# COVID-19 Diagnostics

## COVID-19 Diagnostics Are Tests Used to Detect Infection with the SARS-CoV-2 Virus

### Types of Diagnostic Tests

<table>
<thead>
<tr>
<th></th>
<th>Molecular test</th>
<th>Immunoassay</th>
<th>Non-disease specific tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How does it work?</strong></td>
<td>Detects the presence of viral genetic material in a sample</td>
<td>Detects the presence of anti-viral antibodies in a sample</td>
<td>Detects signs and symptoms of disease</td>
</tr>
<tr>
<td><strong>What technique is used?</strong></td>
<td>Usually based on a technique called polymerase chain reaction (PCR), which makes millions of copies of a specific section of the viral genome, amplifying small amounts to detectable levels</td>
<td>Usually based on a technique called enzyme-linked immunosorbent assay (ELISA), in which molecules attach to the antibodies or antigen in the sample and produce a detectable signal</td>
<td>Techniques include thermal scanning to identify people with a fever (higher than normal temperature) and computed tomography (CT) chest scans to distinguish from other chest infections</td>
</tr>
<tr>
<td><strong>Where does testing take place?</strong></td>
<td>Usually performed in a laboratory due to equipment requirements</td>
<td>May be laboratory based or performed at point of care, depending on test design</td>
<td>Usually performed outside of the laboratory, in clinic or at point of care, depending on equipment needs</td>
</tr>
<tr>
<td><strong>What is the most common use?</strong></td>
<td>Testing people suspected of having COVID-19</td>
<td>Assessing overall infection and immunity rates in a community</td>
<td>Screening/triage to identify candidates for further testing</td>
</tr>
<tr>
<td><strong>A positive result…</strong></td>
<td>Confirms a current SARS-CoV-2 infection</td>
<td>Indicates a recent or past infection, and could be used to screen for current infection (tests may not be reliable in early phase of infection)</td>
<td>Confirms a current SARS-CoV-2 infection or suggests a potential infection (depending on test design)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Confirms a current SARS-CoV-2 infection or suggests a potential infection (depending on test design)</td>
<td>Suggests a potential infection and indicates that further testing is needed</td>
</tr>
</tbody>
</table>
### SAMPLE TYPES
- Nasopharyngeal swabs are commonly taken for COVID-19 diagnostic testing
- Other sample types that may be tested include:
  - Sputum (if you are coughing it up)
  - Blood
  - Stool and/or urine
  - Bronchoalveolar lavage (fluid that has been used to wash the lungs)

### TESTING PROCEDURE
- Samples may be taken:
  - At home, by a visiting healthcare professional
  - At a drive-thru centre (where a nasopharyngeal swab is taken through your car window)
  - At a hospital or clinic
- Samples are then sent to a laboratory for testing
- It will usually take around 72 hours to receive a result

### SARS-COV-2 VERSUS OTHER CORONAVIRUSES
- SARS-CoV-2 is part of the coronavirus family
- Molecular tests for COVID-19 are based on genetic sequences from the SARS-CoV-2 viral genome
- Tests can use sequences that are unique to SARS-CoV-2 to distinguish from infections with other human coronaviruses
- There are currently two known strains of SARS-CoV-2, which are thought to have different infection rates and severity of disease
  - Tests can use sequences common to both strains to ensure that they can both be detected

### MOLECULAR TESTS
- Molecular tests are diagnostics that detect viral genetic material, usually performed in a laboratory
- A molecular test requires a number of basic ingredients:
  - The enzymes and short DNA sequences (known as primers) that copy the genetic material
  - The building blocks of DNA (nucleotides)
  - A buffer solution
  - The viral genetic material (if present), extracted from the sample using a separate kit
- The tests are run in a machine that uses repeated cycles of heating and cooling to drive the amplification of the viral genetic material until it reaches detectable levels

### ‘POINT OF CARE’ TESTS
- Point of care tests are diagnostics that can be performed outside of the laboratory
- They are required for wide-scale global testing
  - Some companies are attempting to develop ‘rapid diagnostic tests’, which are quick, inexpensive and easy to perform without laboratory facilities
    - Rapid diagnostic tests are often based on immunoassays
  - Some companies are adapting molecular tests for use in mobile laboratories

### COVID-19 DIAGNOSTIC TEST QUALITY
- Diagnostic tests are evaluated in validation studies to ensure that they are accurate and reliable
- Validation studies assess:
  - Sensitivity (ability to detect SARS-CoV-2 in samples known to be positive)
  - Specificity (ability to avoid falsely detecting SARS-CoV-2 in samples known to be negative)
- FIND is conducting independent evaluations of COVID-19 molecular tests and immunoassays, in collaboration with WHO and other partners
- Results from these studies will help governments and health authorities decide which tests are most suitable for use in their populations