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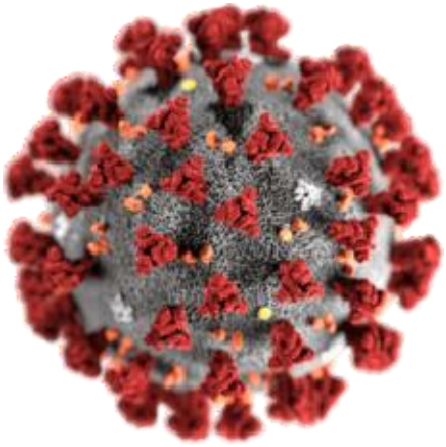

COVID-19 Science Report: Diagnostics

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Contents

Diagnostics

For regular readers of this report, the latest additions have been highlighted in blue.

Some references were from preprints which are preliminary and yet to be peer reviewed, the results should be interpreted with caution.

Laboratory diagnosis plays an important role in disease and outbreak management. Fast and accurate laboratory diagnosis of a specific viral infection of interest contributes to prompt public health surveillance, prevention, and control measures. With wide accessibility and availability of an accurate laboratory diagnosis for early detection, local transmission and clusters can be prevented or at least delayed by isolating the laboratory-confirmed cases in a healthcare facility, and to have their close contacts quarantined and monitored at home. Furthermore, this facilitates the implementation of specific public health intervention such as the closure of specific high-risk facilities and areas associated with the laboratory-confirmed cases for prompt infection control and environmental decontamination.[1,2]

Current Diagnostics

Appendix A contains four summary tables:

1. Table 1 is a list of the latest non-commercial laboratory diagnostic protocols listed on WHO's COVID-19 webpage.
2. Table 2 is a list of available or upcoming commercial and non-commercial diagnostics. Diagnostics that can be used for point-of-care testing have been noted in Table 2 in the first column. FIND has a similar list compiled from publicly available information and from self-submissions by suppliers at https://www.finddx.org/covid-19/pipeline/.[3] Other lists include those compiled by Nature[4,5] and 360Dx/GenomeWeb.[6]
3. Table 3 is a list of approaches for laboratory diagnostics of coronaviruses by Zhang et al (2020).[7]
4. Table 4 is a list of the gene targets and specimen sample types tested with polymerase chain reaction (PCR) as reported in publications on clinical cases of COVID-19 published before 7 March 2020.

Detection of Viral Genetic Material

Chinese health authorities have posted the full genome of SARS-CoV-2 in GenBank and GISAID portal.[1] Several lab assays have been developed to detect SARS-CoV-2, as highlighted in WHO's guidance to COVID-19 laboratory testing of suspected cases. WHO first published five protocols for diagnostics using reverse transcriptase polymerase chain reaction (RT-PCR) on their COVID-19 webpage. These included protocols from Charité Institute of Virology in Germany and The University of Hong Kong (HKU), as well as those from Thailand, Japan, and China. A sixth protocol from US Centers for Disease Control and Prevention (CDC) was subsequently added on WHO's webpage on 29 January 2020.[8] The WHO webpage has since been updated with a different URL and with additional guidance documents.[9] A seventh protocol from Institut Pasteur in Paris, France, was added on WHO's webpage in March 2020.[10]

It should be noted that the protocols for diagnostics using RT-PCR published on WHO's webpage is for guidance and not an exhaustive list. Various institutions and governments

have chosen to develop their own protocols that might not be publicly available or published by WHO on their webpage.

As outlined in the sixth national treatment and diagnostic plan issued by China's National Health Commission, the diagnosis of COVID-19 still requires the detection of the genetic material of SARS-CoV-2 before classification as a confirmed case.[11]

The first validated diagnostic test was designed by Prof Christian Drosten's group from Charité Institute of Virology in Berlin, Germany.[1,12] The initial RT-PCR assay design was based on the SARS-CoV or SARS-related coronavirus, but with the release of the sequence, assays were selected based on the match against the SARS-CoV-2 virus. Two assays were used for the RdRp gene and E gene where E gene assay acts as the first-line screening tool and RdRp gene assay as the confirmatory testing. All assays were highly sensitive and specific, and do not cross- react with other coronavirus and also human clinical samples that contain respiratory viruses.

HKU uses two monoplex assays reactive with coronavirus under the subgenus Sarbecovirus which consist of SARS-CoV-2, SARS-CoV, and SARS-like coronavirus.[13,14] Viral RNA extracted from SARS-CoV could be used as the positive control. The N gene RT-PCR could be used as a screening assay and Orf1b assay as a confirmatory test. However, this protocol has only been evaluated with a panel of controls and only positive control, SARS-CoV RNA. Synthetic oligonucleotide positive control or SARS-CoV-2 have yet to be tested. This protocol has since been published in Clinical Chemistry on 31 January 2020.[14]

US CDC has shared the protocol for rRT-PCR assay with the primers and probes designed for the universal detection of SARS-like coronavirus and the specific detection of SARS-CoV-2.[15,16] However, the protocol has not been validated in other platform or chemistries apart from the protocol described, and the analyst has to be trained and familiar with the testing procedure and result interpretation. As of 4 February 2020, US CDC has obtained emergency use assessment (EUA) from the US Food and Drug Administration (FDA).[17] This allowed US CDC to ship their diagnostic test kits to laboratories that are designated by CDC as qualified or certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests in the US.

With the first batch of US CDC diagnosis kits shipped in February 2020, however, quality control issues were found with reagents pertaining to the third step N3 gene assay for universal detection of SARS-like coronaviruses.[18] As such, US CDC was reportedly producing new test kits, and that those with existing kits were provided with new guidelines to continue without the third step N3 gene assay.[19,20] An investigation had also been launched, with major concerns raised in the preliminary stages.[21,22] The US Food and Drug Administration (FDA) has since announced on 29 February 2020 a change in policy for certain laboratories to develop and begin using validated COVID-19 diagnostics (other than that by US CDC) before the FDA has completed the EUA review.[21,23] By the end of March, over 20 organisations (including US CDC and Wadsworth Center, New York State Department of Public Health) have obtained EUA approvals from US FDA for their diagnostics. IDT[24] and LGC, Biosearch Technologies[25] also have specific lots of their RT-PCR diagnostic kits approved for EUA by US FDA.

Cepheid's Xpert Xpress SARS-CoV-2 test is the first point-of-care diagnostics to obtain EUA approval from the US FDA.[26,27] Using samples obtained from nasopharyngeal swabs or nasal wash/aspirate, the test can produce results in 45 minutes. This point-of-care test can be run on Cepheid's automated GeneXpert Systems machines without having the samples sent to a laboratory. However, as each machine can only run one sample at a time, this

poses a limitation in true volume throughput of diagnostic tests run. Additionally, there are only an estimated 5000 machines in the US as of March 2020.

Mesa Biotech and Abbott Diagnostics also have point-of-care tests for SARS-CoV-2 genetic material that have obtained EUA approval from US FDA.[28,29] Mesa Biotech's Accula SARS-Cov-2 Test takes 30 minutes and runs on the Accula system machines.[30] Abbott Diagnostic's ID Now COVID-19 test takes only 5 to 13 minutes to run completely, and can run on Abbott's ID Now platform, which is reported to have about 18,000 existing machines around the world.[31]

Currently, most of the available diagnostics have focused on packaging the appropriate reagents and genetic primers and probes for using RT-PCR to amplify genetic material for detection of SARS-CoV-2. Additional methods include using microarray or microfluidic lab-on-chip technologies, CRISPR to isolate gene segments for diagnostics, and full genetic sequencing. The use of microarray or microfluidic technologies for miniaturised fast detection of genetic material in some instances could be considered to be rapid point-of-care testing, as samples could be run on miniaturised and/or automation machinery instead of a full laboratory. However, the caveat would be that the accompanying machinery and reagents are widely distributed and available across different sites and/or in the field.

Mammoth Biosciences was previously reported to be developing a CRISPR-based diagnostics for detection of SARS-CoV-2 in partnership with University of California San Francisco.[32-34] In a published *Nature Biotechnology* paper by Broughton et al (2020), the authors described the development and initial validation of the new assay that uses CRISPR Cas12 guide ribonucleic acids (gRNAs).[35] Swab samples first go through the usual RNA extraction, followed by reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) to amplify the SARS-CoV-2 RNA. Cas12 gRNAs then detect for the presence of the SARS-CoV-2 E gene and N2 region of the N gene, and proceed to cleave the FAM-biotin reporter molecules. A lateral flow assay test strip would then detect the uncleaved (first detection line – control line) and cleaved (second detection line – test line) reporter molecules. The complete assay time from start to finish takes only about 40 minutes.

Next generation sequencing (NGS), sometimes referred to as deep sequencing, refers to a sequencing approach that allows for reactions and analysis to occur simultaneously. Multiple sequencing reactions can occur in parallel without having physical separation in tubes, capillaries, or lanes for different reactions.[36] NGS-based tests can be less time consuming and provide higher throughput, and be less labour-intensive than traditional Sanger sequencing. The Fulgent Coronavirus Disease (COVID-19) Next Generation Sequencing (NGS) test is a NGS-based test to detect SARS-CoV-2. In addition to detecting the virus, this test also characterizes the entire viral genome, thereby going beyond just detection of a few gene targets as in RT-PCR tests. NGS tests, like the one by Fulgent Genetics, will not be limited by a shortage of reagents, which has proven to be a roadblock for large scale processing of RT-PCR based tests in the market currently.[37]

Serological Testing

Serological tests can be used to assess both active and historical infection within the community. For diagnosis of acute infections, there is a lag period from start of infection to a true positive diagnosis due to a delay in the immune response of antibodies specifically targeting the SARS-CoV-2 virus. The presence of IgM antibodies for SARS-CoV-2 has been observed in a cohort study to take 10 days or later after the onset of symptoms,[38] but has been separately observed to take as early as 7 days in a patient.[39] However, serological

tests using immunoassay test strips can also provide rapid point-of-care qualitative detection of antibodies for better screening before further confirmatory tests.

Singapore has developed an approach of using serological testing to diagnose cases that earlier had COVID-19.[40,41] This test for the antibodies for SARS-CoV-2 was developed by Prof Wang Linfa's group in Duke-NUS Medical School.

Rapid point-of-care antibody tests have been developed by Guangzhou Medical University under the guidance of famed researcher Dr Zhong Nanshan and are already in use in China.[11,42] Guangzhou Wondfo Biotech and Innovita Biological Technology have already received EUA approvals from the China National Medical Products Administration (NMPA) for their antibody test kits.[43-46] Guangzhou Wondfo Biotech has also obtained CE Mark for their Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) that tests for both IgM and IgG antibodies.[47,48] Pharmact AG from Germany,[49] Zhejiang Orient Gene Biotech,[50,51] and SD Biosensor[52] all have commercially available immunoassay test strips for qualitative detection of antibodies that can be used for point-of-care testing. Other rapid test kit development and commercialisation efforts by Jiangsu Medomics Medical Technologies,[53] Shenzhen Tisenc Medical Devices,[54] and Nankai University[55] are also underway. These test strips are all expected to take about 15 to 20 minutes, a major time reduction compared to using RT-PCR.

Jiangsu Medomics Medical Technologies (China-based sister company of BioMedomics, USA) have created a point-of-care lateral flow immunoassay that simultaneously detects both IgM and IgG antibodies against SARS-CoV-2, named COVID-19 IgM/IgG Rapid Test.[53] In a published *Journal of Medical Virology* paper by Li et al (2020), the team found a sensitivity of 88.66% and specificity of 90.63% through testing samples from 397 positive case patients and 128 negative control patients.[56] The use of whole blood (diluted with buffer to improve flow) can be used and can produce results within 15 minutes. Comparison of fingerstick whole blood with both plasma and serum from venous blood found no differences in results for 7 positive case patients and 3 negative control patients. By using both IgM and IgG, the test can be used for detection of patients at different infection stages. Over 500,000 of the COVID-19 IgM/IgG Rapid Test was reported to have been sold in China, and are currently being sold in Italy having received CE Mark for in vitro diagnostics (IVD) on 8 March 2020.[57] BioMedomics is seeking to obtain EUA approval from US FDA.[58,59]

Cellex is the first company supplying a rapid point-of-care lateral flow immunoassay test to obtain EUA approval from US FDA. However, in the instructions for use (IFU) provided on FDA's website, the test cartridge was specified to only be used to "aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests."[60] The test can be used with serum, plasmas, or whole blood from venepuncture, but not blood from fingerstick.

In March 2020, FIND launched an evaluation of SARS-CoV-2 immunoassays using a standardized independent protocol.[61] Although the initial round of submissions allowed for manual ELISA and machine-based or lateral flow rapid tests, the first selection announced prioritised evaluation of only rapid diagnostic tests (RDTs). The final list of this first selection covered 27 RDTs for detection of antibodies targeting SARS-CoV-2. Five RDTs for detection of SARS-CoV-2 antigen will also be tested. Results are not available as of 9 April 2020.

Carbohydrate based glycation pattern detection diagnostic has been developed by Iceni Diagnostics.[62] They are using lateral flow assays (also known as also known as lateral flow immunochromatographic assays) as a point-of-care test. Lateral flow assays are advantageous because without the need for specialized and costly equipment, you can produce a result quickly (15 minutes) and is relatively inexpensive and simple to use. [63] Being

based on glycan molecules, the virus is unable to mutate and avoid surveillance because even though the genetic sequence of the virus can mutate, the glycans it uses does not change. [64]

Antigen Testing

The test of antigens specific to the SARS-CoV-2, such as the nucleocapsid (N) protein and the S1 or S2 domains of the spike (S) protein, can be done using monoclonal antibodies (mAbs).[5] Such tests would still require respiratory tract specimen samples (eg by nasopharyngeal or oropharyngeal swabs) for detection testing. Commercialisation efforts of antigen testing into rapid point-of-care lateral flow assay cartridges, as well as the validation testing of these commercialised rapid tests, are underway.[5,65] Unlike diagnostics using PCR, which is a process that amplifies the viral RNA, antigen testing using a lateral flow assay with direct swab samples does not have such an amplification process. Such tests thus run a higher risk of not being able to detect viral material from a swab, and producing false negative diagnosis. There have been reports of such lateral flow assay cartridges for antigen testing already in the market, but that have low accuracy and have not been approved for use.[66]

Imaging

In the sixth national treatment and diagnostic plan issued by China's National Health Commission, cases diagnosed using chest CT Scans were not continued as part of the count of new confirmed cases.[11] China had previously announced that they would include in the count of COVID-19 cases, those that were diagnosed using chest CT Scans.[67] This was due to the limited diagnostic kits and resources for testing of SARS-CoV-2 genetic material. This proposed method of early diagnosis has been explored and published in the Radiology journal.[68,69] Some studies have indicated, albeit with small samples, that CT scans could show indications of COVID-19 before onset of symptoms or positive RT-PCR test.[70-72] Alibaba has also developed an artificial intelligence (AI) model using data from 5000 confirmed cases that has 96% accuracy rate in detecting differences in chest CT scans to distinguish patients with COVID-19 vs ordinary viral pneumonia.[73]

Issues with Diagnosis Approaches

Use of Rapid Antibody Tests in Community

The use of rapid point-of-care serological tests for diagnosis of SARS-CoV-2 infection has been a concern for global regulators.[74,75] Immunoassay tests for antibodies against SARS-CoV-2 run the risk of false negatives, particularly in the early stages of infection, since there is usually a delay before antibodies are detectable, with different individuals mounting different immune responses.[75] There is also a risk of false positives if individuals have formed similar antibodies with exposure to other types of coronaviruses.

Rapid point-of-care immunoassay test strips using just blood from fingerstick is convenient, minimises exposure to healthcare workers, and could serve as first-level screening in community before confirmatory testing of viral genetic material. When used for patients already showing symptoms and/or when physicians are suspicious of infection, such tests could save time and maximise limited resources. Adding these tests, instead of full replacement of the PCR tests of genetic material, could be beneficial considering the major global shortage of supplies of key reagents for RNA extraction needed for the PCR test.[76]

Public Health England (PHE) has previously warned against the use of rapid point-of-care serological tests at home or in community pharmacies due to the lack of information on

accuracy and published evidence.[77] However, Prof Sharon Peacock from PHE announced on 25 March 2020 that 3.5 million of such rapid serological tests have been ordered and will be rolled out for use after evaluation.[78] The UK government's chief medical adviser, Prof Chris Whitty, has put in question when the tests would be available. The priority of such tests would likely be for healthcare workers, such that those shown to have immunity are allowed to return to work.

The Australian government has also announced that 500,000 of such rapid point-of-care tests have been ordered to be used in hospitals and clinics for screening purposes.[79] As of 26 March 2020, Australia has five such tests with approval for inclusion in the Australian Register of Therapeutic Goods (ARTG) from the Department of Health Therapeutic Goods Administration (TGA).[80]

Specimen Sample Collection

The sites of biological sampling can affect the sensitivity of diagnostic tests relying on detection of genetic material. A previous study by Kim et al (2011) has found that detection strengths of using nasopharyngeal (nasal) or oropharyngeal (throat) swabs differ for different pathogens infecting the respiratory tract, and that not one is superior than the other for all cases.[81]

For SARS-CoV and MERS-CoV, specimens collected from the lower respiratory tract such as sputum and tracheal aspirate have higher and more prolonged levels of viral RNA. MERS-CoV viral load is also higher for severe cases and has longer viral shedding as compared to the mild case. Although upper respiratory tract specimens such as nasal or throat swabs could be used, it has a lower viral load and could result in false-negative tests among the mild cases.[82,83] This is one key characteristic that may be similar to SARS-CoV-2.

Nasopharyngeal and Oropharyngeal Swabs

Current recommendation by US CDC requires the use of BOTH nasal and throat swabs to obtain specimen from upper respiratory tract of potential case with COVID-19 for diagnostic testing using RT-PCR.[84] However, initial rapid guidelines from China only indicated the use of throat swabs.[85]

Latest published findings from Yang et al (2020) specific for COVID-19 have found that testing of specimens obtained from nasal swabs, as well as from sputum, are more effective than throat swabs, for the detection of SARS-CoV-2.[86] The authors warned that “throat swabs were not recommended for the viruses detection, especially the samples collected 8~14 and ≥15 days after onset of illness (d.a.o.) from mild cases, which may result in a large proportion of false negative results.” The authors concluded that “sputum is most accurate for laboratory diagnosis of (COVID-19), followed by nasal swabs, while throat swabs was [sic] not recommended for the diagnosis.” However, the authors recognised the limitation that preliminary investigations found that only about a quarter of COVID-19 patients showed had production.

To note, nasal and throat swabs:

- could cause discomfort and even bleeding
- would require experienced healthcare provider to administer
- could risk exposure to healthcare provider
- does not obtain specimens from lower respiratory tract

Bronchoalveolar Lavage

Interestingly, the authors found that for severe cases, bronchoalveolar lavage fluid (BALF) had 100% positive detection rate while specimens from upper respiratory tract (sputum, nose swab, and throat swab) did not have as strong detection rates.[86] This might be a case whereby the severe cases reflect the deep infection of the lower respiratory tract, causing the pneumonia-like symptoms. The use of only nasal or throat swabs to get at an official diagnosis could thus prove to be frustrating, particularly when specimens from the upper respiratory tract might show a negative result even though all clinical signs indicate otherwise. This could cause delayed diagnosis, containment actions, and treatment regimes, and as such, the recommendation of CT scans as an added layer. On the contrary, the small sample of three patients that were mild cases with BALF tested had 0% positive detection. It could be these cases are mild because the SARS-CoV-2 did not infect the lower respiratory tract but remained in the upper respiratory tract, which allowed for better detection if using samples from sputum or nasal swabs.

A limitation of the Yang et al (2020) study was that it was conducted with COVID-19 patients that have already been admitted to the hospital and started on antiviral treatments.[86] Their findings might thus be limited in being fully applicable to the scenario of diagnosis of potential cases. However, the study does also raise questions on the risk of false negatives leading to early discharges out of isolation and quarantine of existing diagnosed cases.

Saliva Testing

Several studies have looked at the efficacy of saliva testing for detection of COVID-19 infection. However, it is important to note that there has been variable methods of collection of saliva in these different studies. Some of them involve “deep throat saliva” collected after the patient coughs repeatedly, and others involve patients pooling saliva in their mouths before spitting, or just repeatedly spitting into collection cups. It remains unclear if the method of saliva collection impacts sensitivity of virus detection.

A study by To et al (2020) have found that SARS-CoV-2 was detected in saliva samples from 11 out of 12 COVID-19 patients.[87] This suggests that saliva samples could be a potential alternative or additional specimen for diagnostic testing, especially in scenarios with limited trained healthcare providers outside of the hospital setting, and with aim to reduce exposure risk during specimen collection.

Several studies have shown the feasibility of testing saliva for presence of Viral RNA using RT-PCR, particularly in the setting of limited resources. So far, published studies (mentioned below) have shown saliva testing to be less sensitive for COVID-19 compared to nasopharyngeal swabs. However, saliva testing may be valuable as a scalable first line “self-administered” screening test in certain situations, with nasopharyngeal swabs reserved for patients with higher clinical index of suspicion.

A study done in Italy looked at deep throat saliva (saliva collected from patients coughing out the saliva) salivary samples from 25 severely ill COVID-19 patients. All 25 subjects showed positive results with Cycle Threshold (Ct) < 33, showing that salivary samples may be reliable in the qualitative detection of SARS-CoV-2. The study also showed an inverse association between the Ct levels in salivary rRT-PCR analysis and haematochemical LDH levels recorded on the same day as the swab, suggesting that salivary samples may potentially be useful in charting the course of the illness together with other biological markers. [88]

Similarly, an Australian study also investigated the feasibility and utility of using saliva specimens (via pooling saliva in the mouth for 1-2 minutes then spitting into collection cups)

for detecting COVID-19 in patients who presented to a dedicated COVID-19 screening clinic at the Royal Melbourne Hospital. 622 patients underwent COVID-19 testing by using patients' saliva specimens and nasopharyngeal swabs at the same time for comparison. 39/622 (6.3%) of patients tested positive based on nasopharyngeal samples. Of these 39, saliva testing of COVID-19 was only positive in 33/39 (84.6%) of the patients.[89]

Interestingly, a pre-print study of 44 COVID-19 patients has reportedly found that saliva samples may be more sensitive than nasopharyngeal swabs. Samples were taken from these 44 COVID-19 patients from which a total of 121 saliva samples (collected by continuously spitting into collection cups) and nasopharyngeal swabs were tested. Overall it was found that the saliva samples had higher SARS-CoV-2 titres than the nasopharyngeal samples. SARS-CoV-2 was also detected from saliva but not the nasopharyngeal samples from 8 matching samples (21%). To test variability, longitudinal samples were taken from 22 participants with nasopharyngeal swabs and 12 participants with saliva samples. The NP swabs had 5 instances where a subject NP swab was negative with the subsequent one being positive. However this problem was not encountered with the saliva samples.[90]

As of 9 March 2020, Hong Kong has launched an initiative to have private general practitioners (GPs) and family doctors help collect deep throat saliva (secretions coughed up from the back of the throat) samples from potential cases with COVID-19.[91] The initiative to collect saliva samples is in light of the lack of protective gear by private doctors to collect nasal swabs. This initiative aims to improve community surveillance through expanding testing sample collection beyond that currently done at 17 public hospitals and 64 government-run outpatient clinics.

Singapore's Lucence has also recently launched a viral sample collection kit, the SAFER-Sample (Stabilization of nucleic Acid Formulation for Evaluation of RNA) kit.[92] The kit contains a bottle with stabilization fluid that keeps the viral RNA stable at room temperature for up to a week after mixing with the sample at the point of collection. Non-invasive sample types such as saliva could also be collected with the SAFER-Sample kit. This kit could potentially increase facilitation of initiatives to expand specimen sample collection capabilities, particularly since it does not require immediate refrigeration, a barrier private GPs and family doctors have highlighted as they have limited refrigerator space, with most dedicated to storing medications and vaccines.[91]

Rutgers University's RUCDR Infinite Biologics has obtained first EUA approval from the US FDA to use saliva samples as the main specimen in tests for SARS-CoV-2.[93,94] Unlike swab samples, saliva samples can be collected without requiring close interaction of healthcare provider (self-collection) with the person under investigation. The EUA summary specifies that collection of saliva samples should be done in a healthcare setting under the supervision of a trained healthcare provider, using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.[94] Testing is also limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics. The test is a modified version of the previously authorized Thermo Fisher Applied Biosystems TaqPath COVID-19 Combo Kit. Parallel testing of nasopharyngeal and oropharyngeal swab samples with saliva samples using this test found 100% agreement for positive and negative results.

Nasal Cavity Swabs

As of 16 April, US FDA announced a further expansion of current COVID-19 testing capabilities through the possibility of using spun synthetic swabs, which have a similar design to Q tips, for self-collection of samples at the front of the nose by patients.[95] This would allow improved comfort for the patients, while minimizing exposure of healthcare providers.

Process of Laboratory Diagnosis

A commentary [96] published in the Journal of Clinical Microbiology on 3 April 2020 highlights the current issues and challenges surround the process of laboratory diagnosis. This can be roughly divided into pre-analytical, analytical, and post analytical issues.

Pre-Analytical Issues:

Other than the aforementioned issues with specimen sample collection, there are also theoretical risks of transmission. The possible airborne transmission of SARS-CoV-2 poses risks of transmission during Nasopharyngeal/Oropharyngeal swab collection. Proper PPE must be given to healthcare workers doing these swabs. If proper PPE cannot be administered to those collecting samples, other means of collecting samples must be considered. As mentioned before, possible alternatives include self-collected saliva specimens and nasal washes. However, some saliva/NPS/OPS miss early infection and as such multiple tests may need be done, or samples must be collected from the lower respiratory tract (eg. Bronchoalveolar lavage).

Analytical Issues

Assay selection. Based on previous usage for detection of influenza viruses, rapid antigen lateral flow assays are expected to suffer from poor sensitivity, despite having a fast turnover time and reduced costs. Another concern is the viral load variability in patients, causing the antigen assays to give false negative results. Furthermore, serology methods, like detecting IgG and IgM are best used retrospectively. IgM is thought to be nonspecific and specific IgG takes weeks to develop and as such, is not useful in active case management, apart from diagnosing COVID-19 late in patients.

Assay selection for molecular detection. Advanced techniques such as next generation sequencing and metagenomic next generation sequencing, while currently impractical for diagnosing COVID-19, may still be needed as it can help predict future mutations in the viral genome.

Target selection for real time RT-PCR assays. In such real time RT-PCR assays, at least two molecular targets, ideally one conserved region and one specific region, must be included. This is to mitigate the effect of cross reaction with other coronaviruses as well as the effects of genetic drift, which is expected to increase as the virus expands in new populations.

Post-Analytical

Interpretation of molecular results. Despite possible correlations, COVID-19 disease severity or response to therapy should not be based on viral loads determined by rRT-PCR but they can be used as an indicator of transmissibility in patients.

Test of cure and test of infectivity. Discharge criteria is a critical issue, and it primarily deals with whether hospitals test for complete cure, or test of whether the patients are still infective. Discharged patients are still likely to infect others if they are still shedding the virus, yet may have no remaining symptoms. NP swabs or OP swabs may not be sufficient in determining the test of cure or test of infectivity. The gold standard so far has been two consecutive negative rRT-PCR tests from rectal swabs. However, patients with positive rectal swabs would still be shedding the virus and are still infectious.

Gene Target Choices

In addition to different types of specimen samples being collected by different healthcare teams across institutions and nations, the gene targets of choice and PCR protocols used also differs. Table 4 in Appendix A presents a summary of the gene targets and specimen sample types tested with PCR as reported in selected publications on clinical cases of COVID-19 published before 7 March 2020.

It is important to note that virus mutation might affect sensitivity of test kits. In particular, tests which only target a single target, or that target easily mutated areas of the virus genome are theoretically likely to have lower sensitivity.

Imaging

A recent Lancet study has indicated that CT findings in patients with COVID-19, such as that of ground glass opacities and consolidations, are not specific for COVID-19.[97] Hence, the authors assert that this limitation confers a low positive predictive value to the use of CT in diagnosis, unless disease prevalence is high, and therefore does not believe that the CT adds diagnostic value. Regardless of negative results on a CT, it should still be confirmed with RT-PCR tests, and the patient should still be isolated. The results of the CT scan hence would not influence management in this case. Furthermore, the usage of CT scans during the pandemic raises additional logistical challenges and machines can become vectors of infection, even with proper cleaning protocols.

Search Method

Searches have been conducted for the latest information related to diagnostics for COVID-19 (previously 2019-Novel Coronavirus or 2019-nCoV) since 28 January 2020. Searches were done on PubMed and Google Search using key words that included: coronavirus; Wuhan; diagnostic; diagnostics; diagnosis; diagnoses; novel coronavirus; 2019 novel coronavirus; 2019-nCoV; COVID-19; SARS-CoV-2. Google Search results reviewed included webpages of: government and international bodies with official information and guidelines (WHO, Europe CDC, US CDC, US FDA), diagnostic protocols, scientific commentaries, market news, and press releases. All relevant links in the webpages were reviewed and relevant information used and referenced. A latest list of potential commercial kits in the works was also provided on 29 January 2020 by Dr Kim J Png through personal communications. This list was compiled by Dr Png from web searches and review of latest business news. The list served to verify and supplement our team's own search above for review. Subsequently, a list of biomedical news sites (Bioworld, Genetic Engineering & Biotechnology News, GenomeWeb/360Dx, Verdict Medical Devices) were also reviewed regularly as "go-to" sites to provide latest updates on commercial diagnostics developments. These in turn seed new searches to obtain official press releases, commercial listings, and news reporting. To note, the latest information of diagnostics being used and developed in China remain scarce or difficult to review (in Chinese, not indexed in non-Chinese search engines, or not reported in non-Chinese media news outlets). Therefore, China news sources in English language (CGTN, ChinaDaily, Global Times) were used.

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Appendix A

Table 1. Non-Commercial Laboratory Protocols

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,98]	13 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay Additional confirmatory assay: N gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. Additional confirmatory assay **Technical LOD:** 8.3 RNA copies/reaction, at 95% hit rate; **95% CI:** 6.1-16.3 RNA copies/reaction.	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,12]	17 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. (Preliminary experiment compared single probe assay for SARS-CoV with single probe assay for SARS-CoV-2.)	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control. • Synthetic control RNA for SARS-CoV-2 E gene assay is available via EVAg. • Synthetic control for SARS-CoV-2 RdRp is expected to be available via EVAg from Jan 21st onward.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**School of Public Health, The University**	16 Jan 2020	**Primer and Probe**	Positive control using SARS-CoV RNA Wide dynamic range of 2^{-4} to 2000 $TCID_{50}$/reaction.	Exclusivity Negative results against all of these preparations:	Available • Positive control (Available from HKU)	28 min 40 sec of cycle time for each assay	(no info)

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	of Hong Kong (HKU)[13,14]		Assay 1 (Target: ORF1b-nsp14 gene) Assay 2 (Target: N gene)		• RNA extracted from cultured viruses • RNA from retrospective human clinical specimens previously tested positive for other infections • RNA from control human clinical specimens	Primers and probes: • HKU-ORF1b-nsp14F • HKU- ORF1b-nsp14R • HKU-ORF1b-nsp141P • HKU-NF • HKU-NR • HKU-NP		
rRT-PCR	**Chinese Center for Disease Control and Prevention**, Beijing, China[99]	21 Jan 2020	**Primer and Probe** Target 1 (ORF1ab gene) Target 2 (N gene)	(no info)	(no info)	Available	(no info)	(no info)
RT-PCR	**Department of Medical Sciences, Ministry of Public Health**, Thailand[100]	Jan 2020	**With gel electrophoresis**	(no info)	(no info)	Available Primers: • NbatCoV_F1 • NbatCoV_R1	107 min of cycle time	(no info)
RT-PCR	**National Institute of Infectious Diseases**, Japan[101]	23 Jan 2020	**With gel electrophoresis** (Nested RT-PCR) **Primer and Probe** (Real-time RT-PCR)	(no info)	(no info)	Available Primers and probes: • NIID_2019-nCOV_N_F2 • NIID_2019-nCOV_N_R2 • NIID_2019-nCOV_N_P2	81 min for Nested RT-PCR 95 min for Real-time RT-PCR	(no info)
rRT-PCR	**Centers for Disease Control and Prevention**, Atlanta, USA[15,16]	24 Jan 2020	**Primer and Probe** 3 N gene targets 1 human RNase P gene control	(no info)	(no info)	Available Primers and probes: • 2019-nCOV_N1_F • 2019-nCOV_N1_R • 2019-nCOV_N1_P • 2019-nCOV_N2_F • 2019-nCOV_N2_R • 2019-nCOV_N2_P • 2019-nCOV_N3_F • 2019-nCOV_N3_R • 2019-nCOV_N3_P • RP_F • RP_R • RP_P	43 min 45 sec of cycle time for each assay	(no info)

Molecular tests (rRT-PCR)								
Type	**Organisation**	**Date**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
rRT-PCR	**Institut Pasteur**, Paris, France[10]	2 Mar 2020	**Primer and Probe** 2 RdRp gene targets with Charité's E gene target as confirmatory	100 or more copies of RNA genome equivalent per reaction always detected. Samples containing 10 copies of RNA genome could be detected with multiplex assay.	Cross-reactivity with other respiratory viruses was tested and were all negative in reactivity with the two RdRp gene targets.	Available Primers and probes: • nCoV_IP2-12669Fw • nCoV_IP2-12759Rv • nCoV_IP2-12696bProbe(+) • nCoV_IP4-14059Fw • nCoV_IP4-14146Rv • nCoV_IP4-14084Probe(+) • E_Sarbeco_F1 • E_Sarbeco_R2 • E_Sarbeco_P1	61 min of cycle time for each assay	(no info)

RT-PCR: reverse transcription polymerase chain reaction

rRT-PCR: real-time reverse transcription polymerase chain reaction

LOD: limit of detection

ORF: open reading frame

E gene: envelope gene

RdRp: RNA-dependent RNA polymerase

N gene: nucleocapsid protein gene

RNase P gene: Ribonuclease P gene

Table 2.1 Upcoming/Available Diagnostics: Molecular tests

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
2.1.1 PCR Kits								
RT-PCR Kit	Genosensor, LLC [102]		**GS COVID-19 RT-PCR Kit** Real-time reverse transcription polymerase chain reaction test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs, nasal swabs, mid-turbinate swabs from individuals suspected of COVID-19. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (32/32)	100% (32/32)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	KorvaLabs Inc. [103]		**Curative-Korva SARS-CoV-2 Assay** Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, nasal swab, and oral fluid specimens from individuals suspected of COVID-19. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (5/5)	100% (5/5)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	Genosensor, LLC [102]		**GS COVID-19 RT-PCR Kit** Real-time reverse transcription polymerase chain reaction test intended	100% (32/32)	100% (32/32)	Available. EUA issued on 16th April 2020.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs, nasal swabs, mid-turbinate swabs from individuals suspected of COVID-19. Positive results are indicative of the presence of SARS-CoV-2 RNA.					
RT-PCR Kit	KorvaLabs Inc.[103]		**Curative-Korva SARS-CoV-2 Assay** Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, nasal swab, and oral fluid specimens from individuals suspected of COVID-19. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.	100% (5/5)	100% (5/5)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	Fosun Pharma USA Inc.[104]		**COVID-19 RT-PCR Detection Kit** Real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory specimens (such as anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, sputum, lower respiratory	100% (50/50)	100% (100/100)	Available. EUA issued on 17th April 2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper and lower respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.					
RT-PCR assay	Rhoenix, Inc. [105]		**Rheonix COVID-19 MDx Assay[106]** Qualitative detection of total nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid.	100%[106]	100%	FDA EUA issued on 29/04/2020[106]	(no info)	(no info)
RT-PCR assay	LabGenomics Co., Ltd [107]		**LabGun COVID-10 RT-PCR Kit [108]** Qualitative detection of total nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal washes, nasal aspirates and sputum	100% (50/50)[108]	100% (100/100) [108]	FDA EUA issued on 29/04/2020 [108]	(no info)	(no info)
RT-PCR	Bioperfectus Technologies[109] China	14 Jan 2020	**RT-PCR test kit**	(no info)	(no info)	Available as scientific research product – does not require registration[109]	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
RT-PCR	Co-Diagnostics[110-112] USA	23 Jan 2020	**Logix Smart Coronavirus COVID-19 test** RT-PCR kit with lower false positive	100% (21/21)[113]	No specific statistics but claims to have ability to reliably and accurately differentiate between similar genetic sequences, in order to reduce the likelihood of a false-positive diagnosis. Company shared that it achieves this by creating reactions that are far more specific than competing PCR technologies and 2.5 million times more effective in reducing amplification errors.[110,114] 100%[113]	Commercially available for sale on 10 Feb 2020.[111] Received CE Mark 24 Feb 2020.[115] Obtained EUA approval from US FDA 3 Apr 2020.[112]	Within 2 hours[113]	(no info)
RT-PCR	Altona Diagnostics[116] Germany	23 Jan 2020	**Realstar SARS-CoV-2** RT-PCR kit	Stated to be high, with no accompanying statistics. The kit did not show any unspecific E gene signals[117].	No cross reactivity with 21 human pathogens[117]	Available FDA EUA issued on 22/4/2020	2:15 hours[117]	(no info)
RT-PCR	Roche[118-121] Switzerland	31 Jan 2020	**Cobas SARS-CoV-2 Test** Runs on the Cobas 6800/8800 systems. Tests for two gene targets: ORF1ab & E.	100% (50/50) 50 nasopharyngeal swab clinical samples spiked with cultured SARS-CoV-2 virus Low (1.5x LoD) and moderate (4x LoD) contrived positive samples [121]	100% (100/100) 100 nasopharyngeal swab clinical samples serve as negative controls.[121]	Commercially available. Obtained EUA approval from US FDA 13 Mar 2020.[120] CE Mark for IVD. Approved for inclusion on the Australia's ARTG on 20 March 2020. Date of HSA Provisional Authorisation: 19/03/2020[122]	3 hr 30 min	(no info)
RT-PCR	A*STAR[4,123]	1 Feb 2020	**A*STAR Fortitude 2.0**	100%[125]	100%	Available but not for commercial sale yet.	90 minutes	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	(Manufactured by Singapore's MiRxes which has a nonexclusive license)[124] Singapore		Test is based on rRT-PCR, for the qualitative detection of SARS- CoV-2 specific RNA in nasopharyngeal swab specimens. Supports 188 tests per kit			Provisional authorization for clinical use from Singapore's HSA.[4,124] Date of Provisional Authorisation from HSA: 30 April 2020		
RT-PCR	PCL[126] South Korea	3 Feb 2020	**Multiplex diagnostic kit** PCLMD-nCoV one step RT-PCR kit Organisation: PCL[127] Qualitative detection of SARS-Co-V-2 by sputum samples	Sensitivity: 100% (35/35) [127]	(no info)	Developed as of 3 Feb 2020. CE approved [127]	1 hr 45 min	(no info)
RT-PCR	Biomeme[128,129] USA	4 Feb 2020	Shelf-stable strip with 3 reaction wells, each reaction contains lyophilized master mix, multiplexed primers, and probes for the following triplex: - 2019-nCoV-Orf1ab - 2019-nCoV-S - MS2 bacteriophage as an RNA extraction and RT-PCR control	(no info)	(no info)	Commercially available.	(no info)	$300 for 10 strips + $5,950 for PCR Thermocycler + $450 for sample prep kit
RT-PCR	Livzon[130]	4 Feb 2020	**Novel coronavirus (2019-nCoV) nucleic acid diagnostic kit (PCR-fluorescence method)** Detection of ORF1ab and N genes.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China's NMPA on 27 Jan 2020	30 minutes[131]	(no info)
RT-PCR	Acumen Research Laboratories[132] Singapore	7 Feb 2020	**Acu-Corona™ 2.0/3.0** With specific gene targets.	(no info)	(no info)	Prototype developed. Acu-Corona 2.0 obtained Provisional Authorisation from Singapore Health Sciences Authority on 31 March 2020. Acu-Corona 3.0 obtained Provisional	Allows up to 94 patient samples per 1.5h	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Authorisation from HSA on 14 April 2020. (HSA authorisation for Acu-Corona 2.0: [133] HSA authorisation for Acu-Corona 3.0:[134] Currently CE-IVD pending and approved for research only, seeking approval from US Food and Drug Authorisation		
RT-PCR [Point-of-Care]	Cepheid[27,135,136] (Plus collaboration with Sherlock Biosciences)[137] USA	10 Feb 2020	**SAR-CoV-2 Xpert Xpress** Cartridge-based nucleic acid amplification test. Tests for two gene targets: N2 & E.	100% (30/30) 30 nasopharyngeal swab specimens were spiked with SARS-CoV- (2x to 5x LoD) serving as contrived positive samples.[136]	100% (35/35) 35 nasopharyngeal swab specimens serving as negative controls.[136]	Commercially available. Obtained EUA approval from US FDA 21 Mar 2020.[27] Approved for inclusion on the Australian Register of Therapeutic Goods on 22 March 2020. [138]	45 min	(no info)
RT-PCR	TIB-Molbiol[119,139] (distributed by Roche) Germany	12 Feb 2020	**2019-nCoV Real-Time Reverse Transcription PCR Kit** Tests for three gene targets: E, RdRp, and N.	(no info)	(no info)	Available. Orders for the kit have been placed from World Health Organisation, national health authorities and laboratories in about 60 countries. [139]	(no info)	About €160[139]
RT-PCR	AusDiagnostics[140-142] Australia	16 Feb 2020	**AusDiagnostics respiratory virus panel (including SARS-CoV-2) test** Multiplex panel. Tests for two gene targets: ORF1a & ORF8	100%[142]	100%[142]	Commercially available. Received CE Mark Mar 2020.[142] Approved for inclusion in Australia's ARTG.[80]	3 hr[141]	(no info)
RT-PCR	Seegene[143,144] South Korea	18 Feb 2020	**Allplex 2019-nCoV Assay**	100% (49/49) from upper respiratory specimens	94% (94/100) from upper respiratory specimens	Commercially available.	1 hour 50 minutes after extraction [145]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Single-tube assay that tests for three gene targets: E, RdRp, and N.	(nasopharyngeal/ oropharyngeal swabs) 100% (49/49) from lower respiratory specimens (sputum)[145]	(nasopharyngeal/ oropharyngeal swabs) 97.87% (92/94) from lower respiratory specimens (sputum) [145]	Obtained EUA approval from Korean FDA 12 Feb 2020.[146,147] Product already has CE Mark for IVD. Obtained HSA provisional approval on 2 April 2020, supplied through All Eights (Singapore) Pte Ltd. [148] Approved for inclusion on the Australian Register of Therapeutic Goods on 27 March 2020 [138] FDA EUA issued 21/04/2020		
RT-PCR [Point-of-Care]	Credo Diagnostics Biomedical[149,150] Singapore	21 Feb 2020	**VitaPCR SARS-CoV-2 Assay** Runs on Credo's VitaPCR automated point-of-care molecular testing platform.	(no info)	(no info)	Commercially available. Received CE Mark 17 Mar 2020. Submitted to US FDA for EUA approval. Has provisional authorisation from Singapore's HSA.	20 min	(no info)
RT-PCR	Osang Healthcare[151,152] (partnership with Italy's ELITech Group) South Korea	3 Mar 2020	**GeneFinder COVID-19 Plus RealAmp Kit** Tests for three gene targets: RdRp, E, and N. Runs on all major PCR cyclers as well as on the Sample-to-Result Platform ELITe InGenius.	100% for both upper and lower respiratory tract samples Evaluated using 30 nasopharyngeal swabs (upper respiratory tract) and sputum (lower respiratory tract) specimens spiked with SARS-CoV-2 virus (1x	100% for both upper and lower respiratory tract samples Evaluated using 30 nasopharyngeal swabs and sputum specimens serving as negative controls[153]	Available. Received CE Mark for IVD. Obtained EUA approval from US FDA on 18 April 2020. [153]	About 120 minutes [153]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				to 4x LoD) serving as contrived positive samples [153]				
RT-PCR [Point-of-Care]	Mesa Biotech[28,30,154-156] USA	4 Mar 2020	**Accula SARS-Cov-2 Test** Automated PCR test for the qualitative visual detection of nucleic acid from the SARS-CoV-2 virus that runs on the Accula system machines.	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 RNA (2x to 50x LoD) serving as contrived positive samples.[156]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[156]	Commercially available. Obtained EUA approval from US FDA 23 Mar 2020.	30 min	(no info)
RT-PCR	Luminex[157-159] USA	4 Mar 2020	**NxTag CoV Extended Panel** Multiplex panel that can be run on Luminex's MAGPIX System together with optional NxTag Respiratory Pathogen Panel. Tests for three gene targets: ORF1ab, E, & N	100% (30/30) 30 nasopharyngeal swabs spiked with purified SARS-CoV-2 viral genomic RNA (2x to 5x LoD) serving as contrived positive samples.	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.	Commercially available. Obtained EUA approval from US FDA 27 Mar 2020.	4 hr (2 hr 15 min to 2 hr 25 min cycle time)	(no info)
RT-PCR	LGC Biosearch Technologies[25,160]	10 Mar 2020	**2019-nCoV CDC Probe and Primer Kits for SARS-CoV-2** Lot numbers #143503 and #143764	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 10 Mar 2020 for lot number #143503 and #143764.	(no info)	USD $230 for 1000 rxn[160]
RT-PCR	Fulgent Genetics[161] USA	11 Mar 2020	**COVID-19 Virus Testing by RT-PCR**	Reported 95% sensitivity.	(no info)	Submitted to US FDA for EUA Approval. Commercially Available[162]	(no info)	(no info)
RT-PCR	bioMérieux[163-165] (subsidiary BioFire Defense) France	11 Mar 2020	**BioFire COVID-19 test** Fully automated and designed to run on FILMARRAY® 2.0 and FILMARRAY® TORCH platforms. Tests for two gene targets: ORF1ab & ORF8	100% (30/30) 30 nasopharyngeal swab specimens were spiked with live SARS-CoV-2 virus (1x to 100x LoD) serving as contrived positive samples.[166]	100% (66/66) 66 clinical nasopharyngeal swab specimens serving as negative controls.[166]	Commercially available. Obtained EUA approval from US FDA 24 Mar 2020.[165]	45 min	(no info)
RT-PCR	Hologic[167-169] USA	16 Mar 2020	**Panther Fusion SARS-CoV-2 Assay** Test for two conserved regions of the ORF1ab gene	100% (69/69) 69 remnant clinical nasopharyngeal	100 (109/109) 109 remnant clinical nasopharyngeal	Commercially available.	Can generate results in 3 hours[170]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				specimens were spiked with inactivated cultured SARS-CoV-2 virus (1x to 5x LoD) serving as contrived positive samples.[169]	specimens serving as negative controls.[169]	Obtained EUA approval from US FDA 16 Mar 2020. Approved for inclusion into the Australian Register of Therapeutic Goods on 20 March 2020.[80]		
RT-PCR	LabCorp (Laboratory Corporation of America)[168,171] USA	16 Mar 2020	**COVID-19 RT-PCR Test** Test for three gene targets: N1, N2, & N3	100% (80/80) 40 nasopharyngeal swab specimens and 40 bronchoalveolar lavage specimens were spiked with quantitated live SARS-CoV-2 (1x to 8x LoD) to form 80 contrived positive samples.[171]	100% (100/100) 50 nasopharyngeal swab specimens and 50 bronchoalveolar lavage specimens serving as negative controls.[171]	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020.	Approximately 2-4 days from the date of pickup of a specimen for testing to the release of the test result to the health care provider [172]	(no info)
RT-PCR	Quidel[173,174] USA	17 Mar 2020	**Lyra SARS-CoV-2 Assay** Identification of the SARS-CoV-2 virus occurs by the use of target specific primers and fluorescent-labeled 102 probes that hybridize to a conserved region of the non-structural Polyprotein (pp1ab) of the SARS-CoV-2 virus.[175]	100% (92/92) 92 nasopharyngeal swab specimens were spiked with SARS-CoV-2 RNA (1x to 5x LoD) serving as contrived positive samples.[174]	(100% (92/92) 92 nasopharyngeal swab specimens serving as negative controls.[174]	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	45 min cycle time per gene	(no info)
RT-PCR	Quests Diagnostics[176,177] USA	17 Mar 2020	**Quest SARS-CoV-2 rRT-PCR** Tests on two gene targets: N1 & N3	100% (30/30) 12 pairs of nasopharyngeal swab and sputum specimens from **actual COVID-19 patient** formed 24 samples, together wiith 6 additional randomly selected to be duplicated, serving as total 30 positive samples.[177]	100% (72/72) 72 presumed-negative nasopharyngeal/throat swab specimens from before Oct 2019 servings as negative controls.[177]	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	58 min 40 s cycle time per gene	(no info)
RT-PCR	Abbott Molecular[27,178,179]	18 Mar 2020	**Abbott RealTime SARS-CoV-2 assay**	100% (60/60)	100% (31/31)	Commercially available.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	USA		Will run on the Abbott m2000 RealTime system. Tests for two gene targets: RdRp & N.	61 nasopharyngeal swabs spiked with recombinant virus containing SARS-CoV-2 RNA sequences (1x to 20x LoD) serving as contrived positive samples. 1 sample was invalidated and excluded.[179]	34 nasopharyngeal swabs serving as negative controls. 3 samples were invalidated and excluded.[179]	Obtained EUA approval from US FDA 18 Mar 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 17 April 2020.[138] Date of HAS Provisional Authorisation: 01/04/2020 [180]		
RT-PCR	DiaSorin Molecular[181-183] Italy	19 Mar 2020	**Simplexa COVID-19 Direct** Will run on the DiaSorin's LIAISOn MDX thermocycler. Tests for two gene targets: S & ORF1ab.	100% (52/52) 108 fresh nasopharyngeal swab specimens from 3 clinical site2s were compared with one of two brands of established comparator assay.[183]	100% (56/56) 108 fresh nasopharyngeal swab specimens from 3 clinical sites were compared with one of two brands of established comparator assay.[183]	Commercially available. Obtained EUA approval from US FDA 19 Mar 2020.	(no info)	(no info)
RT-PCR	DiaCarta[184,185] USA	23 Mar 2020	**QuantiVirus SARS-CoV-2** Tests for two gene targets: N, ORF1ab, & E	96.7% Clinically validated in the company's CLIA-certified lab in Richmond, California.	100% Clinically validated in the company's CLIA-certified lab in Richmond, California.	Commercially available. Received CE Mark for IVD Mar 2020. Obtained EUA approval from US FDA 8 Apr 2020.[186]	(no info)	(no info)
RT-PCR	PerkinElmer[28,187,188] USA	24 Mar 2020	**PerkinElmer New Coronavirus Nucleic Acid Detection Kit** Tests for two gene targets: N & ORF1ab.	100% (47/47) 47 oropharyngeal and nasopharyngeal swab specimens spiked with inactivated SARS-CoV-2 virus (1x to 5x LoD) serving as contrived positive samples.[188]	100% (94/94) 94 oropharyngeal and nasopharyngeal swab specimens serving as negative controls.[188]	Commercially available. Obtained EUA approval from US FDA 24 Mar 2020. EUA amendment on April 1st to add an additional nucleic acid extraction method which utilizes the	104 min 30s cycle time per gene target.	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						chemagic Viral DNA/RNA 300 Kit H96 on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor changes and edits to the IFU labeling was granted on 01/04/2020 [189]		
RT-PCR	Genetron Health[190] China	7 Aor 2020	**Detection Kit for Novel Coronavirus (SARS-CoV-2) RNA**	(no info)	(no info)	Commercially available. Received CE Mark 7 Apr 2020. Submitted to US FDA for EUA approval.	(no info)	(no info)
RT-PCR	Mobidiag[191] Finland		**Amplidiag COVID-19** Real-time RT-PCR test with two molecular targets (orf1ab and N) including at least one conserved region and one specific region to mitigate effects of genetic drift and avoid cross-reaction with other endemic coronaviruses.	(no info)	(no info)	Available as an emergency use test in Finland and France, set up for routine use in main clinical laboratories in Finland with capacity to test up to 4000 samples a day.[192] In the process for obtaining emergency use authorisation in Sweden and the UK. In the process for obtaining CE-IVD.	48 samples in <3h	(no info)
RT-PCR	Genetic Signatures Ltd Australia		**EasyScreen™ SARS-CoV-2 Detection Kit** Real time PCR which enables qualitative detection of SARS-CoV-2 via two targets (SARS-CoV-2 N and E genes)	(no info)	(no info)	Available. CE-IVD marked.[193] Approved for inclusion into the Australian Register of Therapeutic Goods on 13 April 2020.[138]	(no info)	(no info)
RT-PCR	Shanghai ZJ Bio-Tech Co Ltd (also called Liferiver)[194]		**Novel Coronavirus (2019-nCoV) Real Time Multiplex**	(no info)	(no info)	Available.	(no info)	

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	China		**RT-PCR Kit (Detection for 3 genes)** Qualitative detection of SARS-CoV-2 by real time PCR			Approved for inclusion into the Australian Register of Therapeutic Goods on 22 March 2020.[138]		
RT-PCR	AITbiotech Pte Ltd[195] Singapore		**abTES™ COVID-19 qPCR I Kit** Qualitative RT-PCR which detects two COVID-19 specific regions from its non-structure polypeptide	(no info)	(no info)	Date of Provisional Authorisation by HSA: 05/03/2020	(no info)	(no info)
RT-PCR	DSO National Laboratories[196] Singapore		**Real-Time PCR Assay for the Detection of SARSCoV-2 Virus** RT-PCR based on specific detection of the polymerase gene region in SARS-CoV-2 virus.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 10/03/2020	(no info)	(no info)
RT-PCR	Biowalker Pte Ltd[197] Singapore		**Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)** Detection of 2019-nCoV RNA in swab and sputum samples	(no info)	(no info)	Date of Provisional Authorisation by HSA: 24/03/2020	(no info)	(no info)
RT-PCR	JN Medsys Pte Ltd[198] Singapore		**ProTect™ COVID-19 RT-qPCR Kit** In-vitro qualitative detection of SARS-CoV-2 from samples. The test targets SARS-CoV-2 N1, N2 and N3 genes and the human RNase P control gene.	High sensitivity and specificity, no statistics given	(no info)	Date of Provisional Authorisation by HSA: 19/03/2020	Within 2 hours[199]	(no info)
RT-PCR	Veredus Laboratories Pte Ltd[122] Singapore		**VereCoV™ Detection Kit** Multiplex RT-PCR/microarray-based in-vitro diagnostic test.			Date of Provisional Authorisation by HSA: 18/02/2020		
RT-PCR	Vela Operations Singapore Pte Ltd[200] Singapore		**ViroKey SARS-CoV-2 RT-PCR Test**	(no info)	(no info)	Date of Provisional Authorisation by HSA: 15/04/2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
RT-PCR	SPD Scientific Pte Ltd[201] Singapore		**Cepheid® Xpert® Xpress SARS-CoV-2**	(no info)	(no info)	Date of Provisional Authorisation by HAS: 26/03/2020	(no info)	(no info)
RT-PCR	PerkinElmer Singapore Pte Ltd [202]		**PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay**	(no info)	(no info)	Provisional Authorisation from HSA: 20/04/2020	(no info)	(no info)
RT-PCR	BioWalker Pte Ltd [203]		**BioWalker SARS-CoV-2 Assay 2.0**[204] The test uses rRT-PCR for qualitative detection of SARS-CoV-2 nucleic acids in human nasopharyngeal or oropharyngeal swab samples.	(no info)	(no info)	Date of Provisional Authorisation from HSA: 30 April 2020	(no info)	(no info)
RT-PCR	Medicell Pharmaceutical (S) Pte Ltd [205]		**Sansure Biotech Novel Coronavirus (2019- nCoV) Nucleic Acid Diagnostic Kit**	(no info)	(no info)	Date of Provisional Authorisation from HSA: 23/04/2020	(no info)	(no info)
RT-PCR	Trax management Services Inc. [206]		**PhoenixDx 2019-CoV**	100% (30/30)	100% (10/10)	FDA EUA issued on 20/4/2020	(no info)	(no info)
RT-PCR	Ustar Biotechnologies (Hangzhou) Co Ltd (China) [207]		**EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)**	(no info)	(no info)	Approved for inclusion on the Australian Register of Therapeutic Goods on 23 April 2020.	(no info)	(no info)
RT-PCR	CTK Biotech Inc (United States of America) [208]		**Aridia COVID-19 Real-Time PCR Test**	95.1%	95.9%	Approved for inclusion on the Australian Register of Therapeutic Goods on 24 April 2020.	(no info)	(no info)
RT-PCR	PCL[127]		**PCL COVID19 Ag Rapid FIA** [127] Qualitative detection of SARS-CoV-2 antigens from human oropharyngeal and deep sputum samples	Sensitivity: 100%		CE approved	10 minutes	(no info)
RT-PCR	Seasun Biomaterials [209]		**RT-PCR Test U-TOP COVID-19 Detection Kit** [210] Qualitative detection of SARS-CoV-2 antigens from	100% (for both nasopharyngeal and sputum)[210]	No cross-reactivity with 33 microorganisms	FDA EUA issued on 27/04/2020	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			oropharyngeal and nasopharyngeal swab specimens, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum samples					
RT-PCR	BioFire Diagnostics, LLC [211]		**BioFire Respiratory Panel 2.1** [212] Multiplex RT-PCR test detecting SARS-CoV-2 spike (S) and membrane (M) gene	98% (48/49)	100% (279/279)	FDA EUA issued on 1 May 2020[212]	(no info)	(no info)
RT-PCR	Bio-Rad Laboratories, Inc. [213]		**Bio-Rad SARS-CoV-2 ddPCR Test** [214] Multiplex RT-PCR test detecting SARS-CoV-2 spike (S) and membrane (M) gene	94.87% (37/39, analysis done after Thermo MagMAX extraction); 94.59% (35/37, analysis done after QIAamp viral RNA extraction)	94.87% (37/39, analysis done after Thermo MagMAX extraction); 95.00% (38/40, analysis done after QIAamp viral RNA extraction)	FDA EUA issued on 1 May 2020 [214]	(no info)	(no info)
RT-PCR	Public Health England[215] UK	10 Feb 2020	Real time RT-PCR (RdRp gene) assay which employs the use of two probes; one which detects 2019-nCoV, SARS-CoV and bat-SARS-related-CoVs, and the other 2019-nCoV only. The assay will be evaluated on the ABI 7500 Fast real-time PCR system.[216]	(no info)	(no info)	Available (non-commercially) to 9 labs across the UK.	(no info)	(no info)
Real-time RT-RAA	Beijing Ditan Hospital[217] China	29 Jan 2020	**Real time Reverse-Transcription Recombinase Aided Amplification (RT-RAA) assay** Novel isothermal nucleic acid amplification technique for detection of SARS-CoV-2.	(Recombinant plasmids containing conserved ORF1ab genes was used to analyse the specificity and sensitivity.)	(Recombinant plasmids containing conserved ORF1ab genes was used to analyse the specificity and sensitivity.)	Clinical trials phase.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			Assay was performed at 42°C within 30min using a portable real-time fluorescence detector,					
Real-time RT-PCR	ScienCell Research Laboratories[218-220] USA	24 Jan 2020	**ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit** Tests for two gene targets: N1 & N2	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 RNA (not actual clinical sample) serving as contrived positive samples.[219]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[219]	Commercially available. Obtained EUA approval from US FDA 3 Apr 2020.	43 min 45 s cycle time for each gene	(by quote)
Real-time RT-PCR	Liferiver Biotech[221,222] China	29 Jan 2020	**Fluorescent PCR**[222]	(no info)	(no info)	Commercially available.	(no info)	€ 991[223]
Real-time RT-PCR	Liferiver Biotech[221,224] China	29 Jan 2020	**Multiplex RT-PCR**[224]	(no info)	(no info)	Commercially available.	(no info)	€ 1347[225]
Real-time RT-PCR	GenScript[221,226,227] USA	29 Jan 2020	**qRT-PCR** Targets RdRp gene, N gene and E gene in Wuhan-Hu-1 genome (GenBank sequences NC_045512.2) [same as Charite's first protocol]	"This assay is RUO and has not been tested on clinical samples. We make no claims on the performance of this assay." [226]	"This assay may have cross-reactivity with other coronavirus family members such as causative agents of the Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS)."[226]	Commercially available for RUO.	(no info)	(by quote)
Real-time RT-PCR	CerTest Biotec[228] Spain	30 Jan 2020	**VIASURE 2019-nCoV Real Time PCR Kit** Amplification of a fragment of the S gene.[229]	97.5%[230]	>99.9%[230]	Available. Received CE Mark for IVD for the version adapted for the BD MAX™ System.[229] Approved for inclusion on Australia's ARTG on 21 March 2020.	120 minutes[230]	(no info)
Real-time RT-PCR	GeneFirst[231] UK	3 Feb 2020	Capable of detecting only the SARS-CoV-2	(no info)	(no info)	Available	< 3 hr	(no info)
Real-time RT-PCR	GeneFirst[231]	3 Feb 2020	Multiplex assay which simultaneously detects	(no info)	(no info)	Available.	< 3 hr	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	UK		SARS-CoV-2 as well as 17 other common viruses and bacteria					
Real-time RT-PCR	Kogene Biotech[126,146] South Korea	3 Feb 2020	**Powerchek 2019-nCoV Real-time PCR kit** Tests for two gene targets: E and RdRp.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 4 Feb 2020.[146,232] Approved for inclusion on the Australian Register of Therapeutic Goods.	(no info)	(no info)
Real-time RT-PCR	Thermo Fisher Scientific[128,233-235] USA	4 Feb 2020	**TaqPath COVID-19 Combo Kit (previously TaqMan 2019-nCoV Assay Kit)** Real-time RT-PCR kit assays specifically target all 44 complete genomes currently available at GISAID, and do not target any of the 2,116 complete genomes of other coronaviruses currently available at NCBI. Tests for three gene targets: ORF1ab, N, & S.	100% (60/60) 30 nasopharyngeal swab specimens and 30 bronchoalveolar lavage specimens were spiked with extracted SARS-CoV-2 viral genomic RNA (2x to 5x LoD) to form 60 contrived positive samples.[235]	100% (60/60) 30 nasopharyngeal swab specimens and 30 bronchoalveolar lavage specimens were used as negative controls.[235]	Commercially available. Received CE Mark for IVD 26 Mar 2020.[236] Obtained EUA approval from US FDA 13 Mar 2020.[234] Obtained HSA provisional approval on 20 March 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 24 March 2020.	36 min cycle time per gene target	(by quote)
Real-time RT-PCR	US CDC[17,237,238] USA	4 Feb 2020	**Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel** Tests for three gene targets: N1, N2, and N3 (subsequently removed[238]) plus 1 human RNase P gene control.	100% (!3/13) 117 respiratory specimens collected from 46 subjects tested with two analytically validated real-time RT-PCR assays for N4 and N5 gene targets.[237]	100% (104/104) 117 respiratory specimens collected from 46 subjects tested with two analytically validated real-time RT-PCR assays for N4 and N5 gene targets.[237]	Available to laboratories designated by CDC as qualified, and in the US, certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. Available to qualified international laboratories.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Not available to U.S. hospitals or other primary care settings. Obtained EUA approval from US FDA 4 Feb 2020.		
Real-time RT-PCR	SolGent[146,147,239] South Korea	28 Feb 2020	**DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit** Tests for two gene targets: Orf1a and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 27 Feb 2020.[146,147] Received CE Mark for IVD.	2 hr PCR	(no info)
Real-time RT-PCR	SD Biosensor[146,147] South Korea	28 Feb 2020	**STANDARD M n-CoV Real-Time Detection Kit** Tests for two gene targets: E and RdRp.	Sensitivity: 100% (30/30) [240]	Specificity: 100% (30/30) [240]	Available. Obtained EUA approval from Korean CDC 27 Feb 2020.[146,147] FDA EUA issued on 23/04/2020	90 min [241]	(no info)
Real-time RT-PCR	Integrated DNA Technologies (IDT)[24,232] USA	3 Mar 2020	**2019-nCoV CDC EUA Kit** Follows US CDC protocol to test for 3 N gene targets, and 1 human RNase P gene as control.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 3 Mar 2020 for lot number #0000500383.	(no info)	USD $125[24] for 500 rxn
Real-time RT-PCR	Luminex[158,159,242,243] USA	4 Mar 2020	**ARIES SARS-CoV-2 Assay** Tests for two gene targets: ORF1ab & N	100% (30/30) 30 nasopharyngeal swabs spiked with purified SARS-CoV-2 viral genomic RNA (2x to 5x LoD) serving as contrived positive samples.[243]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[243]	Commercially available. Obtained EUA approval from US FDA 3 Apr 2020.	2 hr	(no info)
Real-time RT-PCR	Genomica[244,245] Spain	6 Mar 2020	**qCOVID-19** Real-time RT-PCR	Reported **100%.**[244] Tested at the Carlos III Health Institute with 80	Reported **100%.**[244] Tested at the Carlos III Health Institute with 80	Available. Received CE Mark 6 Mar 2020.[245]	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				samples (unclear of sample types).	samples (unclear of sample types).			
Real-time RT-PCR	Avellino Lab[246-248] USA	9 Mar 2020	**AvellinoCoV2 test** Tests for two gene targets from US CDC protocol: N1 & N3	100% (30/30) 30 oropharyngeal and nasopharyngeal swab specimens spiked with whole SARS-CoV-2 viral RNA (1x to 100x LoD) serving as contrived positive samples.[248]	100% (30/30) 30 oropharyngeal and nasopharyngeal swab specimens serving as negative controls.[248]	Commercially available. Obtained EUA approval from US FDA 25 Mar 2020.[246]		(no info)
Real-time RT-PCR	Wadsworth Center, New York State Department of Public Health[186,249] USA	10 Mar 2020	**New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel** Tests for two gene targets: N1 & N2.	(42/43) For the easyMAG extraction, 43 individual sputum samples were spiked with the extracted whole SARS-CoV-2 virus genomic RNA (2x to 200x LoD) to serve as contrived positive samples. Testing was also done with eMAG and EZ1 extraction.[249]	(29/29) For the easyMAG extraction, 30 individual sputum samples were used but 1 was invalidated, leaving 29 samples. Testing was also done with eMAG and EZ1 extraction.[249]	Available. Obtained EUA approval from US FDA for use in Wadsworth Center, New York State Public Department of Health, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories.	42 min 45 s cycle time per gene target	(no info)
Real-time RT-PCR	NeuMoDx[250-252]	12 Mar 2020	**NeuMoDx™ SARS-CoV-2 Assay** Real-time RT-PCR for use on fully automated NeuMoDx™ 288 and 96 Molecular Systems. Tests for two gene targets: Nsp2 & N.	100% (87/87) 87 clinical nasopharyngeal swab specimens were spiked with SARS-CoV-2 genomic RNA (1x to 8x LoD) serving as contrived positive samples.[252]	100% (82/82 82 clinical nasopharyngeal swab specimens serving as negative controls.[252]	Commercially available. Obtained EUA approval from US FDA 30 Mar 2020.[250]	80 min	(no info)
Real-time RT-PCR	Becton Dickinson (BD)[253-255] USA	17 Mar 2020	**BioGX SARS-CoV-2 Reagents for BD MAX System** Tests for two gene targets: N1 & N2	100% (29/29) 30 retrospective collected clinical nasopharyngeal swab specimens spiked with quantified genomic RNA of SARS- CoV-2 (1x to 5x LoD) serving as contrived positive samples. 1 sample	100% (30/30) 30 retrospective collected clinical nasopharyngeal swab specimens serving as negative controls.[253]	Commercially available. Obtained EUA approval from US FDA 2 Apr 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 17 April 2020.[80]	2 hr	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				removed from data analysis.[253]				
Real-time RT-PCR	Maccura Biotechnology[246,256,257] China	22 Mar 2020	**SARS-CoV-2 Fluorescent PCR Kit** Tests for three gene targets: ORF1ab, N, & E.	100% (30/30) 15 nasopharyngeal and 15 oropharyngeal swab samples from suspected cases that tested negative had additional aliquot spiked with SARS-CoV-2 whole genomic RNA (2x to 5x LoD) serving as 30 contrived positive samples.[257]	100% (30/30) 15 nasopharyngeal and 15 oropharyngeal swab samples from suspected cases that tested negative had additional aliquot serving as 30 negative controls.[257]	Commercially available. Received CE Mark in Mar 2020.[256] Obtained EUA approval from US FDA 15 Apr 2020.	37 min 10 s cycle time per gene target	(no info)
Real-time RT-PCR	Ipsum Diagnostics[258,259]	1 Apr 2020	**COV-19 IDx assay** N1 gene target	100% (36/36) 36 nasopharyngeal swabs spiked with BEI ATCC Genomic RNA from SARS Related Coronavirus 2 (not actual clinical sample) serving as contrived positive samples.[259]	100% (30/30) 30 nasopharyngeal swabs serving as negative controls.[259]	Commercially available. Obtained EUA approval from US FDA 1 Apr 2020.	(no info)	(no info)
Real-time RT-PCR	Gnomegen[260,261] (Subsidiary of QuestGenomics) USA (China)	6 Apr 2020	**Gnomegen COVID-19 RT-Digital PCR Detection Kit** Tests for two gene targets: N1 & N2	100% (30/30) 30 oropharyngeal swabs spiked with quantified SARS-CoV-2 whole viral RNA (1x to 5x LoD) serving as contrived positive samples.[261]	100% (30/30) 30 oropharyngeal swabs serving as negative controls.[261]	Commercially available. Obtained EUA approval from US FDA 6 Apr 2020.	129 min 30 s cycle time	(no info)
Real-time RT-PCR	InBios International[238,262,263] USA	7 Apr 2020	**Smart Detect SARS-CoV-2 rRT-PCR Kit** multiplex one-step rRT-PCR that can run on CFX96 Touch Real-Time PCR. Tests for three gene targets: N, E, & ORF1b	100% (30/30) 30 nasopharyngeal swabs spiked with SARS-CoV-2 viral genomic RNA (1x to 5x LoD) serving as contrived positive samples.[262]	96.7% (29/30) 30 nasopharyngeal swabs serving as negative controls.[262]	Commercially available. Obtained EUA approval from US FDA 7 Apr 2020.	4 hr[263] (43 min 45 s cycle time for each gene)[262]	(no info)
Real-time RT-PCR	Becton Dickinson (BD)[264,265] USA	8 Apr 2020	**BD SARS-CoV-2 Reagents for BD MAX System** Test is a rRT-PCR test intended for the qualitative	96% (48/50) 50 retrospective collected clinical	100% (29/29) 29 retrospective collected clinical	Commercially available.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			detection of nucleic acid from the SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider. Tests for two gene targets: N1 & N2	nasopharyngeal swabs spiked with quantified genomic RNA of SARS-CoV-2 (1x to 5x LoD) serving as contrived positive samples.[265]	nasopharyngeal swab specimens serving as negative controls.[265]	Obtained EUA approval from US FDA 8 Apr 2020. Date of Provisional Authorisation from HSA: 6 May 2020[266]		
Real-time PCR and microarray technologies [Point-of-Care]	Mobidiag[267] (collaboration with Autobio Diagnostics, China) Finland	10 Feb 2020	**Novodiag** Cartridge-based qPCR system, fully automated, allowing the rapid detection of both novel coronavirus and influenzas in around 30 minutes. Two gene targets for SARS-CoV-2 (orf1ab and N)[191]	(no info)	(no info)	In development.	Less than an hour	(no info)
Real Time RT-PCR	BGI[268-270] (Pathomics Health as distributor) China	23 Jan 2020	**Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV** In vitro RT-PCR combining fluorescent probing.[271] Real-time RT-PCR assay for qualitative detection of SARS-CoV-2 in throat swabs and bronchoalveolar lavage fluid (BALF).	BALF: 81% Throat Swab: 91.2% RNA: 97.1% Combined: 88.1%[272]	BALF: 100% Throat Swab: 100% RNA: 96.2% Combined: 99.6%[272]	Commercially available. Received CE Mark for IVD 2 Mar 2020.[273] BGI is also engaged with relevant organizations in Hong Kong, Taiwan, Brunei, Thailand, Nigeria, South Africa, to supply the test kits.[268] Passed emergency approval procedure of China's NMPA. Obtained EUA approval from US FDA 27 Mar 2020.[269,270] Approved for inclusion on Australia's ARTG on 10 April 2020.	3 hr	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Date of Provisional Authorisation from HSA: 24 April 2020 [274]		
RT-PCR	CapitalBio[44] (collaboration with Tsinghua University and West China Hospital of Sichuan University) China	24 Feb 2020	Detection of six common respiratory viruses including SARS-CoV-2 within 1.5 hours using samples of patients' oral and pharyngeal Secretions.	(no info)	(no info)	Available. Approved by China's NMPA.	1 hr 30 min	(no info)
qPCR	Primerdesign[275-280] (molecular diagnostics division of Novacyt) France/UK	31 Jan 2020	**Genesig Real-Time PCR COVID-19 (CE)** *[Previously Coronavirus (Strain 2019-nCoV) Easy/Standard Kit]*[276] Can run on multiple molecular testing platforms, including Primerdesign's own genesig® q16 and q32 instrument	96%[281]	100%	Commercially available. Received CE Mark for IVD 17 Feb 2020.[282,283] Obtained EUA approval from US FDA 20 Mar 2020.[279]	< 2 hr 64 min 30 s cycle time per gene[280]	(by quote)
qPCR	Coyote Bioscience[128,284] China	4 Feb 2020	**2019-nCoV Prep Free QPCR Assay** Runs on the Mini8 Portable Molecular Diagnostic QPCR Station (CFDA approved)	(no info)	(no info)	Available. Reportedly being used in China in over 30 hospitals, 16 local CDC offices, and 8 airports.	1 hr	(no info)
qPCR [Point-of-Care]	Molbio Diagnostics[284] India	12 Feb 2020	**qPCR Truenat Beta CoV** [285] Potentially real-time PCR then detection of wavelengths of fluorescent signal.	100% [286]	100% [286]	Available. Approved by the Indian Council of Medical Research for coronavirus testing in India on 4 April 2020.[287]	55 min	Rs 1,000 – Rs 1,500) [287]
qPCR [Point-of-Care]	OnSiteGene[284] (San Diego-based subsidiary of Singapore's Star Array) USA	12 Feb 2020	**Star Array 2019 Novel Coronavirus (SARS-CoV-2) Nucleic Acid Detection Kit 1.0** 2019-nCoV rRT-PCR kit for use on existing Peak V, that performs spatial thermal	(no info)	(no info)	Developed. Currently seeking collaborators to perform clinical tests in China and the US.[288]	10 min	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			cycling using a heated liquid metal for direct amplification without the need for sample prep. Genes detected are the SARS-CoV-2 N gene and ORF1ab gene. [288]					
PCR-based genotyping	Genomica[289,290] Spain	30 Jan 2020	**CLART COVID-19** Based on Genomica's CLART technology of PCR-based genotyping with low-density microarray.	>96%[291]	98%	Available. Received CE Mark 6 Mar 2020.[245]	< 5 hr	(no info)
ddPCR	Bio-Rad Laboratories[292-294] USA	19 Mar 2020	**COVID-19 Droplet Digital PCR (ddPCR) Assay** Quantitative assay for use on Bio-Rad's QX200 and QXDx Droplet Digital PCR Systems.	Reported enhanced sensitivity.[293]	(no info)	Commercially available. EUA Submission Pending[295]	(no info)	(by quote)
Conventional and Real Time RT-PCR	Genekam[296,297] Germany	4 Feb 2020	5 options: 1. Conventional PCR 2. Real Time PCR for nCoV only[298] 3. Multiplex Real Time PCR for nCoV + other Bat CoV[299] 4. Multiplex Real Time PCR for nCoV + other Bat CoV + MERS[300] 5. Multiplex Real Time PCR for nCoV + Influenza A[301]	(no info)	(no info)	In development as of 6 Feb 2020	126 min 15 s[298,300] or 120 min[299,301] of cycle time	€ 599[297] € 699[297] € 799[297] € 999[297] € 899[297]
Combination of RT-PCR and meta-genomics detection	BGI[268] (Pathomics Health as distributor)[302] China	23 Jan 2020	**2019-nCoV PMseq Kit** A metagenomics sequencing kit based on combinatorial Probe Anchor Synthesis. Faster SARS-CoV-2 virus detection, and able to detect both known and novel microorganisms, enabling monitoring of evolution during transmission.	(no info)	(no info)	Has been providing technical support for the scientific clinical prevention and control of the epidemic in Wuhan. Passed emergency approval procedure of China's NMPA.	SARS-CoV-2 detection stated to be faster than Fluorescent RT-PCR kit. For detection of unknown pathogens, Within 5 hours, 128 samples can be simultaneously screened and sequenced by SE50, and 128 samples can be simultaneously tested and	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
							sequenced by PE100 in 22 hours, as well as possible mutation and evolution monitoring	
RT-PCR	Jiangsu Bioperfectus Technologies Co Ltd [303]	11 May 2020	COVID-19 Coronavirus Real Time PCR Kit	(no info)	(no info)	Approved for inclusion in the Australian Register of Therapeutic Goods on 5 May 2020	(no info)	(no info)
RT-PCR	TCM Biosciences[126,304] South Korea	3 Feb 2020	**TCM-Q Corona Ⅲ** RT-PCR using SARS-CoV-2 RdRP gene and E-Sarbeco gene	100%	100%	Developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	70 min	(no info)
RT-PCR	Bioneer[126] South Korea	3 Feb 2020	AccuPower COVID-19 Real-Time RT-PCR kit[305]	(no info)	(no info)	Assumed developed as of 3 Feb 2020. Submitted to Korean CDC for EUA. Received CE mark. Distributed to 20 hospitals in Romania	(no info)	(no info)
RT-PCR	CEVI[126,306] (Partnership with Wells Bio) South Korea	3 Feb 2020	**CareGENE N-CoV RT-PCR Kit** Real time RT-PCR kit to detect SARS-CoV-2 RdRP and E genes in human nasopharyngeal swab, oropharyngeal swab and sputum	(no info)	(no info)	In development as of 6 Feb 2020. CE mark on March 3	83 minutes	(no info)
RT-PCR	QuantuMDx[284,307] UK	12 Feb 2020	(SARS-CoV-2 Detection RT-PCR Testing kit. Detect SARS-CoV-2 in human oropharyngeal and nasopharyngeal swab	100%	100%	EUA application submitted to DFA, CE-IVD mark by mid may	(no info)	(no info)
RT-PCR	Liferiver Bio-Tech [308]		**Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit** Test is used for the in vitro qualitative detection of 2019-nCoV RNA in upper respiratory tract specimens	(no info)	(no info)	Date of Provisional Authorisation from HSA: 4 May 2020	(no info)	

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			and lower respiratory tract specimens.					
2.1.2 Genome Sequencing								
NGS	IDbyDNA[309,310] USA	29 Jan 2020	Next-generation sequencing-based metagenomics, allows enhanced pathogen detection and profiling in comparison to conventional PCR testing.[310]	(no info)	(no info)	Commercially available.	(no info)	(by quote)
NGS	Fulgent Genetics[161] USA	11 Mar 2020	**Kiloplex PCR Plus NGS** Next-generation sequencing using thousands of PCR primers to amplify sample viral genetic material before sequencing on the Illumina platform.	Undergoing validation by joint venture Fujian Fujun Gene Biotech.	Undergoing validation by joint venture Fujian Fujun Gene Biotech.	Available. Soon to be submitted to US FDA for EUA Approval.	4 hr	(by quote)
Genome sequencing	Oxford Nanopore[311,312] UK	22 Jan 2020	Works with public health labs globally to support rapid sequencing of SARS-CoV-2 through sharing of methods / workflows. Nanopore sequencing workflows can provide a consensus viral genome from sample within a day.	(no info)	(no info)	Available. 28 January: US Centers for Disease Control and Prevention (CDC) releases nCoV genomes sequenced with nanopore sequencing 29 January: A paper in the Lancet characterised full-length genomes of 2019-nCoV patients using Nanopore sequencing, providing important information on possible virus origins and cell-binding receptors that is crucial for determining viral transmission capacity. 30 March: Singapore sequences its genome in less than 7 hours	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						14 April: In the UK, more than 600 genomes have been uploaded onto GISAID, using nanopore sequencing[313].		
End-to-end solution of sample processing to epidemiological info generation	Oxford Nanopore[311,314] UK	22 Jan 2020	**ARTIC project** A 'lab-in-a-suitcase' solution for processing samples from viral outbreaks, to generating real-time epidemiological information interpretable and actionable by public health bodies. Deployable to remote/resource-limited locations. Based on viral genome data generated prospectively during similar outbreaks (eg. MERS, SARS etc). Relies on direct amplification of the virus using tiled, multiplexed primers.	Not stated but described to have high sensitivity compared to metagenomic approaches.[315]	(no info)	Available 3 February: First Belgian nCoV sample arrives in a lab at 5pm and using the ARTIC protocol, the sequence is completed by 9am. 3 March: The SARS-CoV2 virus from Scotland's first case is sequenced in under 24 hours using nanopore sequencing and the ARTIC protocol[313].	(no info)	(no info)
2.1.3 Microfluidics								
Microfluidics [Point-of-Care]	Abbott Diagnostics[29,316] USA	27 Mar 2020	**ID Now COVID-19 test** Automated assay that runs on Abbott's ID Now platform.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 27 Mar 2020.	5-13 min (5 min for positive results, 13 min for negative results)	(no info)
Microfluidic	Veredus Laboratories[317-319] Singapore	24 Jan 2020	**VereCoV** Lab-on-Chip platform integrating PCR and microarray Claims to detect MERS-CoV, SARS-CoV and SARS-CoV-2 in a single test	Stated to be high but with no accompanying statistics.[320]	Stated to be high but with no accompanying statistics.[320]	Available for RUO since Jan 2020. Provisional approval for IVD by Singapore's HSA since Mar 2020.[319] Used for testing of swab samples from	2 hours[322]	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						Singapore's land, sea and air checkpoints since Mar 2020.[321]		
Microfluidic	Lexagene[323] USA	27 Jan 2020	Genetic analyser using microfluidic technology	(no info)	(no info)	Expected to be commercially available in Q3 2020.	1 hr	(no info)
Microfluidic	Shenzhen Shineway Technology[324,325] (collaboration with HKUST) Hong Kong	6 Feb 2020	Novel silicon-based micro-heater, which has lower thermal mass and a better thermal conductivity, could speed up temperature rises to around 30°C per second, greatly reducing the detection time compared to conventional PCR devices which has an average of 4-5°C per second.	(no info)	(no info)	Available. In use by the Centers for Disease Control and Prevention (CDCP) in Shenzhen and Guangzhou with two more sets being delivered to the CDCP in Hubei and Nansha.[325] Device already has CE Mark and is qualified for export to all European Union (EU) countries as well as Hong Kong.[324]	40 min	(no info)
Microfluidic	QIAGEN[326-328] The Netherlands	10 Feb 2020	**QIAStat-Dx Respiratory SARS-CoV-2 Panel [Plus]** Tests for two gene targets: ORF1b recommended by the Chinese CDC and N recommended by the US CDC.	100% (30/30) Evaluated using 10 positive clinical samples and 20 low positive contrived samples (1x–2x LOD) from retrospective nasopharyngeal swab clinical specimens in transport medium.[328]	100% (30/30) Evaluated using 30 negative samples from retrospective nasopharyngeal swab clinical specimens in transport medium.[328]	Commercially available. Obtained EUA approval from US FDA 30 Mar 2020.[327] Approved for inclusion in the Australian Register of Therapeutic Goods on 8 May 2020	About an hour (Press release:[329])	(by quote)
Microfluidic	GenMark Diagnostics[280,330,331] USA	11 Mar 2020	**ePlex SARS-CoV-2** Automated single cartridge using digital microfluidics.	100% (17/17) 65 fresh nasopharyngeal swab specimens from 3 clinical site2s were compared with one of two brands of established comparator assay.[280]	97.9% (47/48) 65 fresh nasopharyngeal swab specimens from 3 clinical site2s were compared with one of two brands of established comparator assay.[280]	Commercially available. Obtained EUA Approval 19 Mar 2020.[331]	Less than 2 hours[332]	(no info)
Microfluidic	Fluidigm[333]	16 Mar 2020	Aimed at using Fluidigm's Biomark HD system and	(no info)	(no info)	In development.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	USA		microfluidics technology, to develop integrated fluidic circuits for parallel assays.					
2.1.4 LAMP								
LAMP [Point-of-Care]	HiberGene Diagnostics[334,335] (collaboration with distribution partner in Shenzhen, China, Medcaptain Medical Technologies) Ireland	11 Feb 2020	**Loop-mediated isothermal amplification (LAMP)-based Coronavirus test** Allows for rapid near-patient testing	(no info)	(no info)	In development using the template of existing CE-marked Flu and RSV respiratory tests.	60-70 min (including patient sample preparation time)[335]	(no info)
LAMP	Atila BioSystems[168,336,337] USA	10 Apr 2020	**iAMP COVID-19 Detection Kit** Real-time fluorescent reverse transcription isothermal amplification **without requiring RNA extraction and can run up to 94 samples simultaneously.**[336,337] Tests for two gene targets: N & ORF1ab.	100% (35/35) 35 oropharyngeal swabs from healthy individuals spiked with iAMP COVID-19 Sample Buffer Mix (2x to 10x LoD) serving as contrived positive samples.[336]	100% (40/40) 40 oropharyngeal swabs from healthy individuals serving as negative controls.[336]	Commercially available. Obtained EUA approval from US FDA 10 Apr 2020.	51 min	(by quote)
2.1.5 Enzyme-assisted nanocomplex								
Enzyme-assisted nanocomplex	iHealthtech[318,338] (Asst Prof Shao Huilin) Singapore	3 Feb 2020	**enVision (enzyme-assisted nanocomplexes for visual identification of nucleic acids)** Uses enzyme-assisted nanocomplexes	(no info)	(no info)	In development.	30 min	(no info)
2.1.6 CRISPR-based diagnostics								
CRISPR-based diagnostics	Sherlock Biosciences[34,137,284,339] (Plus collaboration with Cepheid)[137] USA	24 Jan 2020	**SHERLOCK (Specific High-sensitivity Enzymatic Reporter unLOCKing)** SHERLOCK platform uses various CRISPR proteins (Cas13, Cas12a, and Csm6) to allow for simultaneous detection of multiple nucleic acids.[137]	(no info)	(no info)	Protocol published 14 Feb 2020.[340,341]	(no info)	(no info)
CRISPR-based diagnostics	Mammoth Biosciences[32-35]	30 Jan 2020	**SARS-CoV-2 DNA Endonuclease-Targeted CRISPR Trans Reporter (DETECTR)**	95% (Using contrived reference samples and clinical samples from US patients, including 36	Specificity: 100% (Using contrived reference samples and clinical samples from US	Developed. Awaiting EUA from US	45 minutes (with manual RNA extraction)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
	(Partnering with UCSF Researchers) USA		Using the CRISPR Cas12 that cleaves a FAM-Biotin reporter molecule. Tests for two gene targets: E & N2.	patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release:[342] Study:[35]	patients, including 36 patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release:[342] Study:[35]	FDA (pending clinical validation) (Press release:[342] Study:[35]	(Press release:[342] Study:[35]	
2.1.7 Immunoassay for SARS-CoV-2 antigens								
Immunoassay for SARS-CoV-2 viral nucleoprotein antigens	SD Biosensor [343] South Korea		**STANDARD F COVID-19 Ag FIA** Fluorescent immunoassay to detect SARS-CoV-2 infection in human nasopharyngeal swab specimen by identifying the existence of SARS-CoV-2 viral nucleoprotein antigens	Higher sensitivity than rapid test	(no info)	Available. Obtained CE certification	30 minutes	(no info)
Immunoassay for SARS-CoV-2 antigens	SD Biosensor [52] South Korea		**STANDARD Q COVID-19 Ag** Rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in the human nasopharynx	(no info)	(no info)	Available. Obtained CE certification	30 minutes	(no info)
Immunoassay for SARS-CoV-2 antigens [Point-of-Care]	Sona Nanotech[344] (collaboration with GE Healthcare Life Sciences, The Native Antigen Company, Bond)[345] [346] Canada	10 Feb 2020	Proprietary nanotechnology lateral flow test using antigens specific to SARS-CoV-2 produced at Native's Oxford facility using proprietary mammalian VirtuE expression system.	(no info)	(no info)	In development.	5-15 min	<$50
2.1.8 Others								
Carbohydrate-based glycation	Iceni Diagnostics[347]	20 Mar 2020	Carbohydrate-based, lateral flow assay for detection of	(no info)	(no info)	In development.	(no info)	(no info)

Molecular Tests								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
pattern detection	UK		glycation patterns of SARS-CoV-2					
(no info)	Lab Geneomics[126] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Undergoing commercialisation as of 6 Feb 2020	(no info)	(no info)

Table 2.2 Upcoming/Available Diagnostics: Serological tests

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
2.2.1 Total Antibody Immunoassays								
Total Antibody Immunoassay (ELISA)	Bio-Rad Laboratories[213]		**ELISA Total Antibodies Platelia SARS-CoV-2 Total Antibody Assay[348]** Qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma EDTA	100% in Serum, 83.33% in Plasma	99.51% in Serum, 100% in Plasma	FDA EUA issued on 29/04/2020[348]	(no info)	(no info)
Total antibody immunoassay	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd[349] China		**Wantai SARS-CoV-2 Ab Rapid Test Kit** Rapid qualitative detection of total antibodies against SARS-CoV-2 in human serum, plasma or whole blood specimens, employing chromatographic lateral flow device in a cassette format (colloidal gold)	96.6% (131/137) Evaluated using 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals	95.2% (199/209) Evaluated using 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals	Available. CE-IVD marked. Approved for inclusion into the Australian Register of Therapeutic Goods on 27 March 2020.[138]	(no info)	(no info)
Total Antibody Immunoassay	Wadsworth Center[350]		**New York SARS-CoV Microsphere Immunoassay for Antibody Detection** [351] Qualitative detection of total antibodies to SARS-CoV-2 in human serum.	88.0% (95/108)	99.6% (Blood donors), 98.7% (Diverse group of viral pathogens), 96.7% (Respiratory infections), 97.1% (Other study with respiratory infections)	FDA EUA issued on 30/04/2020 [351]	(no info)	(no info)
Total antibody Immunoassay	Roche Diagnostics		**Elecsys Anti-SARS-CoV-2[352]** Immunoassay for qualitative detection of antibodies to SARS-CoV-2	65.5% (76/116, Day 0-6 post-PCR confirmation); 88.1% (52/59, Day 7-13 post-PCR confirmation); 100% (29/29, >/= 14 days post-PCR confirmation)	99.81% (5262/5272)	FDA EUA issued on 2 May 2020[352] Date of Provisional Authorisation from HSA: 5 May 2020 [353]	(no info)	(no info)
Total Antibody immunoassay [Point-of-Care]	Mologic (partnership with the Institut Pasteur de Dakar)[354,355] UK	25 Feb 2020	Lateral flow immunoassay for detection of antibodies for SARS-CoV-2.	98% at days 14-21 [356] [357]	98%[356]	Developed. Ready for manufacture with CE mark.[356]	10 min	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
2.2.2 IgG/IgM antibody immunoassay								
IgG/IgM antibody immunoassay (ELISA)	Livzon[130] (collaboration with Wuhan Institute of Virology, Chinese Academy of Science)	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (ELISA)** Indirect method for ELISA for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China's NMPA on 28 Jan 2020. Approved on 14 March for commercial use. [358]	(no info)	(no info)
IgG/IgM antibody immunoassay (colloidal gold) [Point-of-Care]	Mobidiag (in collaboration with Autobio Diagnostics) [191] Finland		**Anti-SARS-CoV-2 Rapid Test** Immunoassay Anti-SARS-CoV-2 Rapid Test is based on a colloidal gold method for the rapid, qualitative determination of SARS-CoV-2 IgG/IgM antibodies in human serum, plasma or whole blood.	97.4%	96.2%	CE-IVD marked. For in vitro diagnostic use. FDA EUA issued on 24/04/2020	<15 min	(no info)
IgG/IgM antibody immunoassay (colloidal gold)	Livzon[130] (collaboration with Wuhan Institute of Virology, Chinese Academy of Science)	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (colloidal gold)** Immunochromatography assay for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China's NMPA on 2 Feb 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 23 April 2020.	15 mi	(no info)
IgG/IgM antibody immunoassay	Camtech Diagnostics Pte Ltd[359] Singapore		**Camtech COVID-19 IgM/IgG** Immunoassay kit for the rapid and differential detection of IgG and IgM against COVID-19 using serum, plasma and whole blood.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 09/04/2020	10 Minutes	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgG/IgM antibody immunoassay (CLIA)	Shenzhen Tisenc Medical Device[54] (collaboration with Shenzhen University and Shenzhen No.3 People's Hospital) China	12 Feb 2020	**2019 Novel Coronavirus IgM kit (CLIA)** **2019 Novel Coronavirus IgG kit (CLIA)** Chemiluminescence antibody test kit using serum or plasma.	IgM kit - 96.6% (29/30) IgG kit - 96.6% (29/30)[360]	(no info)	Available. Received CE certification on 6 March 2020[360]	22 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG/IgM antibody immunoassay (CLIA)	Snibe Diagnostic[361,362] China	28 Feb 2020	**Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits** Fully automated CLIA using 10µL sample volume of serum or plasma.	Differs across different durations from symptom onset <5 days: IgA – 3.3% (1/30); IgG – 10% (3/30) 5-10 days: IgA – 15.4% (2/13); IgG – 53.8% (7/13) 10-21 days: IgA – 60% (3/5); IgG – 100% (5/5)[363]	(no info)	Available. Have been distributed in China and will soon be in Italy. Received CE Mark 19 Feb 2020.[362]	30 min	(no info)
IgG/IgM antibody immunoassay	GenBody Inc (South Korea)[206]		**GenBody COVID-19 IgM/IgG** Point-of-care chromatographic immunoassay kit for the rapid and differential detection of anti-SARS-CoV-2 IgM and IgG using serum, plasma and whole blood from capillary blood samples.[206]	Sensitivity : 50% at Day 1-6, 91.7% at after Day 7[206]	Specificity : 97.5%[206]	Availability: Approved for inclusion on the Australian Register of Therapeutic Goods on 28 April 2020.	10 minutes	(no info)
IgG/IgM antibody immunoassay	Healgen Scientific Limited Liability Company (USA)[364]		**COVID-19 Antibody Rapid Detection Kit[364]** Rapid test for the qualitative, differential detection of both anti-SARS-CoV-2 IgM and IgG antibodies from whole blood, serum and plasma, using lateral flow method	Sensitivity: IgG 97.2%; IgM 87.9%	Specificity: IgG 100%; IgM 100%	Approved for inclusion on the Australian Register of Therapeutic Goods on 29 April 2020. Pending FDA approval	10 minutes	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgG/IgM antibody immunoassay	PCL		**PCL COVID19 IgG/IgM Rapid Gold**[127] Qualitative detection of COVID-19 IgG/IgM antibodies using lateral flow technique	100%		Approved for inclusion on the Australian Register of Therapeutic Goods on 1 May 2020. [127]	10 minutes	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	BioMedomics / Jiangsu Medomics Medical Technology[53,56,57] USA / China	21 Feb 2020	**COVID-19 IgM/IgG Rapid Test** Lateral flow immunoassay with both IgM and IgG antibodies adhered using colloidal gold. Can be used with fingerstick whole blood.	**88.66%** 352 positives out of 397 positive cases: - 256 both IgG and IgM - 72 IgG - 24 IgM	**90.63%** 12 positives out of 128 negative controls: - 1 both IgG and IgM - 1 IgG - 10 IgM	Commercially available. More than half a million sold in China. Received CE Mark for IVD 8 Mar 2020. Already sold in Italy.[57] Submitted to US FDA for EUA approval.[58,59]	15 min	(no info)
IgG/IgM antibody immunoassay	Shenzen YHLO Biotech Co. Ltd (China)[365]		**iFlash 8000 CLIA analyser**[366] Fully Automated chemiluminescent immunoassay for anti-SARS-CoV-2 IgM and IgG antibodies.	Sensitivity: 81.5% for IgM, 100% for IgG[366]	Specificity: 88.1% for IgM, 92.8% for IgG[366]	(no info)	(no info)	(no info)
IgG/IgM antibody immunoassay	Biolidics Limited[367] Singapore		**Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit** Also marketed as **Biolidics 2019-nCoV IgG/IgM Detection Kit** Detection of 2019-nCoV IgG and IgM in human serum, plasma and whole blood	(no info)	(no info)	Date of Provisional Authorisation by HSA: 20/03/2020	(no info)	(no info)
IgG/IgM antibody immunoassay	Everest Links Pte Ltd[368] Singapore		**VivaDiag™ COVID-19 IgM/IgG Rapid Test** In vitro diagnostic test for the qualitative determination of COVID-19's igM and IgG antibodies in human blood, serum and plasma.	(no info)	(no info)	Date of Provisional Authorisation by HSA: 20/03/2020 Date of approval for inclusion into ARTG: 26/03/2020	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgG/IgM antibody immunoassay	Grit Overseas Pte Ltd [369]		**DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette**	(no info)	(no info)	Date of Provisional Authorisation from HSA: 24/04/2020	(no info)	(no info)
IgG/IgM antibody immunoassay	CTK Biotech Inc[370] USA		**OnSite COVID-19 IgG/IgM Rapid Test** Designed for initial screening by detecting anti-SAR-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood	96.9%	99.4%	Available commercially. Approved for inclusion into the Australian Register of Therapeutic Goods on 19 March 2020. [138]	10 minutes	(no info)
IgG/IgM antibody immunoassay	Qingdao Hightop Biotech Co Ltd[371] China		**SARS-CoV-2 IgM/IgG Antibody Rapid Test** Qualitative detection of SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood samples	IgM – 82% IgG – 93%	IgM – 97% IgG – 97.5%	Available. Approved for inclusion into the Australian Register of Therapeutic Goods on 31 March 2020. [138]	15 minutes	(no info)
IgG/IgM antibody immunoassay	Hangzhou Realy Tech Co Ltd China		**2019-nCOV/COVID-19 IgG/IgM Rapid Test Device** Lateral flow IgG/IgM	(no info)	(no info)	Approved for inclusion on the Australian Register of Therapeutic Goods on 16 April 2020 138	(no info)	(no info)
IgG/IgM antibody immunoassay	Hangzhou Clongene Biotech Co Ltd China		**COVID-19 IgG/IgM Rapid Test Cassette** Rapid point-of-care lateral flow chromatographic immunoassay for the qualitative detective of IgG and IgM antibodies to SARS-CoV-2	IgM – 87.01% (67/77) IgG – 99.42% (75/77) [372]	IgM – 98.89% (89/90) [372]	Available. Received CE mark.[372] Approved for inclusion into the Australian Register of Therapeutic Goods on 26 March 2020 [138]	(no info)	(no info)
IgG/IgM antibody immunoassay	Hangzhou Biotest Biotech Co Ltd China		**COVID-19 IgG/IgM Rapid Test Cassette** Rapid chromatographic immunoassay for the qualitative detection of IgG	IgG – 100% (75/75) IgM – 91.8% (78/85)[373]	IgG – 99.5% (369/371); IgM – 99.2% (368/371)[373]	Available. Received CE mark. Approved for inclusion into the Australian Register of	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma			Therapeutic Goods on 4 April 2020. [138]		
IgG/IgM antibody immunoassay [Point-of-Care]	Guangzhou Wondfo Biotech[43-47] China	20 Feb 2020	**Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)** Colloidal gold method for IgM and IgG antibody detection.	(no info)	(no info)	Available. Approved by China's NMPA. Received CE Mark Mar 2020.[47,48] Obtained HSA provisional approval on 9 April 2020, supplied through SkyQuest Pte Ltd.[374] Approved for inclusion on the Australian Register of Therapeutic Goods on 25 March 2020.[138] Date of Provisional Authorisation from HSA: 27 April 2020[375]	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Hangzhou AllTest Biotech[80,376,377] China	2 Mar 2020	**2019-nCoV IgG/IgM Rapid Test Cassette** Lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimen.	IgM test **85.0%** (17/20) IgG test **100.0%** (20/20) Tested with the results compared to leading commercial PCR.	IgM test **96.0%** (48/50) IgG test **98.0%** (49/50) Tested with the results compared to leading commercial PCR.	Commercially available. Received CE Mark for IVD. Approved for inclusion in Australia's ARTG.[80] Used in study by Lee et al (2020).[378]	10 min	(by quote)
IgG/IgM antibody immunoassay [Point-of-Care]	Pharmact AG[49] Germany	10 Mar 2020	**CoV-2 Rapid Test** Using drops of blood from fingerstick onto test cassette, with two drops of buffer solution.	(no info)	(no info)	Available.	20 min	€39.95

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
IgG/IgM antibody immunoassay [Point-of-Care]	Zhejiang Orient Gene Biotech[50,51] China	10 Mar 2020	**COVID-19 IgG/IgM Rapid Test** Solid phase immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2 using human whole blood, serum or plasma.	IgM test **87.9%** (87/99) IgG test **97.2%** (35/36) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	IgM test **100%** (14/14) IgG test **100%** (14/14) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	Available. Received CE Mark. Currently one of only a few tests used for coronavirus screening in China. Commercialisation and distribution licensing deal with Aytu Bioscience for USA. Approved for inclusion on Australia's ARTG on 1 April 2020.[80]	2-10 min	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	SD Biosensor[52] South Korea	(Webpage found as of 12 Mar 2020)	**STANDARD Q COVID-19 IgM/IgG Duo** Immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2 using human whole blood, serum or plasma.	Sensitivity at 81.8% (27/33)[52]	Specificity at 96.7% (29/30)	Available.	10 min	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Chembio Diagnostic Systems[379-381] USA	20 Mar 2020	**DPP COVID-19 IgM/IgG System** Lateral flow assay testing for IgM and IgG, to be read using the DPP Micro Reader or DPP Micro Reader 2 (not visually).	IgM: 50% (3/6) IgG: 100% (6/6) Tested with fresh, fingerstick blood samples prospectively-collected from 11 hospital workers in the United States (New York), 6 of whom were confirmed positive cases with results from FDA-authorised RT-PCR test.[380]	IgM: 100% (6/6) IgG: 100% (6/6) Tested with fresh, fingerstick blood samples prospectively-collected from 11 hospital workers in the United States (New York), 5 of whom were confirmed negative with results from FDA-authorised RT-PCR test.[380]	Commercially available. Obtained EUA approval from US FDA 14 Apr 2020.	10-15 min	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Cellex[60,331] USA	1 Apr 2020	**qSARS-CoV-2 IgG/IgM Rapid Test** For "aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical	93.8% (120/128) Tested with 98 positive serum or plasma samples collected from individuals who tested	96.0% (240/250) Tested with negative serum or plasma samples collected prior to September 2019.[60]	Commercially available. Obtained EUA approval from US FDA 1 Apr 2020.	15-20min	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			presentation and the results of other laboratory tests."[60] Can be used with serum, plasmas, or whole blood from venepuncture (not fingerstick).	positive with RT- PCR and 30 samples from hospitalised individuals who were clinically confirmed positive and exhibited severe symptoms.[60]		Approved for inclusion in Australia's ARTG 31 Mar 2020.[80]		
IgG/IgM antibody immunoassay	Ortho Clinical Diagnostics[382-384] USA	6 Apr 2020	**VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack** Runs on VITROS ECi/ECiQ/3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems. Can run up to 150 samples per hour.[384]	83.3% (30/36) Tested with 36 samples from patients confirmed to be SARS-CoV-2 positive with PCR.[383]	100% (400/400) 400 presumed SARS-CoV-2 negative samples from healthy blood donors serving as negative controls.[383]	Available. Obtained EUA approval from US FDA 14 Apr 2020.	48 min (Up to 150 samples per hour)	(no info)
IgG/IgM antibody immunoassay	Duke-NUS Medical School[40,41] (Prof Wang Linfa) Singapore	26 Feb 2020	IgM or IgG antibody detection.	(no info)	(no info)	Available (not commercially).	(no info)	(no info)
IgG/IgM antibody immunoassay	Nankai University[55] (in collaboration with KingFocus Biomedical) China	17 Feb 2020	**Novel Coronavirus (2019-nCoV) IgM/IgG antibody detection kit**	75% (30/40) in first clinical trial, but suboptimal in the second trial[385]	(no info)	Available non-commercially in China.[385]	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Hangzhou Laihe Biotech Co Ltd[386] China		**Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)** POCT rapid SARS-CoV-2 IgM/IgG antibody test	(no info)	(no info)	Commercially available. Approved for inclusion into the Australian Register of Therapeutic Goods on 6 April 2020.[138]	Within 10 min	$20 per test kit
IgG/IgM antibody immunoassay	**Shanghai LiangRun** [387] China	27 April 2020	**LionRun Diagnostic Kit for Antibody IgM-IgG of Novel Coronavirus COVID-19** An in vitro diagnostic test for the qualitative and differential detection of IgM	(no info)	(no info)	Date of Provisional Authorisation from HSA: 27 April 2020	(no info)	

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
			and IgG antibodies against SARS-CoV-2					
IgG/IgM antibody immunoassay	Grey Solutions Pte Ltd [388]		**i-Test COVID -19 IgM/IgG Antibody Rapid Test (Colloidal Gold)** The test is an in-vitro qualitative determination of Novel coronavirus (COVID2019) Antibody in human serum or plasma or whole blood.	(no info)	(no info)	Date of Provisional Authorisation from HSA: 30 April 2020	(no info)	
IgG/IgM antibody immunoassay [Point-of-Care]	Innovation Scientific Pty Ltd (Australia) [303]		**InnoScreen COVID-19 IgG/IgM Rapid Test** Lateral Flow IgG/IgM [Point-of-care]	(no info)	(no info)	Approved for inclusion in the Australian Register of Therapeutic Goods on 11 May 2020	(no info)	
2.2.3 IgM Antibody Immunoassay								
IgM antibody immunoassay [Point-of-Care]	Guangzhou Medical University[11,42] (Dr Zhong Nanshan) In collaboration with Jiangsu Medomics Medical Technologies and many other institutes China	15 Feb 2020	**SARS-CoV-2 rapid IgG-IgM combined antibody kit (colloidal gold)** In-vitro detection of IgG/IgM antibodies using lateral flow immunoassay techniques [389, 56]	88.66% (352/397) Evaluated using blood samples from 397 clinically confirmed (including PCR test) SARS-CoV-2-infected patients.[56]	90.63% (116/128) Evaluated using blood samples from 128 non-SARS-CoV-2-infected patients.[56]	Available for use in China but not commercially	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgM antibody immunoassay	Innovita Biological Technology[43] China	23 Feb 2020	**2019-nCoV Antibody Test (colloidal gold)** IgG and IgM antibody detection from venous whole blood/ plasma/ serum samples	87.3% [390]	100% [390]	Available commercially. Approved by China's NMPA. Approved for inclusion on the Australian Register of Therapeutic Goods.[80] CE-IVD approved. [3] Partnered with Scanwell Health to be distributed in US, together with an	(no info)	Projected to be $70 as distributed by Scanwell Health [390]

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
						accompanying smartphone app, pending US FDA EUA approval. [390] Date of Provisional Authorisation from HSA: 27 April 2020		
2.2.4 IgG Antibody Immunoassay								
IgG antibody immunoassay	Abbott Laboratories Inc.[391,392] USA	15 Apr 2020	**SARS-CoV-2 IgG test** Lab-based serology test for the detection of IgG. Can run on ARCHITECT® i1000SR and i2000SR laboratory instruments.	Sensitivity: 0% (Less than 3 days post symptom onset), 25% (3-7 days post symptoms onset), 86.36% (8-13 days post symptoms onset), 100% (more than 14 days post symptoms onset) [393]	Specificity: 100% (73/73) [393]	Commercially available. FDA EUA issued on 23/04/2020 Date of Provisional Authorisation from HSA: 30 April 2020 [394]	(100-200 tests per hour)	(no info)
IgG Antibody immunoassay	Mount Sinai Laboratory [395]		**COVID-19 ELISA IgG Antibody test** ELISA performed for the qualitative detection of human IgG antibodies in serum and plasma specimens collected from individuals suspected of prior infection with the virus that causes COVID-19. Detection of IgG SARS-CoV-2 antibodies. The presence of IgG antibodies defines IgG antibody seroconversion and generally becomes detectable beginning 10-14 days following infection.	92% (37/40)	100% (74/74)	Available. EUA issued on 15th April 2020.	(no info)	(no info)
IgG Antibody detection	Ortho-Clinical Diagnostics, Inc. [396]		**VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack**	87.5% (42/48)	100% (407/407)	FDA EUA issued on 24/4/2020	(no info)	(no info)
IgG Antibody detection	Diasorin Inc.[397]		**LIAISON SARS-CoV-2 S1/S2 IgG**	25% (Less than 5 days from diagnosis), 89.8% (6-14 days from diagnosis),	99.3% (1082/1090)	FDA EUA issued on 24/4/2020	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	**Organisation**	**Reported**	**Test**	**Sensitivity**	**Specificity**	**Availability**	**Turnaround**	**Costs**
				97.56% (More than 15 days from diagnosis)				
2.2.5 IgA/IgG antibody immunoassay								
IgA/IgG antibody immunoassay	EUROIMMUN AG[398-400] Germany	21 Feb 2020	**Anti-SARS-CoV-2 ELISA** ELISA for IgG and IgA antibody detection. S1 domain of the spike protein is used as the substrate in the ELISAs as it is considered immunogenic and is evolutionarily less conserved, leading to high specificity. [401]	Sensitivity: 90% (27/30) Specificity: 100% (80/80)[402]	IgG – 99% IgA – approximately 90%, not recommended for screening [403]	Commercially available. CE-marked since 25 March 2020 [251]	2 hours [404]	(no info)

RT-PCR: reverse transcription polymerase chain reaction

NGS: next generation sequencing

LAMP: loop-mediated isothermal amplification

CLIA: chemiluminescence immunoassay

ddPCR: digital droplet polymerase chain reaction

IgM: Immunoglobulin M

IgG: Immunoglobulin G

IgA: Immunoglobulin A

E: envelope gene

N: nucleocapsid protein gene

Nsp: non-structural protein gene

ORF: open reading frame gene

RdRp: RNA-dependent RNA polymerase gene

S: spike protein gene

RUO: Research Use Only

IVD: In Vitro Diagnostics

CDC: Centers for Disease Control and Prevention

CE Mark: Conformitè Europëenne (CE) Mark – European Union's mandatory conformity marking for regulating goods sold in European Economic Area

EUA: emergency use assessment

FDA: Food & Drug Administration (US)

NMPA: National Medical Products Administration (China)

ARTG: Australian Register of Therapeutic Goods (Australia)

HSA: Health Services Authority (Singapore)

rxn: reactions

Table 3. Approaches for Coronavirus Diagnostics

Type	Test	Coronavirus	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pUC57SARS-pS2	SARS-CoV					
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pGEM-MERSS2	MERS-CoV					
RT-PCR	Singleplex RT-iiPCR assays targeting open reading frame 1a gene: MERS-CoV ORF1a	MERS-CoV	99.3%	(no info)			
RT-PCR	Singleplex RT-iiPCR assays targeting envelope gene: upE RT-iiPCR	MERS-CoV	100%	(no info)			
rRT-PCR	AccuPower (Bioneer, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	Anyplex (Seegene, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	DiaPlexQ (SolGent, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	LightMix (Roche Molecular Diagnostics, Switzerland) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	UltraFast kits (Nanobiosys, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	PowerChek (Kogene Biotech, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	TaqMan probe-based one-step rRT-PCR assays for upE and ORF1b genes.	MERS-CoV					
rRT-PCR	Monoclonal antibodies-based rapid nucleoprotein assay	MERS-CoV	Detection limit of about 103.7-104.2 $TCID^{50}$/ml of MERS-CoV				
RT-LAMP	Two primer sets with one targeting the N gene and one targeting the ORF1a gene	MERS-CoV					
RT-LAMP-VF	Two primer sets with one targeting the N gene and one targeting the ORF1a gene combined with vertical flow visualization strip using nucleic acid visualization technique.	MERS-CoV		No cross-reactivity to multiple SARS-related-CoVs, including HKU1, HKU4, OC43 and 229E.			
(novel)	Arch-shaped multiple-target sensor	MERS-CoV				20 min	

RT-PCR: reverse transcription polymerase chain reaction

rRT-PCR: real-time reverse transcription polymerase chain reaction

RT-LAMP: reverse transcription loop-mediated isothermal amplification

RT-LAMP-VF: reverse transcription loop-mediated isothermal amplification with a vertical flow visualization strip

upE: envelope gene

ORF1a: open reading frame 1a

ORF1b: open reading frame 1b

Table 4. Gene Targets and Specimen Sample Types Tested with PCR

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
Ong et al (2020)[405]	RdRp E	81 min 15 sec	3 cases* Singapore	Surface environment, personal protective equipment, and air samples.
Chan et al (2020)[334]	RdRp S	200 min	6 cases Shenzhen, China	Nasopharyngeal and throat swabs, and stool and urine samples.
Huang C et al (2020)[406]	E	51 min 45 sec	41 cases Wuhan, China	Nasal and pharyngeal swabs, bronchoalveolar lavage fluid, sputum, or bronchial aspirates.
Phan et al (2020)[407]	(no info)	(no info)	2 cases Ho Chi Minh, Vietnam	Throat swab.
Chen Z et al (2020)[408]	E (same as Huang et al)	51 min 45 sec	99 cases Wuhan, China	Throat swab. (Plus sputum or endotracheal aspirates?)
Holshue et al (2020)[409]	N gene (Testing by US CDC)	(US CDC protocol)	1 case Snohomish County, USA	Nasopharyngeal and oropharyngeal swabs, stool and serum.
Lei et al (2020)[410]	(no info)	(no info)	1 case Lanzhou, China	Sputum.
Liu P et al (2020)[411]	(no info)	(no info)	1 case Hunan, China	Throat swab.
Chang et al (2020)[412]	(Testing by Beijing CDC)	(no info)	13 cases Beijing, China	Throat swabs.
Fang Y et al (2020a)[413]	(no info)	(no info)	2 cases Linhai, China	Sputum.
Liu K et al (2020)[414]	ORF1ab N (Biogerm test kit)	51 min 45 sec	137 cases 9 hospitals across Hubei province, China	Sputum and nasopharyngeal swab.
Shi et al (2020a)[71]	(no info)	(no info)	1 case Wuhan, China	Sputum.
Wang D et al (2020)[415]	ORF1ab N	60 min	138 cases Wuhan, China	Throat swab.
Liu Y et al (2020)[416]	ORF1ab N (GeneoDx test kit)	(Chinese CDC protocol)	12 cases Shenzhen, China	Throat swabs and bronchoalveolar lavage fluid.
Wang Z et al (2020)[417]	E (same as Huang et al)	51 min 45 sec	4 cases Shanghai, China	Throat swab.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
Bastola et al (2020)[418]	(Testing by WHO lab in Hong Kong)	(no info)	1 case Nepal	Throat swab.
Chen H et al (2020)[419]	ORF1ab N (Biogerm test kit)	51 min 45 sec	9 cases (pregnant women) Wuhan, China	Throat swab.
Duan et al (2020)[420]	(no info)	(no info)	1 case Guangzhou, China	Pharyngeal swab.
Huang P et al (2020)[421]	(no info)	(no info)	1 case Zhuhai, China	Sputum.
Li X et al (2020)[422]	(no info)	(no info)	1 case Hefei, China	Sputum.
Liu Y et al (2020)[423]	[cited Corman et al (2020) – assume E and RdRp genes]	(no info)	1 case Taiwan	Throat swab.
Liu T et al (2020)[424]	(no info)	(no info)	3 cases Zhuhai, China	Sputum.
Ng et al (2020)[425]	[cited Chan et al (2020) – assume RdRp and S genes]	200 min	21 cases [6 previously reported in Chan et al (2020)] Hong Kong and Shenzhen, China	Nose and throat swabs, and stool and urine samples.
Silverstein et al (2020)[426]	(no info)	(no info)	1 case Toronto, Canada	Mid-turbinate and throat swabs.
China CDC (2020)[427]	(no info)	(no info)	72,314 cases China	Throat swabs.
Wei M et al (2020)[428]	(no info)	(no info)	9 cases (infants under 1 yr) China	Nasopharyngeal swab.
Wu Y et al (2020)[429]	(no info)	(no info)	1 case Wuhan, China	Nasopharyngeal swab.
Van Cuong et al (2020)[430]	(sample ran by National Institute of Hygiene and Epidemiology)	(no info)	1 case Hanoi, Vietnam	Nasopharyngeal swab.
Xu Z et al (2020)[431]	(Testing by Beijing CDC)	(no info)	1 case Beijing, China	Throat swab.
Fang Y et al (2020b)[432]	(Shanghai ZJ Bio-Tech test kit)	(no info)	51 cases	Throat swab or sputum sample.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Taizhou, China	
Huang W et al (2020) [433]	(Testing by Taiwan CDC)	(no info)	2 cases Taichung, Taiwan	Nasopharyngeal swab.
Zou et al (2020)[434]	N ORF1b	(no info)	18 cases Zhuhai, China	Nasal and throat swabs.
Xu X et al (2020a)[435]	(no info)	(no info)	62 cases 7 hospitals in Zhejiang province, China	Throat swabs and sputum samples.
Bernheim et al (2020)[69]	(Test kits by Sansure Biotech, Shanghai Zhijiang Biotechnology, or Da An Gene)	(no info)	121 cases China	Nasopharyngeal or oropharyngeal swab, bronchoalveolar lavage fluid, or endotracheal aspirate.
Zhu N et al (2020)[436]	RdRp	41 min 50 sec	3 cases Wuhan, China	Bronchoalveolar lavage fluid.
Pan et al (2020)[437]	(no info)	(no info)	2 cases Beijing, China	Throat swabs, sputum, urine, and stool samples.
Shi et al (2020b)[71]	E	(no info)	81 cases Wuhan, China	Throat swabs.
Wei J et al (2020)[438]	(no info)	(no info)	1 case Nanchang, China	Sputum.
Yang W et al (2020)[439]	(no info)	(no info)	149 cases Wenzhou, China	Nasal and pharyngeal swabs, sputum.
Lan et al (2020)[440]	ORF1ab N (Biogerm test kit) [cited Wang D et al (2020)]	60 min [cited Wang D et al (2020)]	4 cases Wuhan, China	Throat swabs.
Cai et al (2020)[441]	ORF1ab N	(no info)	10 cases (children) China	Nasopharyngeal and throat swabs, urine and serum samples.
Guan at al (2020)[442]	(no info)	(no info)	1099 cases China	Nasal and pharyngeal swabs.
Kam et al (2020)[443]	N ORF1ab	89 min 10 sec 72 min 30 sec	1 case Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Lillie et al (2020)[444]	(no info)	(no info)	2 cases UK	Nasopharyngeal, nose and throat swabs.
Ling et al (2020)[445]	(no info)	(no info)	66 cases	Oropharyngeal swabs or stool samples.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Shanghai, China	
Tian et al (2020)[446]	(no info)	(no info)	2 cases Wuhan, China	Pharyngeal swab.
Li K et al (2020)[447]	(no info)	(no info)	83 cases Chongqing and Jinan, China	Throat swabs or lower respiratory tract samples.
Wu J et al (2020)[448]	N ORF1ab (Biogerm test kit)	48 min 20 sec	80 cases 3 hospitals across Jiangsu province, China	Nose and/or throat swabs.
Xiong et al (2020)[449]	(no info)	(no info)	42 cases Wuhan, China	Nasopharyngeal or oropharyngeal swabs.
Young et al (2020)[450]	N ORF1ab S	89 min 10 sec 72 min 30 sec 72 min 30 sec	18 cases Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Zhu et al (2020)[451]	(no info)	(no info)	6 cases Guangzhou, China	Oropharyngeal swabs.
Fan et al (2020)[452]	(Testing by NCID)	(no info)	69 cases Singapore	Respiratory samples.
Hu et al (2020)[453]	(Test kit by BGI Genomics)	(no info)	24 cases Nanjing, China	Pharyngeal swabs.
Li Y et al (2020) [454]	(no info)	(no info)	51 cases Wuhan, China	Oropharyngeal swabs.
Yan et al (2020)[455]	N ORF1ab	(no info)	2 cases Singapore	Nasopharyngeal swabs.
Liu Y et al (2020)[456]	(no info)	(no info)	18 cases (pregnant women) China	Oropharyngeal swabs.
Wang et al (2020)[457]	(Testing by Henan CDC)	(no info)	18 cases Zhengzhou, China	Throat swabs.
Xia et al (2020)[458]	(no info)	(no info)	20 cases (children) Wuhan, China	Pharyngeal swabs.
Zhou et al (2020)[459]	(no info)	(no info)	62 cases Wuhan, China	Respiratory samples.

E: envelope gene

N: nucleocapsid protein gene

ORF: open reading frame gene

RdRp: RNA-dependent RNA polymerase gene

S: spike protein gene

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