FDA U.S. FOOD & DRUG ADMINISTRATION

Coronavirus Testing Basics

You've probably heard a lot about coronavirus testing recently. If you think you have coronavirus disease 2019 (COVID-19) and need a test, contact your health care provider immediately. The FDA has been working around the clock to increase the availability of critical medical products, including tests for the coronavirus, 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 (RT-PCR) tests** that detect the virus's genetic material, and **antigen tests** that detect specific proteins on the surface of the virus.

An **antibody test** looks for antibodies that are made by the 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 after recovery. Because of this, antibody tests should not be used to diagnose an active coronavirus infection. At this time researchers do not know if the presence of antibodies means that you are immune to the coronavirus in the future.

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification tests (NAAT), RT-PCR tests	Rapid diagnostic test*	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
How long it takes to get results...	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
Is another test needed...	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but 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 coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past
What it can't do...	Show if you ever had COVID-19 or were infected with the coronavirus in the past	Definitively rule out active coronavirus infection. Antigen tests are more likely to miss an active coronavirus 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 active coronavirus infection at the time of the test or show that you do not have COVID-19

**Some molecular tests are also rapid tests.*

There are some new diagnostic tests 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.

- **At-home collection tests** are prescribed by a doctor but allow the patient to collect the sample at home and send it directly to the lab for analysis.

- **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.

Steps in Molecular Testing

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. The typical steps in this type of molecular testing for the coronavirus are:

1. A health care professional orders a COVID-19 test. All COVID-19 tests, including those used with a home collection kit, require a prescription.

2. You or a health care professional use a specialized, sterile 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, the swab must be kept within a certain temperature range to keep the virus alive so that the test will be accurate. The sample must arrive at the lab within 72 hours.

5. A lab technician mixes chemicals with the swab to extract the genetic material of any virus that may be on the swab.

6. The lab technician uses special chemicals, 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.

7. When DNA binds to specific probes, 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.

The FDA continues to work with test developers to streamline the testing process, making more coronavirus tests available to more people in the future.

Molecular diagnostic tests that detect the genetic material of the virus itself are commonly used for diagnosing COVID-19 or active coronavirus infection. But 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 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 itself, therefore the antibodies may not have developed yet. It can take days to several weeks to develop enough antibodies to be detected in a test.

Americans rely on the FDA to provide an independent review of medical products, such as drugs, diagnostic tests and other medical devices. During a public health emergency like the COVID-19 pandemic, there is an urgent need for products to diagnose, treat or prevent a medical threat. There are three ways a coronavirus test might be used for this emergency:

1. Emergency Use Authorization (EUA)

In certain types of emergencies, the FDA can issue an Emergency Use Authorization, or EUA, to provide more timely access to critical medical products that may help during the emergency when there are no adequate, approved, and available options. The EUA process is different than full approval or clearance because in some emergency situations we cannot wait for all of the evidence needed for full FDA approval or clearance. Instead, the FDA evaluates the options very quickly using the evidence that is available, carefully balancing the risks and benefits of the product as we know them, in addition to evaluating other criteria.

2. Lab Developed Test (LDT)

A laboratory developed test (LDT) is an *in vitro* (or laboratory) diagnostic test that is manufactured by and used within a single laboratory. The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The FDA is providing flexibility to certain labs certified under CLIA to run high-complexity tests during the COVID-19 emergency. The FDA is providing flexibility for labs that develop and perform their own coronavirus testing where the lab validates the test, notifies FDA, and submits the validation data to the FDA within a certain timeframe as part of an EUA request. While many labs purchased commercial tests under an existing EUA, other labs developed and validated their own tests under this temporary policy.

3. State Authorization

The FDA is providing flexibility to states who want to authorize labs certified to conduct high-complexity tests in that state to develop and perform coronavirus testing. Under this policy, the state or territory takes responsibility for the safety and accuracy of COVID-19 testing by laboratories in its state/territory and the lab does not submit an EUA request to the FDA.

The best way to get a coronavirus 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.

The FDA encourages health care professionals and patients to report adverse events or side effects related to the use of coronavirus tests 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.**