Laboratory testing for COVID-19

World Health Organization
REGIONAL OFFICE FOR Africa

Target Audience

This technical guidance is intended for all professional staff involved in laboratory-based surveillance and response to COVID-19

Functions of laboratory during the COVID-19

- Establishing appropriate, accurate, and sustainable diagnostic testing capacities to respond to public health needs
- Ensuring surge capacity to process a large volume of specimens to cope with public health response needs
- Conducting virological monitoring of the pandemic at national, regional and global levels
- Ensuring timely release of laboratory results for diagnosis and patient care
- Collecting, analyzing, and reporting laboratory data and linking data with surveillance data to inform public health decision making and response activities
- Tracking the genetic evolution of COVID-19 and contributing to research and development of vaccines by characterization of viruses

Who should be tested

To be able to detect and treat patients and implement measures to stop transmission, the following persons should be tested:

Suspected COVID-19 cases based on established case definition

Contacts of confirmed cases focusing on those who have developed symptoms or been within 1 meter of the confirmed case

Those presenting with atypical pneumonia and influenza-like illness

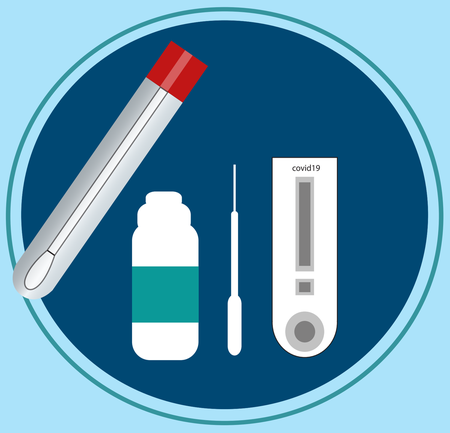
Tests to be used

There are several tests that can be used for epidemiological, clinical and research activities for COVID-19.

Tests are based on either direct or indirect detection of the virus.

- Direct detection of SARS-CoV-2 is the preferred way of detecting SARS-CoV-2 for clinical management and real-time reverse-transcription polymerase chain reaction (rRT-PCR) is the gold standard.
- Direct detection of viral antigens
- Antibody detection assays (serological testing)
- Viral sequencing to provide the pattern of virus transmission
- Virus culture, however this is not recommended as a routine diagnostic procedure

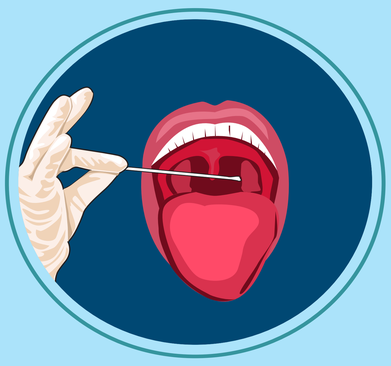
Selection approaches for diagnostic tests



Identify the purpose of the test such as confirmation of suspected cases during the outbreak response or case management outcomes.

- Identify manufacturers who produce materials that align with national technological capacity and needs
- Examine if the test has been approved at global, regional, or national level specifically the national committee for COVID-19 or a national regulatory authority
- Assess the test's performance and accuracy at national level
- Ensure quality assurance of the kit to better design the algorithms for diagnostics

Types of specimens to collect for testing



Respiratory samples have the greatest yield of virus. However, the virus can be detected in other specimens, including stool and blood. Respiratory material should be collected from:

- Upper respiratory specimens: nasopharyngeal or oropharyngeal swab or wash in ambulatory patients and/or
- Lower respiratory specimens: sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease

Preparation, storage, and trans-portation of collected samples

- Specimens should be correctly labelled and accompanied by a diagnostic request form
- Store specimens at 2-8°C for up to 72 hours after collection. If a delay (beyond this period) in testing or shipping is expected, store specimens at -20°C or ideally -70°C and shipped on dry ice if further delays are expected
- Correct handling of specimens during storage and transportation is essential
- Samples should be shipped to the lab without delay and should get to the lab within 24-48 hours
- Transport of specimens within national borders should comply with applicable national regulations
- In the laboratory, specimen should be processed in a certified in a certified Class II biological safety cabinet or primary contain device in a laboratory equivalent to Biosafety Level 2
- Appropriate disinfectants with proven activity against enveloped viruses should be used

Timing of the specimen collection for testing

Viral antigens and nucleic acid can be detected soon after infection and for as long as the virus is replicating in cells. Since antibodies to COVID-19 are not produced immediately after infection, antibody tests are best performed 7 or more days post symptom onset :

- IgM antibodies are produced first, and IgM indicates an active, acute infection and this antibody declines over time
- IgG is produced a little later, these antibodies are called convalescent antibodies and last for a longer time

Interpretations of results

An individual will be considered as a laboratory-confirmed COVID-19 positive case based on the national standard operating procedures delineating requirements/limits for tests to be positive in alignment with recognized standards. However:

- The national senior laboratory professional may adapt the interpretations of the result for better implementation public health control measures considering the national context and the epidemiological situation
- A "no regrets" policy approach could be used to classify cases using all available information including clinical picture, laboratory test results, epidemiological information and medical imaging results; and based on circumstances