

What Types of Diagnostic Tests Exist to Detect COVID-19?

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A critical element for combatting the COVID-19 pandemic is to have suitable diagnostic tests available. There are generally two very different types of COVID-19 tests:

- I. **Molecular based COVID-19 tests:** these tests detect the presence of the virus but not if the person has previously been in contact with the virus
- II. **Serology tests for COVID-19:** these tests detect the immune response against the virus (the production of antibodies), meaning that the person has previously been in contact with the virus

I. Molecular based COVID-19 tests

A. What are molecular based COVID-19 tests?

These tests detect the presence of the virus but not if the person has previously been in contact with the virus.

A molecular test is a highly sensitive and specific technique. The tests allow for testing people at an early stage of the infection. They also allow, when performed in laboratories in larger quantities, for assumptions about the nature and spread of the virus in a whole population. This is an important information for case confirmation and isolation guidance for authorities in order to take appropriate measures to protect the people.

B. How do these tests work?

Molecular based COVID-19 tests work with a sample taken from a person's **nose or back of the throat**. The tests look at a specific viral genetic material showing the presence of the virus in the body.

C. Where are these tests performed?

The first step of taking a sample through a swab, can be done anywhere, if the medical staff is well protected by using 'personal protective equipment' (PPEs).

The preparation and analysis of the sample is usually happening in specialised and approved laboratories by large, immobile molecular machines.

There are also new 'point-of-care' molecular tests. Those can be performed with mobile devices in clinics, doctors' offices or even mobile drive-in sites.

One main difference between laboratory and point-of-care molecular-tests is the throughput: Laboratories can usually run batches of almost 100 samples per time; point-of-care tests run only individual samples or mini batches per time.

D. Components and accessories of COVID-19 molecular tests

- Nasal, nasopharyngeal (NP) or throat swabs (specific long Q-tip style equipment)
- Personal protective equipment for the medical staff taking and processing the swabs
- Molecular testing reagents, including quality controls
- Depending on the platform (laboratory-based or point-of-care), additional reagents may be needed such as extraction reagents
- Molecular testing machines

Increasing production capacity of the tests presumes that all these components and accessories are also needed in larger quantities. A shortage of any of these materials would jeopardise the production capacity. Furthermore, the laboratory capacity, namely the available amount of staff and molecular machines, is another important determinant for the number of tests that could be performed at a given amount of time.

II. Serology tests for COVID-19

A. What are serology tests for COVID-19?

These tests detect the immune response against the virus (the production of antibodies), meaning that the person has previously been in contact with the virus

Serology tests, also called immunoassays, come in many different formats and variations. They detect if a person has developed antibodies against the COVID-19 virus and is thus immune against another infection with this virus for a certain period.

These tests become important at a later stage of an infection, since antibodies need around 5-10 days to develop and be detectable in the blood. When performed in larger numbers of a population, they may become a tool that could also give information about the immunisation rate of a population and could therefore guide authorities in their efforts to ease social restrictive measures appropriately.

B. How do these tests work?

Serology tests work with a blood sample of a person. These immunoassays could run in one or multiple steps with reagents being added and washed away or separated at different points in the assay.

The tests detect the presence and level of antibodies in a person's body, called IgM and IgG. Firstly, the presence of IgM develops and suggests that the person is still in a rather early stage of the infection. Secondly, a bit later in the infection the presence of IgG develops in parallel to the IgM. Finally, when

recovering from the disease, IgM disappears and only IgG remains, and IgG should stay positive for months and possibly years.

Some serology tests give a qualitative result only (positive or negative) indicating if the person has developed antibodies against the virus or not; others can quantify the level of antibodies which may be correlated with a 'level of immunity'.

For a serology test, the accuracy level is important. It is defined by its sensitivity (ability to detect infected people) and its specificity (limiting false positive results). A good sensitivity means no or very few false negative results, a good specificity means no or very few false positive results.

Serology tests can be run as 'point of care' tests or they can also be performed in clinical laboratories on large automated systems. One main difference between laboratory and point-of-care serology tests is the throughput: Laboratories can usually run batches of almost 100 samples per time; point-of-care tests run only individual samples or mini batches per time.

C. Where are these tests performed?

The first step of taking a blood sample can be performed anywhere, if the medical staff is well protected by using 'personal protective equipment' (PPEs).

The preparation and analysis of the blood sample is performed in clinical laboratories on large automated systems.

The point-of-care serology tests can be performed with mobile hand-held devices in clinics, doctors' offices or even mobile drive-in sites.

D. Components and accessories of COVID-19 serology tests

- According to the technology used: lancet or blood sample collectors
- Personal protective equipment for the medical staff taking the blood samples
- Serology testing reagents, including quality controls
- Depending on the platform (laboratory-based or point-of-care), additional reagents may be needed
- Serology testing machines



III. Safety and performance of COVID-19 tests

All COVID-19 tests today must adhere to strict regulatory procedures before they get to the market. These laws establish the essential requirements for safety and performance of diagnostic tests. At the same time, market surveillance mechanisms are set-up to ensure that products are further monitored once they are in the market.

It is crucial, more than ever, that requirements and procedures set by the laws are followed. This ensures that reliable and accurate tests are deployed in the battle against the COVID-19 pandemic.

At the same time, COVID-19 tests must be purchased from reliable diagnostic tests producers. It is recommended that prior to purchasing tests, all safety and performance information is obtained, analysed and properly taken into account.

Tests for SARS-CoV-2/COVID-19 and Potential Uses

Type of Test	Measure	Value	Beneficiary
 <p>Nucleic acid amplification test for viral RNA <i>(nasopharyngeal swab, oropharyngeal swab, sputum, bronchoalveolar lavage fluid, others)</i></p>	Current infection with SARS-CoV-2	<ul style="list-style-type: none"> • Inform individual of infection status so they can anticipate course of illness and take action to prevent transmission • Inform patient management and actions needed to prevent transmission • Inform actions needed to prevent transmission 	<ul style="list-style-type: none"> • Individual • Healthcare or long-term care facility • Public health
 <p>Antibody detection</p>	Past exposure to SARS-CoV-2	<ul style="list-style-type: none"> • Detect susceptible individuals (antibody negative) and those previously infected • Identify individuals with neutralizing antibodies • Facilitate contact tracing and surveillance 	<ul style="list-style-type: none"> • Identify those potentially immune to SARS-CoV-2 (if tests can detect protective immunity, individuals could be returned to work) • Healthcare facilities: Experimental therapy • Public health

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