MedTech Europe
from diagnosis to cure

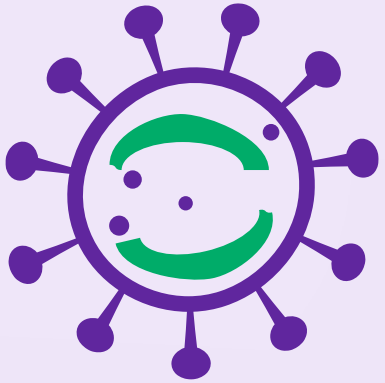
DIAGNOSTIC TESTS TO DETECT COVID-19

September 2020

MedTech Europe

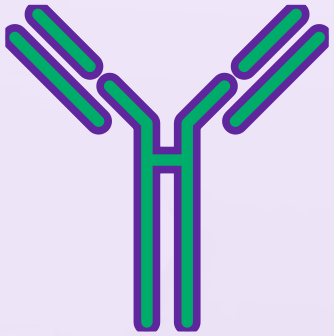
Different types of COVID-19 tests:

Molecular tests



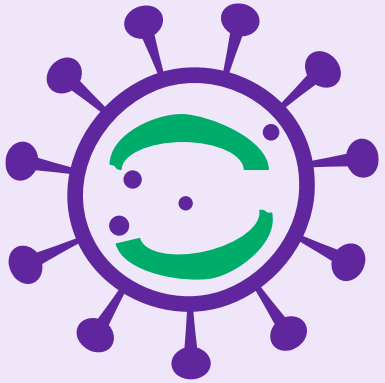
Antigen tests

Serology tests



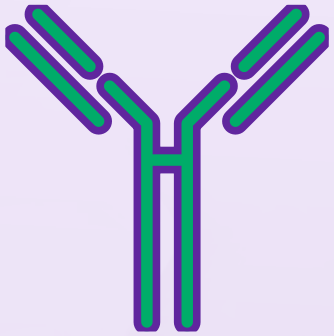
Different types of COVID-19 tests

Molecular tests



Antigen tests

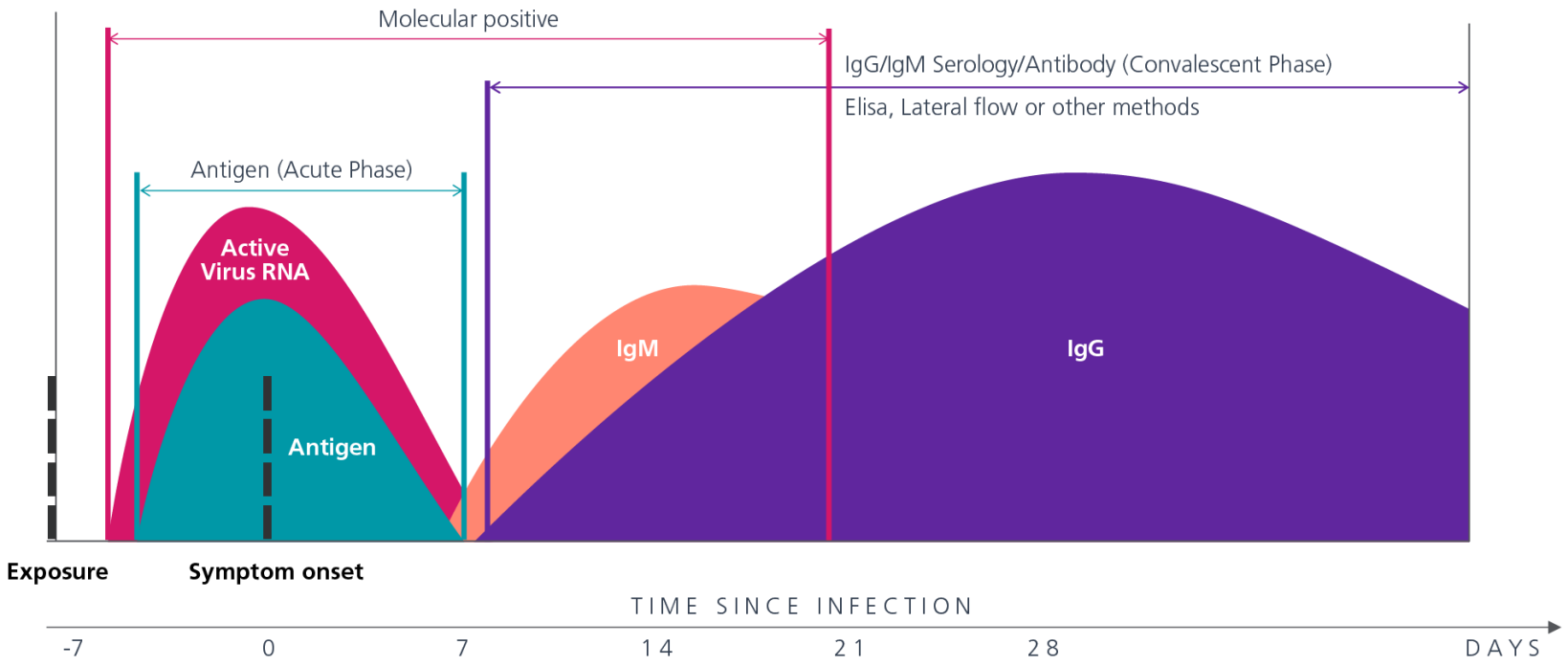
Serology tests



Current presence of virus
(but not previous contact)

Immune response
(previous contact with COVID-19)

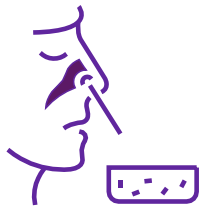
The tests are for different points of disease progression



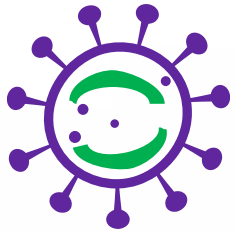
NOTE: This is based on typical viral load patient response and present knowledge about SARS-CoV2. COVID-19 time-lines are not yet precisely and completely documented, particularly for antigen. This graph is for illustrative purpose only.

Molecular-based tests – How do they work?

Sample collection → **Detection** → **What these tests say**



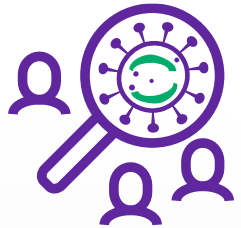
Nose / throat swab



Zoom in on the genetic signature of the virus (DNA)

Detect current COVID-19 infection

Why they are helpful



1. Molecular tests are highly sensitive and specific
2. Allow for testing people at an early stage of the infection
3. Can inform on the spread of the virus
4. Provide relevant information for case confirmation and isolation guidance

Molecular-based tests – Resources

Where tests are performed

- First sample can be **taken anywhere**
- New point-of-care with **mobile devices** e.g. clinics, doctors' offices, mobile drive-in sites

- Preparation / analysis happens in **laboratories**
- Laboratories can run **larger batches** (thousands per day) than point-of-care

Components / accessories

Nose / throat swabs

Personal protective equipment

Additional external reagent may be needed depending on platform (lab or point-of-care)

Molecular testing reagents including quality controls

Molecular testing equipment

Antigen-based tests – How do they work?

Sample collection → **Detection** → **What these tests say** → **Why they are helpful**

Sample types vary (e.g. blood, saliva, faeces)

Identify presence of proteins of the virus **(antigens)**

Detect current COVID-19 infection

Access:

- Can be done in a doctor's office
- Could be developed and validated for self-testing

Antigen-based tests – Resources

Where tests are performed

- First sample can be **taken anywhere**
- New point-of-care with **mobile devices** e.g. clinics, doctors' offices, mobile drive-in sites

- Preparation / analysis **depend on local regulations**
- Done by healthcare professionals on mobile units in **emergency wards, clinics and doctors' offices**

Components / accessories

Swabs, blood samples or other biological fluid collectors

Personal protective equipment

Additional external reagent may be needed depending on platform (lab or point-of-care)

Antigen testing reagents including quality controls

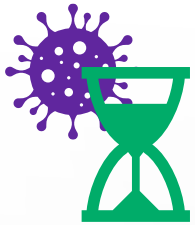
Antigen testing equipment

Serology tests – How do they work?

Sample collection → **Detection** → **What these tests say** → **Why they are helpful**

Blood samples (venous, capillary or serum)

Detect if person has developed antibodies



Detect previous contact with COVID-19

Presence of IgM antibodies suggests that the person is in the early stage of the infection. Presence of both IgM and IgG (which develop later during the course of infection) suggest that the patient is in a later stage of the disease.

1. Provide important information on diffusion of infection for large portions of populations
2. Will play a major role in vaccine development, including monitoring pre / post vaccinal immunity

Serology tests – Resources

Where tests are performed

- First sample can be **taken anywhere**
- Point-of-care tests with **mobile hand-held devices** in clinics, doctors' offices or even mobile drive-in sites

- Preparation / analysis **done in clinical labs on large automated systems**
- Laboratory tests can **run large batches (thousands per day)** when compared to point-of care capacity

Components / accessories

Lancet or blood sample collectors

Personal protective equipment

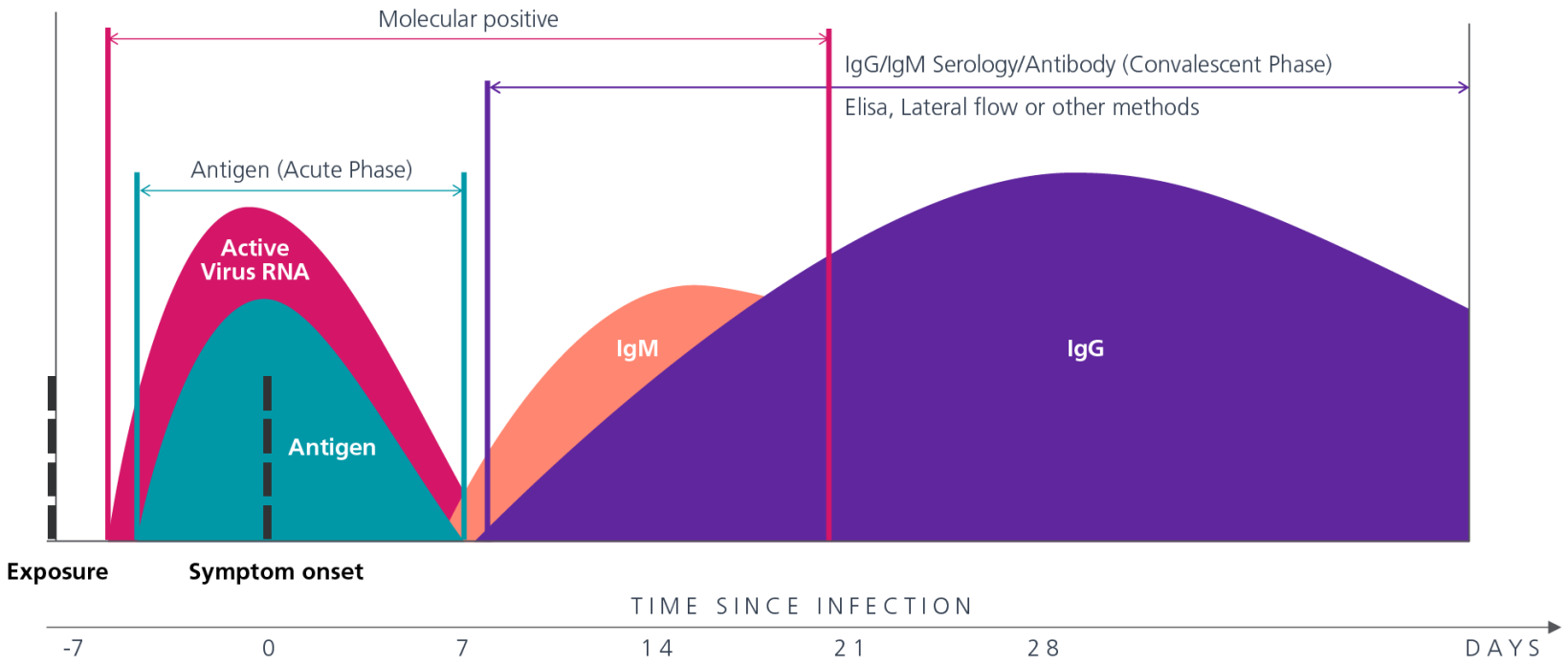
Additional external reagent may be needed depending on platform (lab or point-of-care)

Serology testing reagents including quality controls

Serology testing machines

	Molecular tests	Antigen tests	Serology tests
	• Detect presence of virus	• Detect presence of virus	• Detect immune response to virus
Sample collection	• Nose / throat swab	• Different sample types (e.g. blood, saliva, faeces)	• Blood samples (venous, capillary or serum)
Detection	• Zoom in on genetic signature of the virus (DNA)	• Detect presence of proteins of the virus (antigens)	• Detect if person has developed antibodies
What these tests say	• Detect current COVID-19 infection	• Detect current COVID-19 infection	• Detect previous contact with COVID-19
Why it is helpful	• Molecular tests are highly sensitive and specific • Allow for testing people at an early stage of the infection • Can inform on the spread of the virus • Provide relevant information for case confirmation and isolation guidance	Access: • Can be done in a doctor's office • Could be developed and validated for self-testing	• Provide important information on diffusion of infection for large portions of populations • Will play a major role in vaccine development, inc. monitoring pre / post vaccinal immunity
Where these tests are performed	• First sample taken anywhere • New point-of-care with mobile devices e.g. clinics, doctors' offices, mobile drive-in sites • Preparation / analysis happens in laboratories • Laboratories can run larger batches (thousands per day) than point-of-care	• First sample taken anywhere • New point-of-care with mobile devices e.g. clinics, doctors' offices, mobile drive-in sites • Preparation / analysis depend on local regulations • Done by healthcare professionals on mobile units in emergency wards, clinics and doctors' offices	• First sample taken anywhere • Point-of-care tests with mobile hand-held devices in clinics, doctors' offices or even mobile drive-in sites • Preparation / analysis done in clinical labs on large automated systems • Laboratory tests can run large batches (thousands per day) when compared to point-of care capacity
Components / accessories	• Nose / throat swabs • Personal protective equipment for medical staff • Additional external reagent may be needed depending on platform (lab or point-of-care) • Molecular testing reagents including quality controls • Molecular testing equipment	• Swabs, blood samples or other biological fluid collectors • Personal protective equipment • Additional external reagent may be needed depending on platform (lab or point-of-care) • Antigen testing reagents including quality controls • Antigen testing equipment	• Lancet or blood sample collectors • Personal protective equipment • Additional external reagent may be needed depending on platform (lab or point-of-care) • Serology testing reagents including quality controls • Serology testing machines

The tests are for different points of disease progression



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Safety and performance of COVID-19 tests

All COVID-19 tests must…

Be purchased from reliable diagnostic tests producers

Adhere to strict regulatory procedures before they get to the market

Comply with essential **requirements for safety and performance** of diagnostic tests

Meet market surveillance mechanisms set-up to ensure that products are further monitored once they are in the market

Follow requirements and procedures set by the laws, which in turn ensure reliability and accuracy of these tests

Prior to purchasing tests, all safety and performance information must be obtained, analysed, and properly taken into account

Terminology on testing for COVID-19

Laboratory testing: Testing that takes place in a specialised laboratory with specific infrastructure, equipment, and trained personnel.

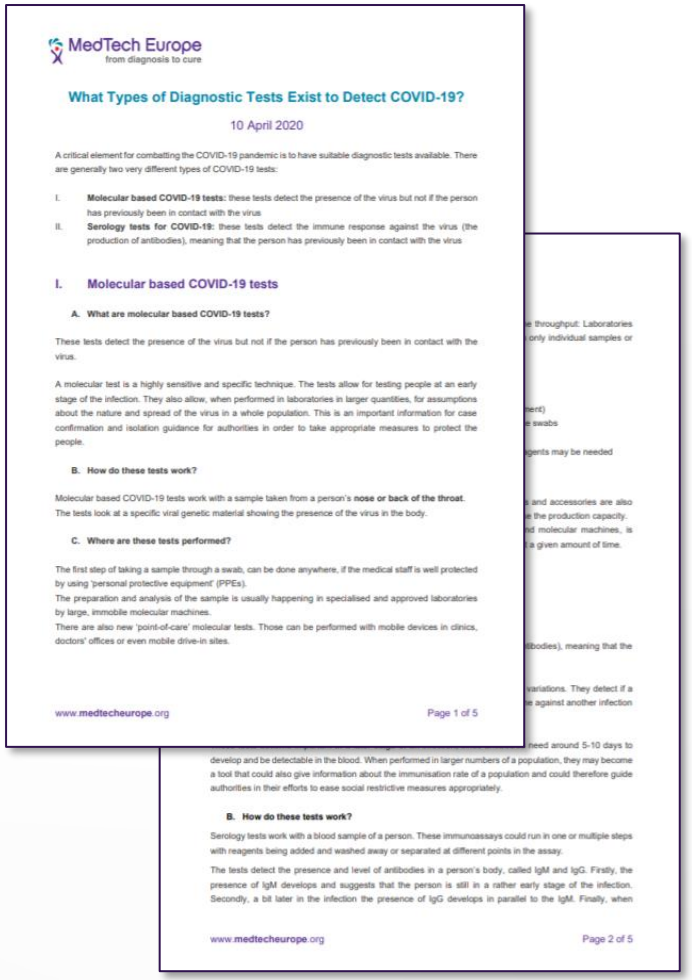
Point-of-care (POC) or near-patient testing: Testing that takes place at the time of the consultation with the results made available in a short time (from few minutes to generally less than one hour).

Rapid tests: These tests are used singly or in small series and involve simple procedures. Devices validated to run these types of tests have been designed to give a fast result (in less than 1 hour). They may be intended either for use in laboratories or in point-of-care settings.

Self-sampling: Self-sampling implies the possibility for patients to collect the sample themselves. The sample can then be sent to a laboratory for central testing or be tested by the patients themselves, in a case where a test is classified as a self-test. *Depends on local regulations.*

Self-testing: Self-testing is performed with a device intended to be used by anyone even without formal healthcare or medical experience in their own environment, such as their homes. (e.g. pregnancy test, blood glucose monitoring...). *Depends on local regulations*.

References



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

10 April 2020

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.

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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

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- This presentation offers information on the **types of diagnostic tests that exist to detect COVID-19: what they are and how they work**

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For more information

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MedTech Europe COVID-19 information hub

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