Testing Individuals for Coronavirus Disease 2019 (COVID-19)

Coronavirus disease 2019 (COVID-19) infection can be diagnosed using a test called polymerase chain reaction (PCR).

What Is the PCR Test for COVID-19 Infection?

Samples are taken from places likely to have the virus that causes COVID-19, like the back of the nose or mouth or deep inside the lungs. After a sample is collected, RNA, which is part of the virus particle, is extracted and converted to complementary DNA for testing. The PCR test involves binding sequences on the DNA that only are found in the virus and repeatedly copying everything in between. This process is repeated many times, with doubling of the target region with each cycle. A fluorescent signal is created when amplification occurs, and once the signal reaches a threshold, the test result is considered positive. If no viral sequence is present, amplification will not occur, resulting in a negative result.

Should You Be Tested?

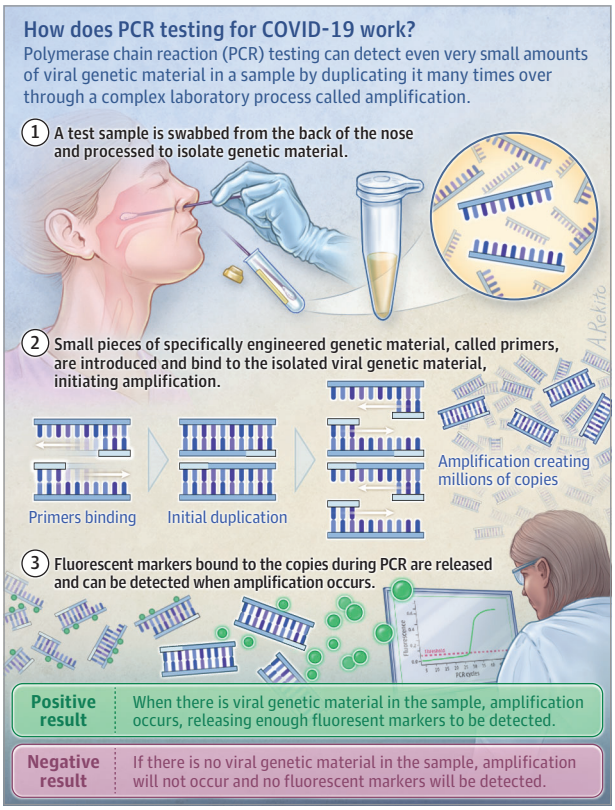
Guidelines for testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for COVID-19, continue to evolve as knowledge of COVID-19 improves and availability of testing increases. Currently, testing in the US is only performed for individuals when a positive result will change treatment. Testing is also prioritized for people who have a high risk for bad outcomes from COVID-19 infection, such as elderly or immunosuppressed patients, and those with high risk of exposure and transmission of the disease to other people, such as health care workers. Recommendations for testing are regularly updated by the Centers for Disease Control and Prevention (CDC). If you have questions about testing, contact your local public health department.

Why Has Adoption of Testing Been Slow in the US?

Regulatory process and time required to validate clinical tests. The regulatory process in the US is designed to ensure patient safety and accurate diagnostic testing. Testing was initially only offered through an assay developed by the CDC; however, only a limited number of test kits were available. Alternate tests required Emergency Use Authorization from the US Food and Drug Administration before use. This policy was changed on February 29, 2020, to allow use of tests before approval, which has improved access.

Initial lack of certified laboratories with PCR capabilities. Most clinical laboratories did not have the capability to perform PCR at the beginning of the outbreak. Skilled laboratories and technicians are needed for PCR, as contamination at any step drastically changes results.

Shortage of chemicals and supplies. Certain chemicals and supplies, such as those used in extraction and PCR kits, were initially in short supply. Reagents have become more available as alternative PCR tests are developed. Personal protective equipment for technicians handling specimens has also been limited.



Are Alternative Tests Available?

Blood antibody testing and viral antigen testing in respiratory samples, similar to the rapid influenza test, are currently being investigated. The clinical value of these tests is not known yet, and challenges such as cross-reactivity with other viruses, and that sometimes the test does not detect the virus when it is there, need to be addressed.

FOR MORE INFORMATION

Centers for Disease Control and Prevention.
Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

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