

Coronavirus Disease At-Home Collection and Testing Options

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.



Home Testing Options

The FDA continues to authorize COVID-19 tests to give more Americans more options for COVID-19

testing. This includes emergency use authorizations (EUAs) for COVID-19 tests where some or all testing process takes place at home.

All tests that have received an EUA, including any authorizations for home collection or at-home tests, can be found in tables of **molecular**, **antigen**, and **serology and adaptive immune response** in vitro diagnostic emergency use authorizations (EUA) for more information.

Ordering a Test

Many tests, including some home collection and athome 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.

Pooled Sample Testing



One way for laboratories to test more people for COVID-19 is by combining samples from several people into one sample and testing them together, also called "pooling." Pooling is most helpful in areas where most samples

are expected to be negative. This saves time and test materials when only a very small number of positives are expected, allowing labs to test more samples.

If the test is negative, or doesn't detect SARS-CoV-2, then none of the people whose samples were included in the pooled sample are likely to have an active COVID-19 infection.

If the test is positive, showing the presence of the virus that causes COVID-19, everyone is retested separately, either by taking a new sample or testing a remaining portion of the original sample, to find the samples that are positive.

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Understanding Your Test Results

Generally, for diagnostic tests, a negative result means the test did not detect the SARS-CoV-2 virus, and a positive result means the test did detect the SARS-CoV-2 virus and you are very likely to have COVID-19.

However, no test is perfect. There is always a chance that a test will return a false result. For diagnostic tests, a false negative means the test says you don't have COVID-19 but you are infected, and a false positive means that the test says you have COVID-19 but you are not infected.

Because of this, even if you receive a negative result, you should keep practicing preventive measures, such as distancing, washing hands, and wearing masks, to reduce the risk of spreading COVID-19.

If you are sick, you should stay home and isolate from others, even if you receive a negative test result. Talk with

your health care provider to determine if you should be retested or for advice on managing your symptoms.

For serology tests, a negative result means the test did not detect antibodies to the virus that causes COVID-19. A positive result means the test did detect antibodies to the virus that causes COVID-19, and it is possible that you had a recent or prior COVID-19 infection and you have developed an adaptive immune response to the virus.

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 as well as performance issues 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.