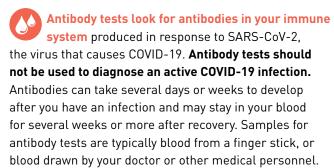


# **Coronavirus Disease 2019 Testing Basics**

You've probably heard a lot about coronavirus disease (COVID-19) testing. If you think you have COVID-19 and need a test, contact your health care provider or local health department immediately. You can also find a community testing site in your state, or buy an FDA-authorized at-home test. Some FDA-authorized at-home tests give you results within minutes. Others require you to mail the sample to a lab for analysis.

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

Diagnostic tests can show if you have an active Covid-19 infection and need to take steps to quarantine or isolate yourself from others. Molecular and antigen tests are types of diagnostic tests than can detect if you have an active COVID-19 infection. Samples for diagnostic tests are typically collected with a nasal or throat swab, or saliva collected by spitting into a tube.



	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Diagnostic test, viral test, rapid test	Serological test, serology, blood test, serology test
How the sample is taken	Nasal swabs, either shallow or deep (most tests). Saliva (some tests)	Nasal or nasopharyngeal swab (most tests)	Blood from a fingerstick or vein
How long it takes to get results	Less than an hour (at-home tests and some point-of-care locations), same day (some point-of-care locations) or 1-3 days (tests sent to a lab for processing). Some tests may take longer in some locations, depending on testing capacity.	Some may be very fast (15-30 minutes), depending on the test	Same day (some point-of-care locations) or 1-3 days (tests sent to a laboratory for processing)
Is another test needed	Not usually. This type of test is typically highly accurate andmusually does not need to be repeated. Some may indicate the need to re-test in certain circumstances.	Maybe. 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.
What it shows	Diagnoses active COVID-19 infection. (Some tests may also diagnose influenza or other respiratory viruses)	Diagnoses active COVID-19 infection. (Some tests may also diagnose influenza or other respiratory viruses)	Shows if you've been infected by the virus that causes COVID-19 in the past
What it can't do	It cannot show if you ever had COVID-19 or were infected with the virus that causes COVID-19 in the past	It may not detect an early COVID-19 infection. Your health care provider may order a molecular test if your antigen test shows a negative result, but you have symptoms of COVID-19. It also cannot show if you ever had COVID-19 or were	It cannot diagnose COVID-19 at the time of the test or show that you do not have COVID-19

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## **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.



- Home Collection Test: sample is collected at home but analyzed in a laboratory
- **Direct to Consumer (DTC) Test:** home collection tests available without

a prescription, but the sample is analyzed in a laboratory

- At-home Testing: consumer completes sample collection and testing at home
- Over the Counter (OTC) Test: consumer completes sample collection and testing at home, without a prescription



 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.

#### Ordering a Test

Many tests, including some home collection and at-home tests, require a prescription or order from a health care provider.

Prescription Tests – Health care providers can determine whether you need a test, and ensure you get the most appropriate test and that you know what the results mean. For example, certain tests are authorized only for people suspected of having COVID-19 or for people with COVID-19 symptoms that started within a certain number of days. A health care provider can help determine which test is best for your situation. Prescription-only home collection and at-home tests may require you to answer some questions online so that a health care provider can determine whether to prescribe or order a specific test.

Non-Prescription Tests – Some tests are available without a prescription. Home collection and at-home tests available without a prescription may be called "direct-to-consumer" (DTC) or "over-the-counter" (OTC). DTC and OTC tests may be available to purchase at a pharmacy or online, but they may not be available everywhere.

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.

## **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.