
Data Science and Tech Innovation Community of Practice

# Purpose and Options for Testing for SARS-Cov2 (the COVID-19 virus):

## Considerations for World Bank Task Teams Managing COVID-19 Fast Track Facility Operations

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**Target audience for this Note:**

Task Teams engaged with clients in policy/ program dialogue, project design, and implementation support. This note is intended to serve a range of staff members, including those with professional training in health and generalists working on health. Therefore, it does not emphasize detailed technical specifications, as those are available on websites of specialized agencies. *References to those websites are provided at the end of this note*.

### 1. Context and Rationales for Testing for COVID-19

For clinical, epidemiological and response planning purposes, diagnostic tests for SARS-CoV-2 (the virus that causes Covid-19 disease) are an important part. Tests for SARS-CoV-2 can be used for different, and sometimes overlapping, purposes, such as:

- *To determine who is currently infected*
  - To provide a basis for isolation and infection prevention and control procedures
  - To enable contact tracing
  - To guide the clinical management of those with symptoms suggestive of COVID-19

- *To determine who has previously been infected*
  - To help build a more complete picture of epidemic course, attack rate, and fatality ratio
  - To help determine the full spectrum of disease severity (for example those with no symptoms or mild symptoms may not have been tested when they were infected)
  - To determine extent of immunity and how long immunity lasts
  - To guide social distancing strategies (for example those who are immune may be able to return to work)

- *For research and surveillance in virology, drug and vaccine development, clinical services, epidemiology, and public health*

## 2. How to evaluate the accuracy of a test or diagnostic examination: Sensitivity and Specificity

*Sensitivity* and *specificity* are the two indices used to evaluate the accuracy of a test. As shown in the table below:

- those testing positive who have the disease are called "true positives";
- those testing positive who **do not** have the disease are called "false positives";
- those testing negative who have the disease are called "false negatives"; and
- those testing negative who **do not** have the disease are called "true negatives.

| | *Is the disease present?* | |
|---|---|---|
| ***Type of Test*** | ***Yes*** | ***No*** |
| *Positive (indicates the disease is probably present)* | *A (true positive)* | *B (false positive)* |
| *Negative (indicates the disease is probably absent)* | *C (false negatives)* | *D (true negative)* |
| **TOTAL** | **A + C** | **B + D** |

**Sensitivity** = percent of those who have the disease and are so indicated by the test

- *Sensitivity (in percent) = (A/(A+C)) x 100*

**Specificity** = percent of those who **do not** have the disease and are so indicated by the test.

- *Specificity (in percent) = (D/(B+D)) x 100*

For all COVID-19 tests, sensitivity and specificity are both important, as they determine the extent to which the test results can be used to draw clinical and epidemiological conclusions, and to understand other evidence that might be needed.

## 3. Types of Tests Available for COVID-19 Pandemic

The field of testing for SARS-Cov2 is a rapidly evolving field. Nevertheless, there are currently two principal types of tests available, one that amplifies and detects genetic segments of the SARS-CoV-2 virus in respiratory specimens - using a technique called reverse transcription polymerase chain reaction (RT-PCR) - and one that detects the body's immunological response to infection (antibodies) in a blood sample (serological tests).

### a) RT-PCR (reverse transcriptase polymerase chain reaction) tests

***RT-PCR tests can determine who is currently infected*** *and as such can provide a basis for isolation and infection prevention and control procedures, enable contact tracing and guide the clinical management of those with symptoms suggestive of COVID-19.*

RT-PCR is typically very accurate and is generally considered the 'gold standard' of diagnostics. It has also been the primary testing method used worldwide as tests are very quick to develop; the first test protocol was developed two weeks after the viral genome sequence was released publicly and formed the basis of the first test kits that were distributed by WHO in January. PCR is a method used widely in molecular biology to make millions to billions of copies of a specific DNA sample rapidly, allowing scientists to take a very small sample of DNA and amplify it to a large enough amount to study in detail. Reverse transcriptase is a method that transforms RNA into DNA. Because RT-PCR tests (sometimes referred to in literature as 'swab tests') rely

on detecting the presence of genetic material of the virus, in this case the RNA of the SARS-COV-2 virus, it only identifies active infection and cannot identify prior infection in those recovered from COVID-19. As a respiratory tract infection, specimens from the respiratory tract (e.g. a nasal or throat swab or a specimen from the lower respiratory tract such as sputum or fluid from lung washings) are typically used for the SARS-Cov2 PCR test. While a positive result generally confirms diagnosis, a negative result does not exclude infection. False negatives are more likely to occur in early and late infection, with respiratory specimens obtained from the upper (nasal or oral swabs[1]) versus lower respiratory tract (sputum or fluid from lung washings)[2], and in asymptomatic or mild infection, due to lower detectable levels of virus. They can also occur due to technical errors. Data from Wuhan, China, suggest a false negative rate of 11-25% with sputum samples and 27-46% with nasal samples (Yang et al. 2020*).* If the initial test is negative in a person clinically suspected of having COVID-19, WHO recommends resampling and testing from multiple respiratory tract sites. Normal infection prevention and control precautions should continue and patients must still be advised to isolate. Efforts are ongoing to improve the accuracy of the tests. It is important to note that countries often use different case definitions of suspected cases (i.e. those they consider eligible for testing) and this has been largely driven by testing capacity.

While several countries have adapted the initial WHO protocol targeting different parts of SARS-CoV-2's genetic sequence, the RT-PCR test protocols are generally complex and expensive (e.g. $60 in India), mainly suited to large, centralized laboratories. It typically takes 4-6 hours for the test to be completed but with the shipment of samples the turnaround time is 24 hours at best. With the large demand for tests resulting in shortages of reagents and limited laboratory capacity and shipping logistics, turn-around times of several weeks have been reported in some areas. To help address this, companies have developed rapid RT-PCR tests that can be conducted in small machines at point of care or near care. These include platforms from Abbott, one from ThermoFisher and another from Cepheid, called the GenXpert platform. These platforms are physical devices located in a laboratory that has to adhere to specific standards. The most common PCR platform in low- and middle-income countries (LMIC) is the GenXpert platform. GenXpert is used for TB testing and HIV viral load testing. Because of the global HIV and TB response, there is an ample supply (sometimes even oversupply) of these devices especially in all the countries that receives development aid for HIV and TB programmes. Calibration of the GenXpert machine for the SARS-Cov2 test is a 15-minute process, done once. Although GenXpert is not typically available point of care in LMIC (i.e. in a facility where healthcare is provided, but rather in a laboratory), laboratory staff know how to use it, and are used to transporting sampling for TB testing. Because of this reason, GenXpert is currently the most feasible testing approach for Africa and South Asia. A SARS-Cov2 Assay by Cepheid currently costs $198 for 10 tests in LMIC ($360 in high income countries), though it is estimated that they could cost as low as $5[3]. Other testing approaches also exist – see attached in Annex 1.

b) **Antibody tests:**

***Antibody tests can determine who has ever been infected*** *and who may be immune to re-infection. This can be very helpful for guiding strategies for non-pharmaceutical interventions such as social distancing measures. Depending on the timing and accuracy of the test, they can potentially also identify who is currently infected.*

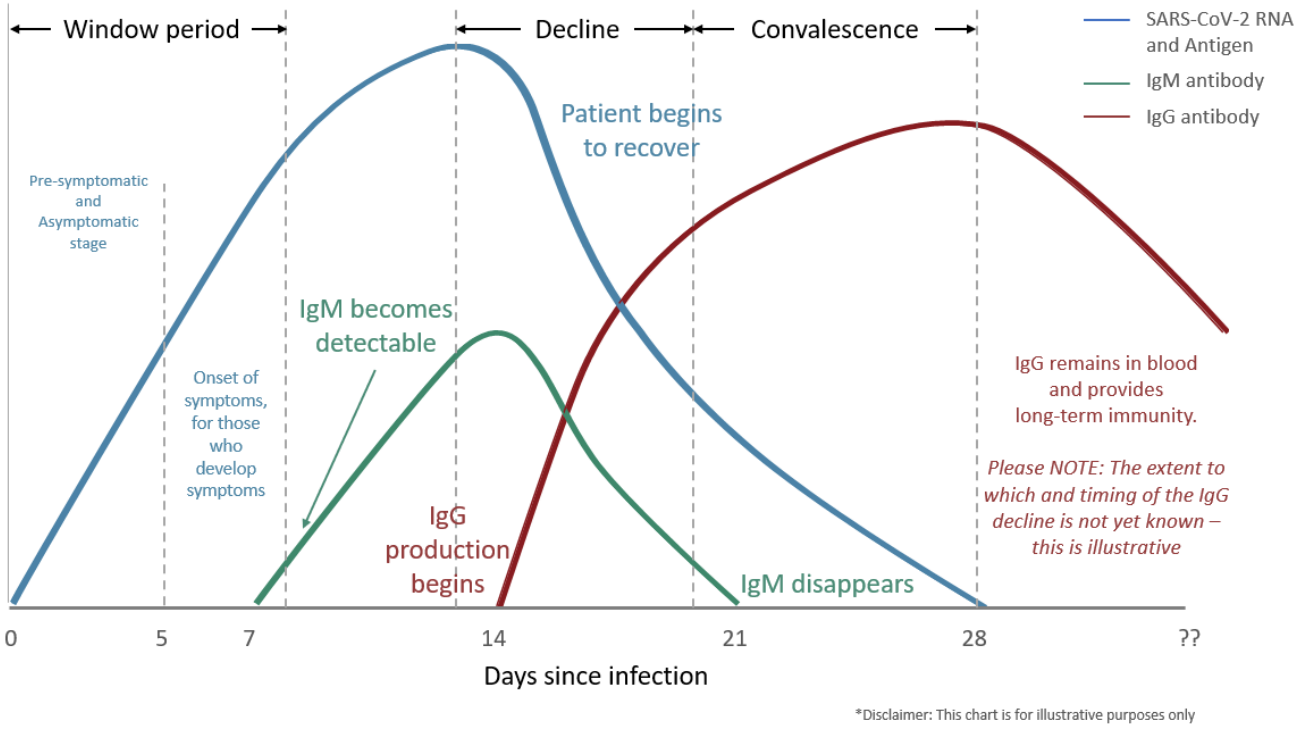
An antibody test is one that looks for evidence of the body's immune response to a virus, in this case SARS-Cov2. When someone gets infected with a virus their immune system must work out how to fight it off and

[1] For upper respiratory tract specimens, nasopharyngeal specimens are usually recommended as a minimum (though often people take both nasopharyngeal and oropharyngeal specimens)

[2] While positivity rate is generally higher for lower respiratory tract specimens, these specimens are typically more difficult to obtain. Not all patients have a productive cough and other specimens typically require a person to be intubated and/or more invasive procedures that are also riskier for the health care worker from an infection prevention control perspective.

[3] https://www.treatmentactiongroup.org/wp-content/uploads/2020/04/fair_pricing_webinar_slides_final.pdf

produce substances called antibodies. These are extremely specific and are usually only able to tackle one strain of one virus. For example, if someone has a SARS-Cov2 infection, they will develop anti-SARS-Cov2 antibodies. The body then stores versions of these antibodies in the immune system so that if it comes into contact with that same virus again it should be able to fight it off and probably avoid someone feeling any symptoms at all or only very minor symptoms. To test for these antibodies, a fluid sample (usually blood) is taken from a person and mixed with a reagent that contains part of the virus to see if there is a reaction between the two. If there is a reaction, it means that it is likely that someone has developed antibodies because they were previously infected or are currented infected. If there is no reaction it means they have not had it yet or that it is too early in the infection for the antibodies to have developed. While there are five kinds of antibodies, there are two principal ones linked to immune response that are of particular interest: Immunoglobulin M (IgM), which is the first antibody to appear and represents signs of recent infection, and Immunoglobulin G (IgG), which remains in the body after convalescence (recovery). The illustration below illustrates how this works – noting that the timings of antibody creation for COVID-19 are approximate and still subject to further research. In this discussion, it is important to note that a proportion of persons with COVID-19 infection clears the infection without showing any symptoms (asymptomatic) and some individuals take a few days before they show symptoms (pre-symptomatic).




**Benefits of and limitations with antibody tests**: With antibody tests, negative results do not rule out infection; antibodies might not have had enough time to form or the virus could have had a minor amino acid mutation in the epitope recognized by the antibodies screened for in the test. False positives can occur due to cross-reactivity with antibodies from previous infections, such as from other coronaviruses. As such, results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. But, antibody tests serve other purposes: they help determine whether someone has ever been infected (including for those that may have been asymptomatic and never tested during active infection) and therefore can help provide a more complete picture of the disease burden and fatality ratio. They may also help with assessment of the extent of immunity and how long immunity lasts. Also, if we knew the number of people who have recovered, strategies to ease the social distancing strategies could be planned with more precision, and it can help determine, for example, which health workers should work on the frontline of treating the highest risk patients.

| | RT-PCR | Antibody |
|---|---|---|
| **Purpose** | Primarily for clinical purposes | Primarily for epidemiological and programming purposes |
| **Kind of sample needed** | Swab typically (nasal and throat) or lower respiratory tract specimen when possible or appropriate (e.g. sputum or fluid from lung washings) | Drop of blood |
| **Can administer point of care?** | Yes, if conducted by a PCR device that is available at point of care (some devices are light enough to install at point of care) | Yes, while some methods are done in laboratories, some can work like a pregnancy test kit or A1C level determination – a simple finger prick |
| **Can administer in a self-test kit environment?** | No as it needs a PCR device. However, swabs can be self-administered including at home. | Yes, at home or point of care or in a surveillance setting |
| **How long it takes for the test to be administered** | It depends: some PCR tests can take several hours, and others can produce results in as early as 15 minutes | Many are rapid test kits and results are available immediately, without a 'device' (like a machine in a laboratory) needed. Some tests will be able to distinguish both IgM and IgG, giving a signal as to the age of the infection. |
| **Cost** | Wide range for laboratory based RT-PCR but typically $50+. Rapid near-care test around $20 in LMIC. | Inexpensive. As little as $3 |

The different test kits and their purposes in the scope of scaling up a country is summarized below:

| **Test results** | | | **Clinical significance** |
|---|---|---|---|
| PCR | IgM | IgG | |
| + | - | - | Patient may be in the window period of infection |
| + | + | - | Patient may be in the early stage of infection |
| + | + | + | Patient is in the active phase of infection |
| + | - | + | Patient may be in the late or recurrent stage of infection |
| - | + | - | Patient may be in the early stage of infection. PCR result may be false-negative. Antibody test could be false positive |
| - | - | + | Patient may have had a past infection, and has recovered or antibody test could be false positive |
| - | + | + | Patient may be in the recovery stage of an infection, or the PCR result may be false-negative. Antibody test could also be false positive. |

Source: https://www.medscape.com/viewarticle/928150

**Other diagnostic options:** While viral culture is currently not recommended for safety reasons, testing for **SARS-COV-2 viral load** using PCR may be a promising strategy for the future to help determine prognosis (patients with higher viral load typically have or will develop more severe disease). Radiological imaging (Chest X-ray but especially Chest CT where available, with potential for these to be read by AI) may be helpful in making the diagnosis, but no finding can completely rule in or rule out the possibility of COVID-19. Classic signs of CV-induced pneumonia are described as 'ground glass' opacification. Other testing approaches are

also being considered and reviewed by scientists. For example, CRISPR diagnostic methods that work in a similar way to RT-PCR in that they can identify segments of the virus are in the pipeline.

**4. Procurement of test kits and related laboratory paraphernalia**

Test kits can be procured by countries through the WHO, UNICEF, or the Global Drug Facility (GDF). A specific point to note about using the Cepheid SARS-Cov2 tests on the GeneXpert platform: The GDF also enables the procurement of the biosafety level II storage devices, which is needed when the GeneXpert machines are used for COVID-19 testing. It was confirmed that the GDF that will include cartridges for rapid testing of COVID-19 in their catalogue of medicines available to the public sector. LMICs that already procure supplies through the GDF will have quicker and more equitable access to COVID-19 test kits. There are more than 23,000 automated GeneXpert® Systems worldwide. The use of GeneXpert was welcomed by the TB community but with 2 caveats: (a) to avoid cross contamination, it is recommended that GeneXpert machines be dedicated to COVID-19 testing only; and b) the use of GeneXpert for COVID-19 testing should not interrupt the TB testing, which is also necessary and should continue. A solid supply chain of both kinds of tests should be maintained. See Annex B for a detailed write up about GeneXpert's use for COVID-19 testing.

**5. Helping countries decide which test kits to use**

WHO manages a Diagnostics Supply Consortium, in which the WB is represented. For normative guidance on diagnostics, the local WHO representative should be contacted for advice, or you can contact Zara Shubber (zshubber@worldbank.org. That said, WB task teams can help countries ask the right questions. Decisions about testing:

a) Purpose of testing – for clinical or epidemiological and programming purposes
b) Laboratory capacity and logistics of laboratory supplies
c) Volume and kind of PCR machines already available in the country
d) Physical location of the PCR machines
e) Donated test kits available
f) Test kits available through the different pooled procurements
g) Test kit approval status – test kits not pre qualified by WHO requires a 2nd sample to be taken and sent to a WHO reference laboratory before the case will be noted as a confirmed case by WHO
h) Any other advice from WHO

In summary, there are different tests available for COVID-19 diagnostics, each with their benefits and limitations. Task teams are encouraged to consider these benefits and limitations along with the country objectives and realities on the ground.

For more information and the latest updates on laboratory testing for COVID-19 infection, please refer to:

- **Coronavirus disease (COVID-19) technical guidance**: Laboratory testing for 2019-nCoV in humans. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

- **CDC Tests for COVID-19**. https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html

# Annex A: Test Kit Options from WHO Diagnostics Consortium

| Manufacturer | Type of Test | Technical Notes | Sample Collection Type | Test Target | Test Designation (Lab or RDT) | Country Approved (incl EUAs) | CE Certified | Source |
|---|---|---|---|---|---|---|---|---|
| CDC | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Wadsworth Center, NYSDOH | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Roche cobas | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | CE mark | FDA Website |
| Thermo Fisher Scientific, Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | CE mark | FDA Website |
| Hologic, Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Laboratory Corporation of America | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Quidel Corp. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Quest Diagnostics Infectious Disease, Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Abbott Molecular | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| DiaSorin Molecular LLC | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| GenMark Diagnostics, Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Primerdesign Ltd | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Cepheid (Point of care test) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider does not need to be sent to lab | Swab of nose and throat | Viral RNA | Lab test | USA | CE Mark | FDA Website |
| BioFire Defense, LLC | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Mesa Biotech Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| PerkinElmer, Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | USA | | FDA Website |
| Roche Molecular Systems Inc. | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |
| ThermoFisher Scientific | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | CE Mark | Government of Canada Website |
| Luminarie Canada Inc. (SK) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |
| Diagnostic Hybrids, Inc. (US) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |
| Hangzhou Alltest Biotech Co., Ltd. (China) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |
| Life Sciences Research Institute (South Korea) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |
| Hologic (United States) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab test | Canada | | Government of Canada Website |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cepheid (United States) | Lab and POC based PCR | Lab based test to be collected by trained professional. POC means at point of care including doctor's office | Swab of nose and throat | Viral RNA | Lab test and POC | Canada | Government of Canada Website |
| Hangzhou Alltest Biotech Co Ltd (China) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Government of Canada Website |
| AusDiagnostics Pty Ltd (Australia) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Government of Canada Website |
| Roche Molecular Systems Inc (USA) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Government of Canada Website |
| VivaCheck Biotech (Hangzhou) Co Ltd (China) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Government of Canada Website |
| Shanghai ZJ Bio-Tech Co Ltd (China) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Government of Canada Website |
| CTK Biotech Inc (USA) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Government of Canada Website<br>Australian Government Health Department |
| Hologic Inc (USA) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | |
| Guangzhou Wondfo Biotech Co Ltd (China) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Australian Government Health Department |
| Life Technologies Corporation (USA) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Australian Government Health Department |
| CerTest Biotec SL (Spain) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Australian Government Health Department |
| VivaChek Biotech (Hangzhou) Co Ltd (China) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Australian Government Health Department |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Guangzhou Wondfo Biotech Co Ltd (China) | Lateral Flow IgG/IgM | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Australia | Australian Government Health Department |
| Cepheid (USA) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Australia | Australian Government Health Department |
| kogenebiotech (South Korea) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | South Korea | Sheet Provided |
| Seegene (South Korea) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | South Korea | Sheet Provided |
| SolGent Co.,Ltd. (South Korea) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | South Korea | Sheet Provided |
| SD BIOSENSOR (South Korea) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | South Korea | Sheet Provided |
| BioSewoom Inc. (South Korea) | Nucleic Acid Test | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | South Korea | Sheet Provided |
| Diagnostics Development Hub (DxD) (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| Veredus Laboratories Pte Ltd (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| AITbiotech Pte Ltd (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| DSO National Laboratories (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| Roche Diagnostics Asia Pacific Pte Ltd | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| JN Medsys Pte Ltd (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| Life Technologies Holdings Pte Ltd (Singapore) | Real-Time RT-PCR Diagnostic Panel | Lab test. Taken by trained provider | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| Everest Links Pte Ltd (Singapore) | IgM/IgG Rapid Test | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Singapore | Singapore Health Science Authority Website |
| Biolidics Limited (Singapore) | IgG/IgM Detection Kit | lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies | Blood | Antibody Test | Rapid Diagnostic | Singapore | Singapore Health Science Authority Website |

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|---|---|---|---|---|---|---|---|
| Biowalker Pte Ltd (Singapore) | Isothermal Amplification-Real Time Fluorescence Assay | Loop-mediated isothermal amplification (LAMP) is a method that can amplify DNA under isothermal conditions. Helps avoid false-positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| SPD Scientific Pte Ltd (Singapore) | Real-Time RT-PCR Diagnostic Panel | Subject to false positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | Singapore | Singapore Health Science Authority Website |
| Shanghai Liferiver Bio-Tech (United States) Corp | Real-Time RT-PCR Diagnostic Panel | Subject to false positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Shanghai GeneoDx Biotech Co., Ltd. | Real-Time RT-PCR Diagnostic Panel | Subject to false positives | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| BGI Tech (Wuhan) Co., Ltd. | cPAS, combinatorial probe-anchor synthesis sequencing method | Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| BGI Tech (Wuhan) Co., Ltd. | fluorescent PCR method | Subject to false positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Da An Gene Co., Ltd. | fluorescent PCR method | Subject to false positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Sansure Biotech | fluorescent PCR method | Subject to false positives Lab test. Taken by trained provider. | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Shanghai BioGerm | fluorescent PCR method | Subject to false positives | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Guangzhou Wondfo Biotech Co., Ltd. | Antibody Test Kit (Colloidal gold method) | Ten-minute lateral flow immunoassay that detects IgM and IgG antibodies directed against SARS-CoV-2 | Blood | Antibody Test | Rapid Diagnostic | China | |
| Innovita (Tangshan) Biotech Co., Ltd. | Antibody Test Kit (Colloidal gold method) | Ten-minute lateral flow immunoassay that detects IgM and IgG antibodies directed against SARS-CoV-3 | Blood | Antibody Test | Rapid Diagnostic | China | |
| Chengdu Capital Biotech Co., Ltd. | Virus Nucleic Acid Detection Kit (isothermal amplification chip method) | PCR | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Beijing X-ABT Biotech Co., Ltd. | fluorescent PCR method | PCR | Swab of nose and throat | Viral RNA | Lab diagnostic test | China | |
| Bioscience (Chongqing) Biotech Co., Ltd. | IgM Antibody Test Kit（magnetic particle chemiluminescence method） | Most effective for accute infection | Blood | Antibody Test | Rapid Diagnostic | China | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Bioscience (Chongqing) Biotech Co., Ltd. | IgG Antibody Test Kit（magnetic particle chemiluminescence method） | Can show if ever exposed Lab test. Taken by trained provider. | Blood | Antibody Test | Rapid Diagnostic | China |
| Maccura Biotech Co., Ltd. | fluorescent PCR method | Subject to false positives | Swab of nose and throat | Viral RNA | Lab diagnostic test | China |
| Xiamen InnoDx Biotech Co., Ltd. | Antibody Test Kit（CLIA method） | Antibody test kit with flourescence | Blood | Antibody Test | Rapid Diagnostic | China |
| Guangdong Hecin Biotech Co., Ltd. | IgM Antibody Test Kit（colloidal gold method） | Ten-minute lateral flow immunoassay that detects IgM and IgG antibodies directed against SARS-CoV-3 Lab test. Taken by trained provider. | Blood | Antibody Test | Rapid Diagnostic | China |
| Wuhan Easy Diagnosis Biomedicine Co., Ltd. | PCR Kit (fluorescent PCR method) | Subject to false positives | Swab of nose and throat | Viral RNA | Lab diagnostic test | China |
| Nanjing Vazyme Biotech Co., Ltd. | IgM/IgG Antibody Test Kit （colloidal gold method） | Ten-minute lateral flow immunoassay that detects IgM and IgG antibodies directed against SARS-CoV-3 | Blood | Antibody Test | Rapid Diagnostic | China |
| Zhuhai Livzon Pharmaceutical Group Inc. | IgM/IgG Antibody Test Kit （colloidal gold method） | Ten-minute lateral flow immunoassay that detects IgM and IgG antibodies directed against SARS-CoV-3 | Blood | Antibody Test | Rapid Diagnostic | China |
| CERTEST BIOTEC SL - SPAIN Equipamentos Hospitales LTDA - CNPJ | VIASURE SARS-CoV-2 Real-Time PCR Detection Kit | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| GUANGZHOU WONDFO BIOTECH CO., LTD. - CHINA, PEOPLE'S REPUBLIC CELER BIOTECNOLOGIA S / A | One Step COVID-2019 Test | IgM/IgG antibody test | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| GUANGZHOU WONDFO BIOTECH CO., LTD - CHINA, PEOPLE'S REPUBLIC DIAGNÓSTICA INDÚSTRIA E COMÉRCIO LTDA - ME | IgM/IgG antibody test | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| EBRAM PRODUTOS LABORATORIAIS LTDA - BRAZIL EBRAM PRODUTOS LABORATORIAIS LTDA | IgG / IgM | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| Eco Diagnostica Ltda - BRAZIL Eco Diagnostica Ltda | ECO F COVID-19 Ag | Ag | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | Brazil |
| Eco Diagnostica Ltda - BRAZIL Eco Diagnostica Ltda | IgG / IgM ECO Test | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| Eco Diagnostica Ltda - BRAZIL Eco Diagnostica Ltda | Ag ECO Test | | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | Brazil |
| LABTEST DIAGNOSTICA S / A - BRAZIL LABTEST DIAGNOSTICA S / A | IgG / IgM Rapid Test | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| HANGZHOU BIOTEST BIOTECH CO., LTD. - CHINA, PEOPLE'S REPUBLIC LUMIRADX HEALTHCARE LTDA | LUMIRATEK COVID-19 (IgG / IgM) | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| HANGZHOU BIOTEST BIOTECH CO., LTD. - CHINA, PEOPLE'S REPUBLIC MEDLEVENSOHN COMÉRCIO E REPRESENTAÇÕES DE PRODUTOS HOSPITALARES LTDA | MedTest Coronavirus (COVID-19) IgG / IgM | | Blood | Antibody Test | Rapid Diagnostic | Brazil |
| MOBIUS LIFE SCIENCE INDÚSTRIA E COMERCIO DE PRODUTOS PARA LABORATÓRIOS LTDA - BRAZIL | FAMILY KIT XGEN MASTER COVID-19 - Master Kit for Detection of the SARS-CoV-2 Coronavirus RT-qPCR | | Swab of nose and throat | Viral RNA | Lab diagnostic test | Brazil |
| ORANGELIFE COMÉRCIO E INDÚSTRIA LTDA - BRAZI | DPP® COVID-19 IgM / IgG System | | Blood | Antibody Test | Rapid Diagnostic | Brazil |

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|---|---|---|---|---|---|---|---|---|
| ACRO BIOTECH INC. - USA QR Consulting, Import and Distribution of Medical Products Ltda | Family Rapid Test Cassette 2019-nCoV IgG / IgM (whole blood / serum / plasma) | | Blood | Antibody Test | Rapid Diagnostic | Brazil | | |
| ROCHE MOLECULAR SYSTEMS, INC. - USA | Cobas family SARS-CoV-2 | PCR Test | Swab of nose and throat | Viral RNA | Lab diagnostic test and Point of Care | Brazil | | |
| SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO., LTD (SNIBE) - CHINA, PEOPLE'S REPUBLIC VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA | IgG-nCoV (CLIA) | | Blood | Antibody Test | Rapid Diagnostic | Brazil | | |
| SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO., LTD (SNIBE) - CHINA, PEOPLE'S REPUBLIC VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA | IgM-nCoV (CLIA) | | Blood | Antibody Test | Rapid Diagnostic | Brazil | | |
| VYTTRA DIAGNOSTICOS IMPORTACAO E EXPORTACAO SA - BRAZIL | Covid-19 Vyttra Smart Test | | Blood to Serum | Antibody Test | Rapid Diagnostic | Brazil | | |
| Viasure Sars-CoV-2 real time PCR detection kit, developed under a partnership between Becton Dickinson and the much smaller group Certest Biotec. | Real-Time PCR assay | PCR | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Novacyt (British-French) | Real-Time PCR assay | PCR | Swab of nose and throat | Viral RNA | Lab Test | Emergency authorization in US and will make in UK | CE Mark | News |
| Co-Diagnostics (Utah, USA) | Real-Time PCR assay | PCR | Swab of nose and throat | Viral RNA | Lab Test | USA | CE Mark | News |
| 1drop Inc | qPCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| AB Analitica | Nucleic Acid Test | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Beijing Applied Biological Technologies Co. Lts | Multiple Real-Time PCR | Lab and POC | Swab of nose and throat | Viral RNA | Lab Test and POC | | CE Mark | |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | Nucleic Acid Test | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Cancer Rop Co., Ltd. | RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Chaozhou Hybribio Biochemistry Ltd., | RT-PCR manual & automated lab-based | manual & automated lab-based | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Clonit | | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| CTK Biotech, Inc. | RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Daan Gene Co., Ltd. of Sun Yat-sen University | Real Time Multiplex RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Edinburgh Genetics Limited | RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Eurobio Scientific | Real Time Multiplex RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Gencurix Inc. | Nucleic acid test | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Getein Biotech, Inc. | RT-PCR Kit | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| KH Medical Co. Ltd, | Real Time Multiplex RT-PCR? | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| KogeneBiotech Co. Ltd | RT-PCR Kit | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Liferiver | Real Time Multiplex RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Liming Bio-Products Co. | Real Time Multiplex RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |
| Nanjing Vazyme Medical Technology Co., LTD. | Triplex RT-qPCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | | CE Mark | |

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| Novacyt/Primerdesign Ltd | RT-PCR Kit | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| PerkinElmer Inc. | RT-PCR Kit | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Sansure Biotech, Inc. | PCR-Fluorescence Probing | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| SD BIOSENSOR Inc. | RT-PCR Kit | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Shaanxi Lifegen Co., Ltd. | fluorescent PCR method | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Shenzhen Puruikang Biotech Co., Ltd | RT-PCR-Fluorescence Probing | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Shenzhen Tailored Medical Ltd | PCR-Fluorescent Probe Method | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Vircell, S.L. | RT-PCR | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Wuhan Easydiagnosis Biomedicine Co., Ltd | Nucleic acid test | Lab | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| 3D Medicine Science & Technology Co., Ltd. | RT-qPCR | Automated lab-based, near-POC NAT or POC NAT | Swab of nose and throat | Viral RNA | Lab Test or POC | CE Mark |
| AITbiotech | qPCR | lab based | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Anatolia Geneworks | | lab based | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Bai-care | Multiplex Nucleic Acid Detection Kit for Respiratory Pathogens | | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| Beijing Microread Genetics Co.,Ltd, | | lab-based or near-POC | Swab of nose and throat | Viral RNA | Lab Test or POC | CE Mark |
| BIONEER Corporation | RT-PCR | lab based automated kit | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| CerTest Biotec, S.L. | RT-PCR | | Swab of nose and throat | Viral RNA | Lab Test | CE Mark |
| QIAGEN GmbH | | lab-based or near-POC | Swab of nose and throat | Viral RNA | Lab Test or POC | CE Mark |
| Beijing Savant Biotechnology Co., Ltd. | Antigen Fluorescence Rapid Detection Kit | | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Epitope Diagnostics, Inc. | IgG ELISA Kit | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Epitope Diagnostics, Inc. | IgM ELISA Kit | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| EUROIMMUN AG | ELISA (IgA) | (manual; automated; CE-IVD) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| EUROIMMUN AG | ELISA (IgG) | (manual; automated; CE-IVD) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Liming Bio-Products Co., Ltd | Antigen Rapid Test Device | | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| LOMINA AG. | IgM/IgG Antibody Fast Detection Kit | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| SD BIOSENSOR, Inc. | Ag FIA (manual | | Swab of nose and throat | Antigen | Rapid Diagnostic | CE Mark |
| Shenzhen Yhlo Biotech Co. Ltd | IgM antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Shenzhen Yhlo Biotech Co. Ltd | IgG antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgM/IgG antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgM antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgG antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Taizhou ZECEN Biotech Co. | IgM antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Taizhou ZECEN Biotech Co. | IgG antibody test | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| AmonMed Biotechnology Co., Ltd. | IgM/IgG test kit (Rare Earth Nano Fluorescence Immunochromatography) | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| AmonMed Biotechnology Co., Ltd. | IgM/IgG test kit (Colloidal Gold) | | Blood | Antibody Test | Rapid Diagnostic | CE Mark |

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| AmonMed Biotechnology Co., Ltd. | COVID-19/Influenza A virus/Influenza B virus IgM combo test kit (Rare Earth Nano Fluorescence Immunochromatography) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| AmonMed Biotechnology Co., Ltd. | COVID-19/Influenza A virus/Influenza B virus test kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| AmonMed Biotechnology Co., Ltd. | COVID-19 Antigen Test Kit | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Beijing Abace Biology Co., Ltd | COVID-19 Antibody (IgG/IgM)Test Kit (Colloidal Gold Immunochromatography) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Diagreat Biotechnologies Co., Ltd. | IgG Antibody Determination Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Diagreat Biotechnologies Co., Ltd. | IgM Antibody Determination Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | IgM ELISA Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | IgG ELISA Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | IgG/IgM Fluorescence Rapid Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | Antigen ELISA Test Kit (Nasal/Throat Swab) | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Beijing Kewei Clinical Diagnostic Reagent Inc. | Antigen Fluorescence Rapid Test Kit (Nasal/Throat Swab) | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Beijing Tigsun Diagnostics Co.,Ltd. | Combo IgM/IgG Rapid Test (Lateral Flow Method) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| BIOMAXIMA S.A. | IgG/IgM Rapid Test Cassette | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| BioMedomics, Inc. | COVID-19 IgM-IgG Dual Antibody Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Cellex, Inc. | Cellex qSARS-CoV-2 IgGIgM Cassette Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Changsha Sinocare Inc. | Antibody Test Strip (Colloidal Gold Method) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Core Technology Co., Ltd. | IgM/IgG Ab Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| CTK Biotech, Inc. | IgG/IgM Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Dynamiker Biotechnology (Tianjin) Co., Ltd. | IgG/IgM Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Edinburgh Genetics Limited | novel coronavirus antibody detection reagent (Colloidal gold) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| GenBody, Inc. | IgM/IgG | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| GenBody, Inc. | IgM/IgG DUO | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Getein Biotech, Inc. | IgM/IgG antibody (Colloidal Gold) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Hanghzhou AllTest Biotech Co., Ltd | IgG/IgM Detection Kit (Colloidal Gold) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Innovita Biological Technology Co. Ltd | Ab Test (Colloidal Gold) (IgM/IgG Whole Blood/Serum/Plasma Combo) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Jiangsu Bioperfectus Technologies Co. Ltd | Ag Rapid Test Kit | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Jiangsu Bioperfectus Technologies Co. Ltd | IgM/IgG Rapid Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Liming Bio-Products Co., Ltd | COVID-19 IgG/IgM Combo Rapid Test Device | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| MedicalSystem Biotechnology Co., Ltd. | IgM/IgG Rapid Test Cassette | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Nantong Egens Biotechnology Co., LTD | IgG/IgM Rapid Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| PerGrande BioTech Development Co., Ltd. | Antibody Detection Kit (Colloidal Gold Immunochromatographic assay) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| RayBiotech | Coronavirus (SARS-CoV-2) IgM/IgG Test Kit (Colloidal Gold) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| SD BIOSENSOR, Inc. | STANDARD Q COVID-19 IgM/IgG Duo Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| SD BIOSENSOR, Inc. | STANDARD Q COVID-19 Ag Test | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| SensingSelf, Pte, Ltd, Singapore, | Rapid Test Kit (IgM/IgG) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |

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| Shanghai Chemtron Biotech Co. Ltd. | IgM Antibody Diagnostic Kit (Colloidal gold) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Shenzhen Bioeasy Biotechnology Co., Ltd. | Fluorescence Antigen Rapid Test | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Shenzhen Bioeasy Biotechnology Co., Ltd. | Colloidal Gold Antigen Rapid Test | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Shenzhen Bioeasy Biotechnology Co., Ltd. | IgG/IgM detection kit (colloidal gold immunochromatography) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Shenzhen Bioeasy Biotechnology Co., Ltd. | Ag Fluorescence Rapid Test Kit (Time-Resolved Fluorescence) | Swab of nose and throat | Viral Antigen | Rapid Diagnostic | CE Mark |
| Shenzhen Tailored Medical Ltd. | IgM/IgG Antibody Assay Kit (Colloidal Gold Method) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgM/IgG | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgM | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sugentech, Inc. | IgG | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sure Bio-Tech (USA) Co., Ltd. | IgM Ab Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sure Bio-Tech (USA) Co., Ltd. | IgG Ab Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Sure Bio-Tech (USA) Co., Ltd. | IgM/IgG Ab Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Tianjin MNCHIP Technologies Co., Ltd. | IgM/IgG rapid test kit (Colloidal gold assay) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| VivaChek Biotech (Hangzhou) Co., Ltd | VivaDiag COVID-19 IgM/IgG Rapid Test | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Wuhan EasyDiagnosis Biomedicine Co.,Ltd | IgM antibody test kit (colloidal gold method) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Wuhan EasyDiagnosis Biomedicine Co.,Ltd | IgG antibody test kit (colloidal gold method) | Blood | Antibody Test | Rapid Diagnostic | CE Mark |
| Xiamen Biotime Biotechnology Co., Ltd. | IgG/IgM Rapid Qualitative Test Kit | Blood | Antibody Test | Rapid Diagnostic | CE Mark |

# Annex B: The Use of GeneXpert

World Health Organization
REGIONAL OFFICE FOR Europe

# Rapid communication on the role of the GeneXpert® platform for rapid molecular testing for SARS-CoV-2 in the WHO European Region

**European Laboratory Initiative on TB, HIV and Viral Hepatitis**

**1 April 2020**

## Abstract

In view of the current COVID-19 pandemic and consequent need for automated rapid diagnostic technologies with a rapid turnaround time, the European Laboratory Initiative on TB, HIV and Viral Hepatitis (ELI) has developed this rapid communication to inform Member States of the WHO European Region on the potential use of the Xpert® Xpress SARS-CoV-2 cartridge (Cepheid, Sunnyvale, United States of America). These cartridges, which received Emergency Use Authorization from the United States Food and Drug Administration on 20 March 2020, can be run on GeneXpert® platforms that are already available in the Region and currently used for diagnosis of tuberculosis and rifampicin resistance (as recommended by WHO), hepatitis C and seasonal influenza, and for HIV viral load testing and early infant diagnosis of HIV infection. Based on the best available evidence and current knowledge, this rapid communication by ELI provides a short overview of (i) the major points when considering the use of GeneXpert machines for COVID-19 testing and (ii) the support that ELI is working to provide to Member States of the Region.

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Rapid communication on the role of the GeneXpert® platform for rapid molecular testing for SARS-CoV-2 in the WHO European Region



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## Background

On 30 January 2020 WHO declared coronavirus disease 2019 (COVID-19) a public health emergency of international concern, and on 11 March declared it as a global pandemic. From the onset of this public health crisis, the need for rapid and accurate laboratory testing was highlighted, and laboratory scientists responded by developing the first diagnostic tests for COVID-19 within days of the release of the viral genome sequence.

The WHO European Region is currently the epicentre of the COVID-19 outbreak, with the disease reportedly most prevalent in the western part of the Region; however, this information needs to be carefully interpreted because countries are in different stages of disease transmission and the lower numbers reported in some eastern European countries may be due to the lack of available diagnostic services. All countries need to plan ahead to ensure sufficient diagnostic capacity, as outlined in the WHO guidance document, Laboratory testing strategy recommendations for COVID-19.[1]

In this context, one of the key questions faced by countries is which diagnostic assay(s) to adopt to meet the demand for the four transmission scenarios identified by WHO *(1,2)*. Serological or rapid antigen tests are currently not recommended by WHO for COVID-19 case detection: instead, nucleic acid amplification tests should be used. However, this guidance may change based on the availability of new serological tests *(1)*. An overview of tests under development can be found on the FIND website *(3)*. Some have already received Emergency Use Authorization by the United States Food and Drug Administration (FDA) and/or are CE-IVD marked[2] for diagnostic use in the European Union. WHO is continuously updating technical guidance for COVID-19, including recommendations on laboratory testing *(2)*. No comprehensive comparison of the performance of rapid diagnostic has been performed to date, although several evaluations are ongoing or planned *(5)*. For the time being, the following logistic and financial factors, among other factors, can be weighed to inform the choice of nucleic acid amplification test: turnaround time, throughput (i.e. number of tests that can be run simultaneously in one round), degree of automation, supply considerations and cost (list not exhaustive).

## Key updates and considerations

### COVID-19 testing with the Xpert® Xpress SARS-CoV-2 cartridge

In view of FDA Emergency Use Authorization of the Xpert® Xpress SARS-CoV-2 cartridge (Cepheid, Sunnyvale, United States of America) *(6,7)* on 20 March 2020, one option for COVID-19 testing may be to leverage the spare capacity of existing GeneXpert® machines. Possible advantages of this approach are that the assay is fully automated and provides results within

[1] For the latest update, please check the following version of the document, Laboratory testing strategy recommendations for COVID-19. Interim guidance: 22 March 2020 *(1)*.

[2] CE marking is required for all in vitro diagnostic (IVD) devices sold in Europe. It indicates that an IVD device complies with the European In-Vitro Diagnostic Devices Directive (98/79/EC) and that the device may be legally commercialized in the European Union *(4)*.

45 minutes. Laboratory staff may be already familiar with the GeneXpert® platform, given that the Xpert® MTB/RIF assay serves as the primary diagnostic assay for tuberculosis (TB) and its drug-resistant forms in eastern and central European countries in accordance with WHO recommendations *(8)*. Therefore, the possibility of applying GeneXpert® platforms can be considered providing cartridge production capacity and cost are optimal. However, it is important to note that according to WHO guidelines and recommendations GeneXpert®-based COVID-19 testing should not be used outside of laboratories with adequate containment practices, which may diminish the value of the rapid turnaround time in the absence of efficient sample transport/logistics *(9)*. Moreover, the WHO Emergency Use Listing procedure is ongoing (timeline for completion is not yet known) *(10,11)* and there is a possibility that the cartridge will not be endorsed or will be reserved only for narrow applications. Moreover, the throughput of Xpert® Xpress SARS-CoV-2 is limited (e.g. in a machine with four modules, only four tests can be done with a turnaround time of 45 minutes). Assuming one test is performed per module per hour and a 24-hour working pattern, the total theoretical capacity of 10 GeneXpert® machines with four modules would be approximately 960 samples per day. Crucially, however, the spare testing capacity is likely to be considerably lower.

Taken together, this means that although Xpert® Xpress SARS-CoV-2 is a potentially promising option for testing a limited number of samples (e.g. from patients in intensive care units or from health-care workers with the highest public health priority), it is probably not the optimal solution for the vast majority of samples, particularly in settings with large outbreaks. The Xpert® Xpress SARS-CoV-2 cartridge is probably best suited to complement a wider testing strategy that primarily relies on one or more higher throughput assays. Indeed, the latter strategy has been adopted by all countries that have or are currently experiencing large-scale disease transmission. In this context, it should be noted that no single high-throughput assay is considered optimal. Countries must assess the capacity of existing platforms, taking into account the aforementioned considerations for Xpert® Xpress SARS-CoV-2, to decide which assay(s) to select.

### Testing for COVID-19 and TB

On 20 March 2020 the WHO Global TB Programme circulated an information note on TB and the COVID-19 response stating that, on a programmatic level, countries would need to develop targeted strategies for COVID-19 testing in TB patients, including those with previous disease *(12)*. It also points out that testing for TB in individuals presenting for COVID-19 testing is becoming necessary, as is COVID-19 testing among individuals presenting to TB services with respiratory signs and symptoms.

## Next steps

While awaiting additional regional and national approval for Xpert® Xpress SARS-CoV-2, as well as production of the first cartridges, core group members of the European Laboratory Initiative on TB, HIV and Viral Hepatitis (ELI) will focus on the following major areas to provide further

clarification and to support the WHO European Region with materials to be ready once this test becomes available in countries (in order of priority):

- identify and share the list of supplies that will be needed to run the test (e.g. viral transport tube, swabs);
- provide standard operating procedures in English and Russian;
- develop technical support materials to help countries rationalize their laboratory network and use the existing GeneXpert® machines for the maximal COVID-19 response without compromising their use for TB, HIV and viral hepatitis;
- provide remote or in-country support:
  - on necessary biosafety measures and considerations;
  - on workflow organization for GeneXpert® machines that will be used for several diseases (i.e. TB, HIV/viral hepatitis and COVID-19);
  - for sample transportation;
  - on data management tools (e.g. GxAlert) and laboratory record and report forms; and
  - for integration of rapid diagnostic tests into the overall diagnostic algorithms and testing strategies.

## Acknowledgements

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**The WHO Regional Office for Europe**

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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