machine to conduct several controlled heating and cooling cycles to convert the virus's RNA into DNA, and then make millions of copies of the DNA. Some tests use only one warming cycle to make copies of the DNA.
7. When specific probes bind to DNA, a special type of light is produced that can be seen by the machine and the test shows a "positive" result for infection with SARS-CoV-2, the virus that causes COVID-19.

## Increasing Access to Testing

The FDA continues to work with test developers to make more coronavirus tests available to more people. One way to test more people is by combining genetic material from several people's swabs into one test. If the test is "negative," or doesn't show coronavirus, then none of the people whose swabs were included in that batch are likely to have an active coronavirus infection. If the test is "positive," showing the presence of the virus that causes COVID-19, each swab is retested to find the ones that are positive. This saves time and test materials, allowing lab technicians to test more samples. This process is called pooling, or pooled sample testing, and is most helpful in areas where most samples are expected to be negative.

No test is 100% accurate all of the time. Some things that may affect the test's accuracy include:

- You may have the virus, but the swab might not collect it from your nose or throat.
- The swab or mucus sample may be accidentally contaminated by the virus during collection or analysis.
- The nasal or throat swab may not be kept at the correct temperature before it can be analyzed.
- The chemicals used to extract the virus genetic material and make copies of the virus DNA may not work correctly.



**Antigen tests** usually provide results diagnosing an active coronavirus infection faster than molecular tests, but antigen tests have a higher chance of missing an active infection. If an antigen test shows a negative result indicating that you do not have an active coronavirus infection, your health care provider may order a molecular test to confirm the result.



**Antibody (Serology) tests** may provide quick results, but should not be used to diagnose an active infection. Antibody tests only detect antibodies the immune system develops in response to the virus, not the virus. It can take days to several weeks to develop enough antibodies to be detected by a test.

We do not know how long antibodies stay in the body following infection with the virus that causes COVID-19. We do not know if antibodies give you protective immunity against the virus, so results from a serology test should not be used to find out if you have immunity from the virus. The FDA cautions patients against using the results from any serology test as an indication that they can stop taking steps to protect themselves and others, such as stopping social distancing or discontinuing wearing masks.

## COVID-19 Testing in Your Community

**The best way to get a COVID-19 test is to contact your health care provider. You may also visit your [state](#) or [local](#) health department's website to look for the latest local information on testing.**

**Some communities are also testing asymptomatic people (people who do not have COVID-19 symptoms). Often these people are health workers or other essential workers with a lot of public contact.**

## Report Adverse Events

**The FDA encourages health care professionals and patients to report adverse events or side effects related to the use of COVID-19 tests or other medical products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:**

- **Complete and submit the [report online](#) through the FDA's MedWatch website.**
- **[Download the form](#) or call 1-800-332-1088 to request a form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178.**