

HOW CAN WE TEST FOR SARS-COV-2?

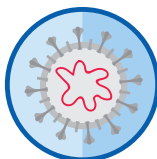
There are two types of SARS-CoV-2 tests: **diagnostic tests** and **antibody tests**.

Diagnostic Tests

- Determine if a patient is currently infected with SARS-CoV-2; cannot determine if a person was previously infected.
- The samples tested are nasopharyngeal, nasal, or throat swabs, or saliva samples.
- Currently there are two types of diagnostic tests.

Molecular tests

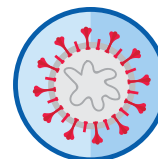
The sample is tested using a technique called polymerase chain reaction (PCR) that detects the virus's genetic material.



- Take more time than antigen tests, i.e., results can take up to three days.
- More sensitive compared to an antigen test
- Less chance of inaccurate results compared to an antigen test

Antigen tests

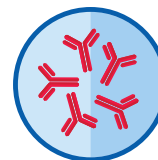
The sample is tested using techniques that detect specific proteins, called antigens, on the surface of the virus.



- Quicker than molecular tests, i.e., results can be available within few hours.
- Less sensitive compared to a molecular test
- More chance of inaccurate results compared to a molecular test, e.g., may miss some people who are infected

Antibody Tests

- Determine if a patient was previously infected with SARS-CoV-2; cannot determine if a person is actively infected.
- The samples tested are blood samples.
- The sample is tested to determine whether proteins called antibodies that the patient's immune system would have made during a previous infection with SARS-CoV-2 are present.



To address the urgency of controlling the COVID-19 pandemic FDA has allowed for three independent pathways for the development of SARS-CoV-2 tests (106):

Emergency Use Authorization (EUA) – EUA provides faster access to critical medical products that may help during an emergency when there are no adequate, approved, and available options. To issue an EUA, FDA quickly evaluates the evidence that is currently available, carefully balancing the risks and benefits of a product as known at the time, among other criteria.

Lab Developed Test (LDT) – LDT is a diagnostic test that is manufactured by and used within a single laboratory. The Centers for Medicare & Medicaid Services regulates most laboratory testing performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). During the pandemic, FDA has provided flexibility to certain laboratories certified under CLIA to run COVID-19 tests. Laboratories that develop and perform their own testing must validate the test, notify FDA, and submit the validation data to FDA within a certain time as part of an EUA request.

State Authorization – FDA has provided flexibility to states that want to authorize laboratories certified to conduct high-complexity tests in that state to develop and perform COVID-19 testing. Under this policy, the state takes responsibility for the safety and accuracy of the tests and the laboratory does not submit an EUA request to FDA.

As of **January 1, 2022** there were **419 tests** and sample collection devices authorized by FDA under EUAs. These include **290 molecular** tests and sample collection devices, **87 antibody** and other immune response tests, and **42 antigen** tests. Detailed information on all of these tests is provided by FDA.