DIAGNOSTIC TESTS TO DETECT COVID-19

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MedTech Europe
Different types of COVID-19 tests:

Molecular tests

Antigen tests

Serology tests
Different types of COVID-19 tests

- **Molecular tests**: Current presence of virus (but not previous contact)
- **Antigen tests**: Current presence of virus (but not previous contact)
- **Serology tests**: Immune response (previous contact with COVID-19)
The tests are for different points of disease progression.
# Molecular-based tests – How do they work?

<table>
<thead>
<tr>
<th>Sample collection</th>
<th>Detection</th>
<th>What these tests say</th>
<th>Why they are helpful</th>
</tr>
</thead>
</table>
| Nose / nasopharyngeal (NP) / throat swab | Zoom in on the genetic signature of the virus (RNA) | Detect current COVID-19 infection | 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/nasopharyngeal (NP) / 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?

<table>
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</table>
| Sample types vary according to technology used (e.g., upper respiratory tract swabs or other biological fluid collectors) | Identify presence of proteins of the virus (antigens) | Detect current COVID-19 infection | Access:  
• Can be done in a doctor’s office  
• Laboratories can run large batches  
• 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
- **Laboratories** can run **larger batches** (thousands per day) than point-of-care.
- Preparation / analysis **depend on local regulations**
- Done by healthcare professionals on mobile units in **emergency wards, clinics and doctors’ offices**

Components / accessories

- **Upper respiratory tract** Swabs 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?

<table>
<thead>
<tr>
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<th>Detection</th>
<th>What these tests say</th>
<th>Why they are helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood samples (venous, capillary or serum)</td>
<td>Detect if person has developed antibodies</td>
<td>Detect previous contact with COVID-19</td>
<td>1. Provide important information on diffusion of infection for large portions of populations</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>2. Will play a major role in vaccine development, including monitoring pre / post vaccinal immunity</td>
</tr>
</tbody>
</table>

*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.*
**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**

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*MedTech Europe from diagnosis to cure*
### Molecular tests

- Detect presence of virus

| Sample collection | • Nasal / Nosopharyngal / throat swab or other different sample types (e.g. bronchoalveolar lavage fluid, saliva) |
| Detection         | • Zoom in on genetic signature of the virus (RNA) |
| What these tests say | • Detect current or recent COVID-19 infection |
| Why it is helpful | • Molecular tests are highly sensitive and specific |
| Where these tests are performed | • First sample taken anywhere |
| Components / accessories | • Upper respiratory tract swabs or other biological fluid collectors |

### Antigen tests

- Detect presence of virus

| Sample collection | • Nasal / Nosopharyngal / throat swab or other different sample types (e.g. bronchoalveolar lavage fluid, saliva) |
| Detection         | • Detect presence of proteins of the virus (antigens) |
| What these tests say | • Detect current COVID-19 infection |
| Why it is helpful | • Can be done from point of care to centralized testing in automated laboratories |
| Where these tests are performed | • First sample taken anywhere |
| Components / accessories | • upper respiratory tract swabs or other biological fluid collectors |

### Serology tests

- Detect immune response to virus

| Sample collection | • Blood samples (venous, capillary or serum) |
| Detection         | • Detect if person has developed antibodies |
| What these tests say | • Detect previous contact with COVID-19 |
| Why it is helpful | • Provide important information on diffusion of infection for large portions of populations |
| Where these tests are performed | • First sample taken anywhere |
| Components / accessories | • Lancet or blood sample collectors |

### Components / accessories

- 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
- Additional external reagent may be needed depending on platform (lab or point-of-care)
The tests are for different points of disease progression.
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.*
This presentation offers information on the types of diagnostic tests that exist to detect COVID-19: what they are and how they work.
For more information

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