



COVID-19 Science Report: Diagnostics

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Announcement

We started the first of our COVID-19 Science Reports in the last week of January 2020, as the very first wave of the COVID-19 pandemic reached Singapore. It was a rapid scan for the current state of development of diagnostics, therapeutics and vaccines that could be useful against the novel coronavirus, as it was called then. It was an urgent request made on a Monday night, and we managed to deliver by that week Friday afternoon.

Since then, it has been a weekly saga (some might call it a nightmare), as we continued to scan and update these reports (highlighting the updated text and paragraphs each week) and added more chapters, first on symptoms and signs, then on laboratory and imaging findings, and then on containment measures. Each addition was responding to yet another urgent request and delivered in the same three to four days, and subsequently updated each week as we continued our scans.

By the fifth week, the Science Report had grown to well over a hundred pages (not counting of course the references) and had become somewhat unwieldy. This was also the same time we were requested to make the report available for downloading on the School's website. We broke up the report into five stand-alone Science Reports and launched them online on 28 February. We were pleasantly surprised by its reception. What started off as "national service" to support our local healthcare and government sector was praised, shared, and even tweeted about.

As the pandemic progressed, we did other reports as well, of course, for the government and for other agencies, not all of which made it online for various reasons. We summarised the available data on fomite-mediated transmission, the risks and management of persons in high density accommodations, how different countries are moving into lockdowns, the use of digital technologies in containment, business continuity measures for enterprises, stay home strategies, and more.

Through it all, our small team were able to deliver on time each week, working through weekends, juggling pieces of work in progress and helped by a group of enthusiastic and hardworking medical students and Public Health interns (some of whom were volunteering their vacations to help). It's been 19 weeks since we started the Science Reports and it is a good time to review and consolidate.

There are now many repositories that cover much of the same ground as our clinical characteristics, diagnostics, therapeutics and vaccines reports. There is also a lot more known about these aspects as clinicians around the world treat their patients. Our student interns have to move on as well, some to examinations, others back to their courses. We will therefore freeze our reports on 1 June 2020, enabling us to focus on the ones that continue to be of critical importance in the global and national responses to COVID-19.

For continuing information on **diagnostics** of COVID-19, please see:

- **FIND SARS-CoV-2 Diagnostic Pipeline**. *Outlines the diagnostics that have been commercialised, are in development or withdrawn.*
- **WHO COVID-19 Pandemic EUL open for IVD**. *Compiles the diagnostic products that have obtained emergency use approvals in countries under International Medical Device Regulators Forum jurisdictions.*
- **360Dx Coronavirus Test Tracker**. *A regularly updated list of select commercially available diagnostics, highlighting those with regulatory approval.*
- **American Chemical Society Central Science review**. *Covers the background of the various test targets and technologies. The review includes lists of select commercially available diagnostics for different categories of test targets.*
- **Nature** *Covers the rapid point-of-care tests for SARS-CoV-2 and includes a list of select commercially available antibodies and antigen tests.*

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Diagnostics

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. IDT²⁴ and LGC, Biosearch Technologies²⁵ 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. The team has partnered up with the Agency for Science, Technology and Research's (A*Star) Diagnostics Development Hub (DxD Hub) and biotech company GenScript Biotech Corporation in development and manufacture of the kit.⁴²

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.^{11,43} 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.⁴⁴⁻⁴⁷ 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.^{48,49} Pharmact AG from Germany,⁵⁰ Zhejiang Orient Gene Biotech,^{51,52} and SD Biosensor⁵³ 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,⁵⁴ Shenzhen Tisenc Medical Devices,⁵⁵ and Nankai University⁵⁶ 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.⁵⁴ 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.⁵⁷ 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 2020.⁵⁸ BioMedomics is seeking to obtain EUA approval from US FDA.^{59,60}

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."⁶¹ 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.⁶² 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 Icen Diagnostics.⁶³ They are using lateral flow assays (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.⁶⁴ 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.⁶⁵

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.^{5,66} 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.⁶⁷

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.⁶⁸ 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.^{69,70} 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.⁷¹⁻⁷³ 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.⁷⁴

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.^{75,76} 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.⁷⁶ 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.⁷⁷

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.⁷⁸ 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.⁷⁹ 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.⁸⁰ 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).⁸¹

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.⁸²

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.^{83,84} 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.⁸⁵ However, initial rapid guidelines from China only indicated the use of throat swabs.⁸⁶

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-2.⁸⁷ 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.⁸⁷ 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.⁸⁷ 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.⁸⁸ 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.⁸⁹

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.⁹⁰

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.⁹¹

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-19.⁹² 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.⁹³ 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.⁹²

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.^{94,95} 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.⁹⁵ 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.⁹⁶ This would allow improved comfort for the patients, while minimizing exposure of healthcare providers.

Process of Laboratory Diagnosis

A commentary ⁹⁷ 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-19.⁹⁸ 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 ^{1,99}	13 Jan 2020	Primer and Probe First line screening assay: E gene assay Confirmatory assay: RdRp gene assay Additional confirmatory assay: N gene assay	<u>First line screening assay</u> Technical LOD: 5.2 RNA copies/reaction, at 95% hit rate 95% CI: 3.7-9.6 RNA copies/reaction. <u>Confirmatory assay</u> Technical LOD: 3.8 RNA copies/reaction, at 95% hit rate 95% CI: 2.7-7.6 RNA copies/reaction. <u>Additional confirmatory assay</u> Technical LOD: 8.3 RNA copies/reaction, at 95% hit rate; 95% CI: 6.1-16.3 RNA copies/reaction.	<u>Chemical stability</u> No positive signal detected for non-specific reactivity of oligonucleotides. <u>Cross-reactivity with other coronaviruses</u> No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV <u>Tests of human clinical samples previously tested to contain respiratory viruses</u> 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	<u>First line screening assay</u> Technical LOD: 5.2 RNA copies/reaction, at 95% hit rate 95% CI: 3.7-9.6 RNA copies/reaction. <u>Confirmatory assay</u> 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.)	<u>Chemical stability</u> No positive signal detected for non-specific reactivity of oligonucleotides. <u>Cross-reactivity with other coronaviruses</u> No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV <u>Tests of human clinical samples previously tested to contain respiratory viruses</u> 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	<u>Positive control using SARS-CoV RNA</u> Wide dynamic range of 2 ⁻⁴ to 2000 TCID ₅₀ /reaction.	<u>Exclusivity</u> 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)		<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 ¹⁰⁰	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 ¹⁰¹	Jan 2020	With gel electrophoresis	(no info)	(no info)	Available Primers: <ul style="list-style-type: none"> • NbatCoV_F1 • NbatCoV_R1 	107 min of cycle time	(no info)
RT-PCR	National Institute of Infectious Diseases, Japan ¹⁰²	23 Jan 2020	With gel electrophoresis (Nested RT-PCR) Primer and Probe (Real-time RT-PCR)	(no info)	(no info)	Available Primers and probes: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 103		<p>GS COVID-19 RT-PCR Kit</p> <p>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.</p>	100% (32/32)	100% (32/32)	<p>Available.</p> <p>EUA issued on 16th April 2020.</p>	(no info)	(no info)
RT-PCR Kit	KorvaLabs Inc. 104		<p>Curative-Korva SARS-CoV-2 Assay</p> <p>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.</p>	100% (5/5)	100% (5/5)	<p>Available.</p> <p>EUA issued on 16th April 2020.</p>	(no info)	(no info)
RT-PCR Kit	Genosensor, LLC 103		<p>GS COVID-19 RT-PCR Kit</p> <p>Real-time reverse transcription polymerase chain reaction test intended</p>	100% (32/32)	100% (32/32)	<p>Available.</p> <p>EUA issued on 16th April 2020.</p>	(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. 104		<p>Curative-Korva SARS-CoV-2 Assay</p> <p>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.</p>	100% (5/5)	100% (5/5)	Available. EUA issued on 16th April 2020.	(no info)	(no info)
RT-PCR Kit	Shanghai Fosun Long March Medical Science Co. Ltd ¹⁰⁵ Manufactured for: Fosun Pharma USA Inc.		<p>COVID-19 RT-PCR Detection Kit</p> <p>Real-time RT-PCR for qualitative detection of SARS-CoV-2 ORF1ab, N and E gene targets</p> <p>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</p>	99.51% (203/204) ¹⁰⁶	96.44% (379/393) ¹⁰⁶	Available. EUA issued on 17th April 2020 Received CE mark on 17 March 2020. Received emergency approval from the National Medical Products Administration	Within 2 Hours	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			nasal swabs, mid-turbinate nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, sputum, lower respiratory 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.			(NMPA) on 27 March 2020. Approved for inclusion in the Australian Register of Therapeutic Goods on 8 May 2020 ¹⁰⁷		
RT-PCR assay	Rhoenix, Inc. ¹⁰⁸		Rhoenix COVID-19 MDx Assay ¹⁰⁹ 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% ¹⁰⁹	100%	FDA EUA issued on 29/04/2020 ¹⁰⁹	(no info)	(no info)
RT-PCR assay	LabGenomics Co., Ltd ¹¹⁰		LabGun COVID-10 RT-PCR Kit ¹¹¹ 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) ¹¹¹	100% (100/100) ¹¹¹	FDA EUA issued on 29/04/2020 ¹¹¹	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Biopertectus Technologies ¹¹² China	14 Jan 2020	RT-PCR test kit	(no info)	(no info)	Available as scientific research product – does not require registration ¹¹²	(no info)	(no info)
RT-PCR	Co-Diagnostics ¹¹³⁻¹¹⁵ USA	23 Jan 2020	Logix Smart Coronavirus COVID-19 test RT-PCR kit with lower false positive	100% (21/21) ¹¹⁶	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. ^{113,117} 100% ¹¹⁶	Commercially available for sale on 10 Feb 2020. ¹¹⁴ Received CE Mark 24 Feb 2020. ¹¹⁸ Obtained EUA approval from US FDA 3 Apr 2020. ¹¹⁵	Within 2 hours ¹¹⁶	(no info)
RT-PCR	Altona Diagnostics ^{119,120} Germany	23 Jan 2020	RealStar SARS-CoV-2 RT-PCR Kit 1.0 Real time RT-PCR for qualitative detection of SARS-CoV-2 RNA (target genes E gene and S gene).	95% (24/25) detection for S gene; 100% (25/25) detection for E gene.	35/35 for both S and E gene.	Available FDA EUA issued on 22 April 2020 Received CE mark for IVD HSA provisional authorisation approved on 15 May 2020 ¹²¹	2:15 hours ¹²²	(no info)
RT-PCR	Roche ¹²³⁻¹²⁶ 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)	100% (100/100) 100 nasopharyngeal swab clinical samples serve as negative controls. ¹²⁶	Commercially available. Obtained EUA approval from US FDA 13 Mar 2020. ¹²⁵ CE Mark for IVD.	3 hr 30 min	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
				contrived positive samples ¹²⁶		Approved for inclusion on the Australia's ARTG on 20 March 2020. Date of HSA Provisional Authorisation: 19/03/2020 ¹²⁷		
RT-PCR	A*STAR ^{4,128} (Manufactured by Singapore's MiRxes which has a nonexclusive license) ¹²⁹ Singapore	1 Feb 2020	A*STAR Fortitude 2.0 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	100% ¹³⁰	100%	Available but not for commercial sale yet. Provisional authorization for clinical use from Singapore's HSA. ^{4,129} Date of Provisional Authorisation from HSA: 30 April 2020	90 minutes	(no info)
RT-PCR	PCL ¹³¹ South Korea	3 Feb 2020	Multiplex diagnostic kit PCLMD-nCoV one step RT-PCR kit Organisation: PCL ¹³² Qualitative detection of SARS-Co-V-2 by sputum samples	Sensitivity: 100% (35/35) ¹³²	(no info)	Developed as of 3 Feb 2020. CE approved ¹³²	1 hr 45 min	(no info)
RT-PCR	Biomeme ^{133,134} 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 ¹³⁵	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 ¹³⁶	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Acumen Research Laboratories ¹³⁷ 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 Authorisation from HSA on 14 April 2020. (HSA authorisation for Acu-Corona 2.0: ¹³⁸ HSA authorisation for Acu-Corona 3.0: ¹³⁹ Currently CE-IVD pending and approved for research only, seeking approval from US Food and Drug Authorisation	Allows up to 94 patient samples per 1.5h	(no info)
RT-PCR [Point-of-Care]	Cepheid ^{27,140,141} (Plus collaboration with Sherlock Biosciences) ¹⁴² 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. ¹⁴¹	100% (35/35) 35 nasopharyngeal swab specimens serving as negative controls. ¹⁴¹	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. ¹⁴³	45 min	(no info)
RT-PCR	TIB-Molbiol ^{124,144} (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. ¹⁴⁴	(no info)	About €160 ¹⁴⁴

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	AusDiagnostics ¹⁴⁵⁻¹⁴⁷ Australia	16 Feb 2020	AusDiagnostics respiratory virus panel (including SARS-CoV-2) test Multiplex panel. Tests for two gene targets: ORF1a & ORF8	100% ¹⁴⁷	100% ¹⁴⁷	Commercially available. Received CE Mark Mar 2020. ¹⁴⁷ Approved for inclusion in Australia's ARTG. ⁸¹	3 hr ¹⁴⁶	(no info)
RT-PCR	Seegene ^{148,149} South Korea	18 Feb 2020	Allplex 2019-nCoV Assay Single-tube assay that tests for three gene targets: E, RdRp, and N.	100% (49/49) from upper respiratory specimens (nasopharyngeal/oropharyngeal swabs) 100% (49/49) from lower respiratory specimens (sputum) ¹⁵⁰	94% (94/100) from upper respiratory specimens (nasopharyngeal/oropharyngeal swabs) 97.87% (92/94) from lower respiratory specimens (sputum) ¹⁵⁰	Commercially available. Obtained EUA approval from Korean FDA 12 Feb 2020. ^{151,152} Product already has CE Mark for IVD. Obtained HSA provisional approval on 2 April 2020, supplied through All Eights (Singapore) Pte Ltd. ¹⁵³ Approved for inclusion on the Australian Register of Therapeutic Goods on 27 March 2020 ¹⁴³ FDA EUA issued 21/04/2020	1 hour 50 minutes after extraction ¹⁵⁰	(no info)
RT-PCR [Point-of-Care]	Credo Diagnostics Biomedical ^{154,155} 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)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Osang Healthcare ^{156,157} (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 to 4x LoD) serving as contrived positive samples ¹⁵⁸	100% for both upper and lower respiratory tract samples Evaluated using 30 nasopharyngeal swabs and sputum specimens serving as negative controls ¹⁵⁸	Available. Received CE Mark for IVD. Obtained EUA approval from US FDA on 18 April 2020. ¹⁵⁸ Date of Provisional Authorisation from HSA: 14 May 2020, supplied through SPD Scientific Pte Ltd ¹⁵⁹	About 120 minutes ¹⁵⁸	(no info)
RT-PCR [Point-of-Care]	Mesa Biotech ^{28,30,160-162} 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. ¹⁶²	100% (30/30) 30 nasopharyngeal swabs serving as negative controls. ¹⁶²	Commercially available. Obtained EUA approval from US FDA 23 Mar 2020.	30 min	(no info)
RT-PCR	Luminex ¹⁶³⁻¹⁶⁵ USA	4 Mar 2020	NxTAG CoV Extended Panel Assay 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. Date of Provisional Authorisation from HSA: 8 May 2020 ¹⁶⁶	4 hr (2 hr 15 min to 2 hr 25 min cycle time)	(no info)
RT-PCR	LGC Biosearch Technologies ^{25,167}	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 ¹⁶⁷
RT-PCR	Fulgent Therapeutics, LLC ¹⁶⁸ USA	11 Mar 2020	COVID-19 Virus Testing by RT-PCR Real-time RT-PCR for the qualitative detection of SARS-CoV-2 N1 and N2	100% (30/30)	100% (64/64)	Submitted to US FDA for EUA Approval. Commercially Available ¹⁶⁹	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			genes in upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal direct swab specimens)			FDA EUA issued on 15/5/2020 ¹⁷⁰		
RT-PCR	bioMérieux ¹⁷¹⁻¹⁷³ (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. ¹⁷⁴	100% (66/66) 66 clinical nasopharyngeal swab specimens serving as negative controls. ¹⁷⁴	Commercially available. Obtained EUA approval from US FDA 24 Mar 2020. ¹⁷³	45 min	(no info)
RT-PCR	Hologic ¹⁷⁵⁻¹⁷⁷ 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 specimens were spiked with inactivated cultured SARS-CoV-2 virus (1x to 5x LoD) serving as contrived positive samples. ¹⁷⁷	100 (109/109) 109 remnant clinical nasopharyngeal specimens serving as negative controls. ¹⁷⁷	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020. Approved for inclusion into the Australian Register of Therapeutic Goods on 20 March 2020. ⁸¹	Can generate results in 3 hours ¹⁷⁸	(no info)
RT-PCR	LabCorp (Laboratory Corporation of America) ^{176,179} 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. ¹⁷⁹	100% (100/100) 50 nasopharyngeal swab specimens and 50 bronchoalveolar lavage specimens serving as negative controls. ¹⁷⁹	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 ¹⁸⁰	(no info)
RT-PCR	Quidel ^{181,182} 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	100% (92/92) 92 nasopharyngeal swab specimens were spiked with SARS-CoV-2 RNA (1x to 5x LoD) serving as contrived positive samples. ¹⁸²	(100% (92/92) 92 nasopharyngeal swab specimens serving as negative controls. ¹⁸²	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	45 min cycle time per gene	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			(pp1ab) of the SARS-CoV-2 virus. ¹⁸³					
RT-PCR	Quests Diagnostics ^{184,185} 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 with 6 additional randomly selected to be duplicated, serving as total 30 positive samples. ¹⁸⁵	100% (72/72) 72 presumed-negative nasopharyngeal/throat swab specimens from before Oct 2019 servings as negative controls. ¹⁸⁵	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 ^{27,186,187} USA	18 Mar 2020	Abbott RealTime SARS-CoV-2 assay Will run on the Abbott m2000 RealTime system. Tests for two gene targets: RdRp & N.	100% (60/60) 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. ¹⁸⁷	100% (31/31) 34 nasopharyngeal swabs serving as negative controls. 3 samples were invalidated and excluded. ¹⁸⁷	Commercially available. Obtained EUA approval from US FDA 18 Mar 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 17 April 2020. ¹⁴³ Date of HAS Provisional Authorisation: 01/04/2020 ¹⁸⁸	(no info)	(no info)
RT-PCR	DiaSorin Molecular ¹⁸⁹⁻¹⁹¹ 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 sites were compared with one of two brands of established comparator assay. ¹⁹¹	100% (56/56) 108 fresh nasopharyngeal swab specimens from 3 clinical sites were compared with one of two brands of established comparator assay. ¹⁹¹	Commercially available. Obtained EUA approval from US FDA 19 Mar 2020.	(no info)	(no info)
RT-PCR	DiaCarta ^{192,193} USA	23 Mar 2020	QuantiVirus SARS-CoV-2 Tests for two gene targets: N, ORF1ab, & E	96.7%	100%	Commercially available.	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
				Clinically validated in the company's CLIA-certified lab in Richmond, California.	Clinically validated in the company's CLIA-certified lab in Richmond, California.	Received CE Mark for IVD Mar 2020. Obtained EUA approval from US FDA 8 Apr 2020. ¹⁹⁴		
RT-PCR	PerkinElmer ^{28,195,196} 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. ¹⁹⁶	100% (94/94) 94 oropharyngeal and nasopharyngeal swab specimens serving as negative controls. ¹⁹⁶	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 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 ¹⁹⁷	104 min 30s cycle time per gene target.	(no info)
RT-PCR	Genetron Health ¹⁹⁸ China	7 Apr 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 ¹⁹⁹ 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-	(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. ²⁰⁰	48 samples in <3h	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			reaction with other endemic coronaviruses.			In the process for obtaining emergency use authorisation in Sweden and the UK. In the process for obtaining CE-IVD.		
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. ²⁰¹ Approved for inclusion into the Australian Register of Therapeutic Goods on 13 April 2020. ¹⁴³	(no info)	(no info)
RT-PCR	Shanghai ZJ Bio-Tech Co Ltd (also called Liferiver) ²⁰² China		Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes) Qualitative detection of SARS-CoV-2 by real time PCR	(no info)	(no info)	Available. Approved for inclusion into the Australian Register of Therapeutic Goods on 22 March 2020. ¹⁴³	(no info)	
RT-PCR	AITbiotech Pte Ltd ²⁰³ 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 ²⁰⁴ 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 ²⁰⁵ 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)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	JN Medsys Pte Ltd ²⁰⁶ 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 ²⁰⁷	(no info)
RT-PCR	Veredus Laboratories Pte Ltd ¹²⁷ 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 ²⁰⁸ 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)
RT-PCR	SPD Scientific Pte Ltd ²⁰⁹ 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 ²¹⁰		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 ²¹¹		BioWalker SARS-CoV-2 Assay 2.0 ²¹² 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 ²¹³		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. ²¹⁴		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) ²¹⁵		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)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	CTK Biotech Inc (United States of America) ²¹⁶		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 ¹³²		PCL COVID19 Ag Rapid FIA ¹³² 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 ²¹⁷		RT-PCR Test U-TOP COVID-19 Detection Kit ²¹⁸ Qualitative detection of SARS-CoV-2 antigens from oropharyngeal and nasopharyngeal swab specimens, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum samples	100% (for both nasopharyngeal and sputum) ²¹⁸	No cross-reactivity with 33 microorganisms	FDA EUA issued on 27/04/2020	(no info)	(no info)
RT-PCR	bioMérieux SA ²¹⁹		BioFire Respiratory Panel 2.1 ²²⁰ 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 ²²⁰ Date of Provisional Authorisation from HSA: 14 May 2020 ²²¹	Around 45 mins	(no info)
RT-PCR	Bio-Rad Laboratories, Inc. ²²²		Bio-Rad SARS-CoV-2 ddPCR Test ²²³ 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 ²²³	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Public Health England ²²⁴ 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. ²²⁵	(no info)	(no info)	Available (non-commercially) to 9 labs across the UK.	(no info)	(no info)
Real-time RT-RAA	Beijing Ditan Hospital ²²⁶ 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. Assay was performed at 42°C within 30min using a portable real-time fluorescence detector,	(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)
Real-time RT-PCR	ScienCell Research Laboratories ²²⁷⁻²²⁹ 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. ²²⁸	100% (30/30) 30 nasopharyngeal swabs serving as negative controls. ²²⁸	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 ^{230,231} China	29 Jan 2020	Fluorescent PCR ²³¹	(no info)	(no info)	Commercially available.	(no info)	€ 991 ²³²
Real-time RT-PCR	Liferiver Biotech ^{230,233} China	29 Jan 2020	Multiplex RT-PCR ²³³	(no info)	(no info)	Commercially available. Date of Provisional Authorisation from HSA: 4 May 2020 ²³⁴	(no info)	€ 1347 ²³⁵
Real-time RT-PCR	GenScript ^{230,236,237} USA	29 Jan 2020	qRT-PCR Targets RdRp gene, N gene and E gene in Wuhan-Hu-1	"This assay is RUO and has not been tested on clinical samples. We	"This assay may have cross-reactivity with other coronavirus family	Commercially available for RUO.	(no info)	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			genome (GenBank sequences NC_045512.2) [same as Charite's first protocol]	make no claims on the performance of this assay." ²³⁶	members such as causative agents of the Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS). ²³⁶			
Real-time RT-PCR	CerTest Biotec ²³⁸ Spain	30 Jan 2020	VIASURE 2019-nCoV Real Time PCR Kit Amplification of a fragment of the S gene. ²³⁹	97.5% ²⁴⁰	>99.9% ²⁴⁰	Available. Received CE Mark for IVD for the version adapted for the BD MAX™ System. ²³⁹ Approved for inclusion on Australia's ARTG on 21 March 2020.	120 minutes ²⁴⁰	(no info)
Real-time RT-PCR	GeneFirst ²⁴¹ 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 ²⁴¹ UK	3 Feb 2020	Multiplex assay which simultaneously detects SARS-CoV-2 as well as 17 other common viruses and bacteria	(no info)	(no info)	Available.	< 3 hr	(no info)
Real-time RT-PCR	Kogene Biotech ^{131,151} 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. ^{151,242} Approved for inclusion on the Australian Register of Therapeutic Goods.	(no info)	(no info)
Real-time RT-PCR	Thermo Fisher Scientific ^{133,243-245} 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	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	100% (60/60) 30 nasopharyngeal swab specimens and 30 bronchoalveolar lavage specimens were used as negative controls. ²⁴⁵	Commercially available. Received CE Mark for IVD 26 Mar 2020. ²⁴⁶ Obtained EUA approval from US FDA 13 Mar 2020. ²⁴⁴	36 min cycle time per gene target	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			genomes of other coronaviruses currently available at NCBI. Tests for three gene targets: ORF1ab, N, & S.	form 60 contrived positive samples. ²⁴⁵		Obtained HSA provisional approval on 20 March 2020. Approved for inclusion on the Australian Register of Therapeutic Goods on 24 March 2020.		
Real-time RT-PCR	US CDC ^{17,247,248} 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 ²⁴⁸) plus 1 human RNase P gene control.	100% (13/13) 117 respiratory specimens collected from 46 subjects tested with two analytically validated real-time RT-PCR assays for N4 and N5 gene targets. ²⁴⁷	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. ²⁴⁷	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. Not available to U.S. hospitals or other primary care settings. Obtained EUA approval from US FDA 4 Feb 2020.	(no info)	(no info)
Real-time RT-PCR	SolGent ^{151,152,249} South Korea	28 Feb 2020	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 N, ORF1a and PCRC genes in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes, bronchoalveolar lavage (BAL) fluid and sputum.	100%	100%	Commercially available. Obtained EUA approval from Korean CDC 27 Feb 2020. ^{151,152} Received CE Mark for IVD. FDA EUA issued on 21 May 2020 ²⁵⁰	2 hr PCR	(no info)
Real-time RT-PCR	SD Biosensor ^{151,152} South Korea	28 Feb 2020	STANDARD M n-CoV Real-Time Detection Kit	Sensitivity: 100% (30/30) ²⁵¹	Specificity: 100% (30/30) ²⁵¹	Available.	90 min ²⁵²	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Tests for two gene targets: E and RdRp.			Obtained EUA approval from Korean CDC 27 Feb 2020. ^{151,152} FDA EUA issued on 23/04/2020		
Real-time RT-PCR	Integrated DNA Technologies (IDT) ^{24,242} 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 ^{164,165,253,254} 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. ²⁵⁴	100% (30/30) 30 nasopharyngeal swabs serving as negative controls. ²⁵⁴	Commercially available. Obtained EUA approval from US FDA 3 Apr 2020.	2 hr	(no info)
Real-time RT-PCR	Genomica ^{255,256} Spain	6 Mar 2020	qCOVID-19 Real-time RT-PCR	Reported 100% . ²⁵⁵ Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Reported 100% . ²⁵⁵ Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Available. Received CE Mark 6 Mar 2020. ²⁵⁶	(no info)	(no info)
Real-time RT-PCR	Avellino Lab ²⁵⁷⁻²⁵⁹ 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. ²⁵⁹	100% (30/30) 30 oropharyngeal and nasopharyngeal swab specimens serving as negative controls. ²⁵⁹	Commercially available. Obtained EUA approval from US FDA 25 Mar 2020. ²⁵⁷		(no info)
Real-time RT-PCR	Wadsworth Center, New York State Department of Public Health ^{194,260} 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	(29/29) For the easyMAG extraction, 30 individual sputum samples were used but 1 was invalidated, leaving 29 samples. Testing was	Available. Obtained EUA approval from US FDA for use in Wadsworth Center, New York State Public	42 min 45 s cycle time per gene target	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
				to 200x LoD) to serve as contrived positive samples. Testing was also done with eMAG and EZ1 extraction. ²⁶⁰	also done with eMAG and EZ1 extraction. ²⁶⁰	Department of Health, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories.		
Real-time RT-PCR	NeuMoDx ²⁶¹⁻²⁶³	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. ²⁶³	100% (82/82) 82 clinical nasopharyngeal swab specimens serving as negative controls. ²⁶³	Commercially available. Obtained EUA approval from US FDA 30 Mar 2020. ²⁶¹	80 min	(no info)
Real-time RT-PCR	Becton Dickinson (BD) ²⁶⁴⁻²⁶⁶ 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 removed from data analysis. ²⁶⁴	100% (30/30) 30 retrospective collected clinical nasopharyngeal swab specimens serving as negative controls. ²⁶⁴	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. ⁸¹	2 hr	(no info)
Real-time RT-PCR	Maccura Biotechnology ^{257,267,268} 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. ²⁶⁸	100% (30/30) 15 nasopharyngeal and 15 oropharyngeal swab samples from suspected cases that tested negative had additional aliquot serving as 30 negative controls. ²⁶⁸	Commercially available. Received CE Mark in Mar 2020. ²⁶⁷ Obtained EUA approval from US FDA 15 Apr 2020.	37 min 10 s cycle time per gene target	(no info)
Real-time RT-PCR	Ipsium Diagnostics ^{269,270}	1 Apr 2020	COV-19 IDx assay N1 gene target	100% (36/36) 36 nasopharyngeal swabs spiked with BEI	100% (30/30)	Commercially available.	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
				ATCC Genomic RNA from SARS Related Coronavirus 2 (not actual clinical sample) serving as contrived positive samples. ²⁷⁰	30 nasopharyngeal swabs serving as negative controls. ²⁷⁰	Obtained EUA approval from US FDA 1 Apr 2020.		
Real-time RT-PCR	Gnomegen ^{271,272} (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. ²⁷²	100% (30/30) 30 oropharyngeal swabs serving as negative controls. ²⁷²	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 ^{248,273,274} 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. ²⁷³	96.7% (29/30) 30 nasopharyngeal swabs serving as negative controls. ²⁷³	Commercially available. Obtained EUA approval from US FDA 7 Apr 2020.	4 hr ²⁷⁴ (43 min 45 s cycle time for each gene) ²⁷³	(no info)
Real-time RT-PCR	Becton Dickinson (BD) ^{275,276} USA	8 Apr 2020	BD SARS-CoV-2 Reagents for BD MAX System Test is a rRT-PCR test intended for the qualitative 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	96% (48/50) 50 retrospective collected clinical nasopharyngeal swabs spiked with quantified genomic RNA of SARS-CoV-2 (1x to 5x LoD) serving as contrived positive samples. ²⁷⁶	100% (29/29) 29 retrospective collected clinical nasopharyngeal swab specimens serving as negative controls. ²⁷⁶	Commercially available. Obtained EUA approval from US FDA 8 Apr 2020. Date of Provisional Authorisation from HSA: 6 May 2020 ²⁷⁷	(no info)	(no info)
Real-time PCR and microarray technologies [Point-of-Care]	Mobidiag ²⁷⁸ (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) ¹⁹⁹	(no info)	(no info)	In development.	Less than an hour	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Real Time RT-PCR	BGI ²⁷⁹⁻²⁸¹ (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. ²⁸² 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% ²⁸³	BALF: 100% Throat Swab: 100% RNA: 96.2% Combined: 99.6% ²⁸³	Commercially available. Received CE Mark for IVD 2 Mar 2020. ²⁸⁴ BGI is also engaged with relevant organizations in Hong Kong, Taiwan, Brunei, Thailand, Nigeria, South Africa, to supply the test kits. ²⁷⁹ Passed emergency approval procedure of China's NMPA. Obtained EUA approval from US FDA 27 Mar 2020. ^{280,281} Approved for inclusion on Australia's ARTG on 10 April 2020. Date of Provisional Authorisation from HSA: 24 April 2020 ²⁸⁵	3 hr	(no info)
RT-PCR	CapitalBio ⁴⁵ (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 ²⁸⁶⁻²⁹¹ (molecular diagnostics division of Novacyt)	31 Jan 2020	Genesig Real-Time PCR COVID-19 (CE) <i>[Previously Coronavirus (Strain 2019-nCoV) Easy/Standard Kit]²⁸⁷</i>	96% ²⁹²	100%	Commercially available. Received CE Mark for IVD 17 Feb 2020. ^{293,294}	< 2 hr 64 min 30 s cycle time per gene ²⁹¹	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	France/UK		Can run on multiple molecular testing platforms, including Primerdesign's own genesig® q16 and q32 instrument			Obtained EUA approval from US FDA 20 Mar 2020. ²⁹⁰		
qPCR	Coyote Bioscience ^{133,295} 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 ²⁹⁵ India	12 Feb 2020	qPCR Truenat Beta CoV ²⁹⁶ Potentially real-time PCR then detection of wavelengths of fluorescent signal.	100% ²⁹⁷	100% ²⁹⁷	Available. Approved by the Indian Council of Medical Research for coronavirus testing in India on 4 April 2020. ²⁹⁸	55 min	Rs 1,000 – Rs 1,500) ²⁹⁸
qPCR [Point-of-Care]	OnSiteGene ²⁹⁵ (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 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. ²⁹⁹	(no info)	(no info)	Developed. Currently seeking collaborators to perform clinical tests in China and the US. ²⁹⁹	10 min	(no info)
PCR-based genotyping	Genomica ^{300,301} Spain	30 Jan 2020	CLART COVID-19 Based on Genomica's CLART technology of PCR-based genotyping with low-density microarray.	>96% ³⁰²	98%	Available. Received CE Mark 6 Mar 2020. ²⁵⁶	< 5 hr	(no info)
ddPCR	Bio-Rad Laboratories ³⁰³⁻³⁰⁵ 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. ³⁰⁴	(no info)	Commercially available. EUA Submission Pending ³⁰⁶	(no info)	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Conventional and Real Time RT-PCR	Genekam ^{307,308} Germany	4 Feb 2020	5 options: 1. Conventional PCR 2. Real Time PCR for nCoV only ³⁰⁹ 3. Multiplex Real Time PCR for nCoV + other Bat CoV ³¹⁰ 4. Multiplex Real Time PCR for nCoV + other Bat CoV + MERS ³¹¹ 5. Multiplex Real Time PCR for nCoV + Influenza A ³¹²	(no info)	(no info)	In development as of 6 Feb 2020	126 min 15 s ^{309,311} or 120 min ^{310,312} of cycle time	€ 599 ³⁰⁸ € 699 ³⁰⁸ € 799 ³⁰⁸ € 999 ³⁰⁸ € 899 ³⁰⁸
Combination of RT-PCR and meta-genomics detection	BGI ²⁷⁹ (Pathomics Health as distributor) ³¹³ 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 sequenced by PE100 in 22 hours, as well as possible mutation and evolution monitoring	(no info)
RT-PCR	Jiangsu Biopertectus Technologies Co Ltd ³¹⁴	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 ^{131,315} 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)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Bioneer ¹³¹ South Korea	3 Feb 2020	AccuPower COVID-19 Real-Time RT-PCR kit ³¹⁶	(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 ^{131,317} (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 ^{295,318} 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 ³¹⁹		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 and lower respiratory tract specimens.	(no info)	(no info)	Date of Provisional Authorisation from HSA: 4 May 2020	(no info)	(no info)
RT-PCR	Fast Track Diagnostics Luxembourg Sàrl. (a Siemens Healthineers Company)		FTD SARS-CoV-2. Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in oropharyngeal swabs, nasopharyngeal swabs, nasopharyngeal wash and bronchoalveolar lavage.	100% (44/44)	100% (30/30)	FDA EUA issued on 5 May 2020 ³²⁰	(no info)	(no info)
RT-PCR	bioMérieux SA ³²¹		ARGENE® SARS-CoV-2 R-gene test Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal	100% (76/76)	100% (50/50)	FDA EUA issued on 6 May 2020 ³²² CE marked on 10 April 2020, validated in France since 11 March 2020.	4-5 Hours	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes and bronchoalveolar lavage (BAL) fluid.					
RT-PCR	OPTI Medical Systems, Inc		OPTI SARS-CoV-2 RT-PCR Test Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in upper and lower respiratory specimens (such as nasal, nasopharyngeal, oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).	100% in both sputum and NP swab	100% in both sputum and NP swab	FDA EUA issued on 6 May 2020 ³²³	(no info)	(no info)
RT-PCR	Zymo Research Corporation		Quick SARS-CoV-2 rRT-PCR Kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in upper and lower respiratory specimens (such as nasal, nasopharyngeal, oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).	100% (30/30)	100% (30/30)	FDA EUA issued on 7 May 2020 ³²⁴	(no info)	(no info)
RT-PCR	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University		Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, and	100% for nasopharyngeal and oropharyngeal swabs (30/30) as well as saliva	100% for nasopharyngeal and oropharyngeal swabs (30/30) as well as saliva	FDA EUA issued on 7 May 2020 ³²⁵	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			bronchoalveolar lavage (BAL) fluid.					
RT-PCR	Abbott Molecular Inc. ³²⁶		Alinity m SARS-CoV-2 assay Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in oropharyngeal (throat) swab, nasopharyngeal swab, nasal swabs, and bronchoalveolar lavage (BAL) fluid	100% (31/31)	100% (40/40)	FDA EUA issued on 11 May 2020	(no info)	(no info)
RT-PCR	1drop Inc. ³²⁷		1 copy™ covid-19 qPCR multi kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 E and ³²⁶ RdRp gene in nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal swab specimens as well as nasopharyngeal wash/aspirate and nasal aspirate specimens.	100% (30/30)	(No info)	FDA EUA issued on 11 May 2020	(no info)	(no info)
RT-PCR	Applied DNA Sciences, Inc. ³²⁸		Linea™ COVID-19 Real Time PCR Assay Kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in nasopharyngeal, oropharyngeal and nasal swab specimens as well as nasopharyngeal wash/aspirate and nasal aspirate specimens.	98% (62/63)	93% (63/67)	FDA EUA issued on 13 May 2020	(no info)	(no info)
RT-PCR	GeneMatrix, Inc. ³²⁹		NeoPlex™ COVID-19 Detection Kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in nasopharyngeal, oropharyngeal and nasal swab specimens as well as nasopharyngeal	100% for nasopharyngeal, oropharyngeal and sputum samples (40/40)	100% for nasopharyngeal, oropharyngeal and sputum samples (40/40)	FDA EUA issued on 14 May 2020	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			wash/aspirate and nasal aspirate specimens.					
RT-PCR	Assurance Scientific Laboratories ³³⁰		Assurance SARS-CoV-2 Panel Real-time RT-PCR for the qualitative detection of SARS-CoV-2 E, N1 and N2 genes in upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs).	100% (38/38 using samples extracted with Abnova Precipitor; 34/34 using samples extracted with Zymo Research Kit on the IndiMag)	100% (30/30 using samples extracted with Abnova Precipitor; 48/48 using samples extracted with Zymo Research Kit on the IndiMag)	FDA EUA issued on 15 May 2020	(no info)	(no info)
Real Time RT-PCR	Quidel Corporation ³³¹		Lyra® Direct SARS-CoV-2 Assay Real-time RT-PCR for the qualitative detection of SARS-CoV-2 RNA in upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs).	97% (29/30)	100% (30/30)	FDA EUA issued on 18 May 2020	(no info)	(no info)
RT-PCR	Wuhan EasyDiagnosis Biomedicine Co Ltd (China) ³³²		COVID-19 (SARS-CoV-2) Nucleic Acid Test kit Real-time RT-PCR test kit, intended for the qualitative detection of nucleic acid from the SARS-CoV-2, in upper and lower respiratory tract specimens. Gene targets are the SARS-CoV-2 N and ORF1ab gene.	(no info)	(no info)	Approved for inclusion on the Australian Register of Therapeutic Goods on 19 May 2020. ³³³	(no info)	(no info)
RT-PCR	AMT Pte Ltd		AMT RESOLUTE 1.0 Real-time RT-PCR for the qualitative detection of SARS-CoV-2 RNA. RNA extraction is not required as this kit is intended for direct amplification of SARS-CoV-2 RNA from nasopharyngeal swabs in universal transport medium.	(no info)	(no info)	HSA provisional authorisation approved on 20 May 2020 ³³⁴	(no info)	(no info)
RT-PCR	P23 Labs ³³⁵		P23 Labs TaqPath SARS-CoV-2 Assay Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 RNA in oropharyngeal (throat) swab, nasopharyngeal swab,	100% (31/31)	100% (11/11)	FDA EUA issued on 21 May 2020	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens as well as bronchoalveolar lavage (BAL) specimens.					
RT-PCR	BioCore		BioCore 2019-nCoV Real Time PCR Kit Real time RT-PCR Kit designed to qualitatively detect SARS-CoV-2 N and RdRp genes in upper respiratory specimens (such as nasal, mid-turbinate, oropharyngeal, and nasopharyngeal swabs) and lower respiratory specimens (such as sputum, bronchoalveolar lavage (BAL), and tracheal aspirates).	100% (20/20) for both nasopharyngeal and sputum specimens	100% (40/40) for both nasopharyngeal and sputum specimens	FDA EUA issued on 21 May 2020	(no info)	(no info)
2.1.2 Genome Sequencing								
NGS	IDbyDNA ^{336,337} USA	29 Jan 2020	Next-generation sequencing-based metagenomics, allows enhanced pathogen detection and profiling in comparison to conventional PCR testing. ³³⁷	(no info)	(no info)	Commercially available.	(no info)	(by quote)
NGS	Fulgent Genetics ¹⁶⁸ 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 ^{338,339} 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	(no info)	(no info)	Available. 28 January: US Centers for Disease Control and Prevention (CDC) releases nCoV genomes sequenced with nanopore sequencing	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			consensus viral genome from sample within a day.			<p>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.</p> <p>30 March: Singapore sequences its genome in less than 7 hours</p> <p>14 April: In the UK, more than 600 genomes have been uploaded onto GISAID, using nanopore sequencing³⁴⁰.</p>		
End-to-end solution of sample processing to epidemiological info generation	Oxford Nanopore ^{338,341} UK	22 Jan 2020	<p>ARTIC project</p> <p>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.</p> <p>Deployable to remote/resource-limited locations.</p> <p>Based on viral genome data generated prospectively during similar outbreaks (eg. MERS, SARS etc).</p>	Not stated but described to have high sensitivity compared to metagenomic approaches. ³⁴²	(no info)	Available	(no info)	(no info)
						<p>3 February: First Belgian nCoV sample arrives in a lab at 5pm and using the ARTIC protocol, the sequence is completed by 9am.</p> <p>3 March: The SARS-CoV2 virus from Scotland's first case is sequenced in under 24 hours using nanopore sequencing and the ARTIC protocol³⁴⁰.</p>		

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Relies on direct amplification of the virus using tiled, multiplexed primers.					
2.1.3 Microfluidics								
Microfluidics [Point-of-Care]	Abbott Diagnostics ^{29,343} 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 ³⁴⁴⁻³⁴⁶ 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. ³⁴⁷	Stated to be high but with no accompanying statistics. ³⁴⁷	Available for RUO since Jan 2020. Provisional approval for IVD by Singapore's HSA since Mar 2020. ³⁴⁶ Used for testing of swab samples from Singapore's land, sea and air checkpoints since Mar 2020. ³⁴⁸	2 hours ³⁴⁹	(no info)
Microfluidic	Lexogene ³⁵⁰ 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 ^{351,352} (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. ³⁵² Device already has CE Mark and is qualified for export to all European Union (EU) countries as well as Hong Kong. ³⁵¹	40 min	(no info)
Microfluidic	QIAGEN ³⁵³⁻³⁵⁵ The Netherlands	10 Feb 2020	QIAStat-Dx Respiratory SARS-CoV-2 Panel [Plus]	100% (30/30)	100% (30/30)	Commercially available.	About an hour (Press release: ³⁵⁶)	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Tests for two gene targets: ORF1b recommended by the Chinese CDC and N recommended by the US CDC.	Evaluated using 10 positive clinical samples and 20 low positive contrived samples (1x–2x LOD) from retrospective nasopharyngeal swab clinical specimens in transport medium. ³⁵⁵	Evaluated using 30 negative samples from retrospective nasopharyngeal swab clinical specimens in transport medium. ³⁵⁵	Obtained EUA approval from US FDA 30 Mar 2020. ³⁵⁴ Approved for inclusion in the Australian Register of Therapeutic Goods on 8 May 2020		
Microfluidic	GenMark Diagnostics ^{291,357,358} 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 sites were compared with one of two brands of established comparator assay. ²⁹¹	97.9% (47/48) 65 fresh nasopharyngeal swab specimens from 3 clinical sites were compared with one of two brands of established comparator assay. ²⁹¹	Commercially available. Obtained EUA Approval 19 Mar 2020. ³⁵⁸	Less than 2 hours ³⁵⁹	(no info)
Microfluidic	Fluidigm ³⁶⁰ USA	16 Mar 2020	Aimed at using Fluidigm's Biomark HD system and microfluidics technology, to develop integrated fluidic circuits for parallel assays.	(no info)	(no info)	In development.	(no info)	(no info)
2.1.4 LAMP								
LAMP [Point-of-Care]	HiberGene Diagnostics ^{361,362} (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) ³⁶²	(no info)
LAMP	Atila BioSystems ^{176,363,364} 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. ^{363,364} 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. ³⁶³	100% (40/40) 40 oropharyngeal swabs from healthy individuals serving as negative controls. ³⁶³	Commercially available. Obtained EUA approval from US FDA 10 Apr 2020.	51 min	(by quote)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-LAMP	Seasun Biomaterials ³⁶⁵		AQ-TOP™ COVID-19 Rapid Detection Kit RT-LAMP test designed to qualitatively detect SARS-CoV-2 RNA in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens, bronchoalveolar lavage (BAL) specimens as well as sputum.	100% (20/20) for both nasopharyngeal and sputum specimens	100% (25/25) for both nasopharyngeal and sputum specimens	FDA EUA issued on 21 May 2020	(no info)	(no info)
2.1.5 Enzyme-assisted nanocomplex								
Enzyme-assisted nanocomplex	iHealthtech ^{345,366} (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 ^{34,142,29} ^{5,367} (Plus collaboration with Cepheid) ¹⁴² 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. ¹⁴² Designed to detect RNA from upper respiratory specimens (such as nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, nasopharyngeal wash/aspirate or nasal aspirate) and bronchoalveolar lavage specimens. Step one is a reverse transcriptase loop-mediated amplification (RT-LAMP) where targeted	100% (30/30)	100%	Protocol published 14 Feb 2020. ^{368,369} FDA EUA issued on 6/5/2020 ³⁷⁰	(no info)	(no info)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			SARS-CoV-2 genomic RNA is reverse transcribed to DNA, and this DNA is amplified by a strand-displacing DNA polymerase. Step two is the transcription of the amplified DNA to activate the collateral cleavage activity of a CRISPR complex programmed to the target RNA sequence.					
CRISPR-based diagnostics	Mammoth Biosciences ³²⁻³⁵ (Partnering with UCSF Researchers) USA	30 Jan 2020	SARS-CoV-2 DNA Endonuclease-Targeted CRISPR Trans Reporter (DETECTR) Using the CRISPR Cas12 that cleaves a FAM-Biotin reporter molecule. Tests for two gene targets: E & N2.	95% (Using contrived reference samples and clinical samples from US patients, including 36 patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release: ³⁷¹ Study: ³⁵	Specificity: 100% (Using contrived reference samples and clinical samples from US patients, including 36 patients with COVID-19 infection and 42 patients with other viral respiratory infections) (Press release: ³⁷¹ Study: ³⁵	Developed. Awaiting EUA from US FDA (pending clinical validation) (Press release: ³⁷¹ Study: ³⁵	45 minutes (with manual RNA extraction) (Press release: ³⁷¹ Study: ³⁵	(no info)
2.1.7 Immunoassay for SARS-CoV-2 antigens								
Immunoassay for SARS-CoV-2 viral nucleoprotein antigens	SD Biosensor ³⁷² 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 ⁵³ 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)

Molecular Tests								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Immunoassay for SARS-CoV-2 antigens [Point-of-Care]	Sona Nanotech ³⁷³ (collaboration with GE Healthcare Life Sciences, The Native Antigen Company, Bond) ³⁷⁴ ³⁷⁵ 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
Immunoassay for SARS-CoV-2 antigens	Quidel Corporation ³⁷⁶		Sofia 2 SARS Antigen FIA Lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens.	100% (47/47)	80% (84/96)	FDA EUA issued on 8 May 2020	(No info)	(No info)
2.1.8 Others								
Carbohydrate-based glycation pattern detection	Iceni Diagnostics ³⁷⁷ UK	20 Mar 2020	Carbohydrate-based, lateral flow assay for detection of glycation patterns of SARS-CoV-2	(no info)	(no info)	In development.	(no info)	(no info)
(no info)	Lab Geneomics ¹³¹ South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Undergoing commercialisation as of 6 Feb 2020	(no info)	(no info)
Target amplification assay	Hologic, Inc. ³⁷⁸		Aptima® SARS-CoV-2 Assay (Panther® System) Nucleic acid amplification in vitro diagnostic test designed to qualitatively detect RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/ aspirate or nasal aspirates.	98.2% (54/55)	100% (50/50)	FDA EUA issued on 14 May 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 ²²²		ELISA Total Antibodies Platelia SARS-CoV-2 Total Antibody Assay ³⁷⁹ 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 ³⁷⁹	(no info)	(no info)
Total antibody immunoassay	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd ³⁸⁰ 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. ¹⁴³	(no info)	(no info)
Total Antibody Immunoassay	Wadsworth Center ³⁸¹		New York SARS-CoV Microsphere Immunoassay for Antibody Detection ³⁸² 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 ³⁸²	(no info)	(no info)
Total antibody Immunoassay	Roche Diagnostics		Elecsys Anti-SARS-CoV-2 ³⁸³ 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 ³⁸³ Date of Provisional Authorisation from HSA: 5 May 2020 ³⁸⁴ Approved for inclusion on the Australian Register of Therapeutic Goods on 20 May 2020. ³⁸⁵	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Total Antibody immunoassay [Point-of-Care]	Mologic (partnership with the Institut Pasteur de Dakar) ^{386,387} UK	25 Feb 2020	Lateral flow immunoassay for detection of antibodies for SARS-CoV-2.	98% at days 14-21 ^{388 389}	98% ³⁸⁸	Developed. Ready for manufacture with CE mark. ³⁸⁸	10 min	(no info)
Total Antibody immunoassay	Ortho Clinical Diagnostics ³⁹⁰⁻³⁹² 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. ³⁹²	83.3% (30/36) Tested with 36 samples from patients confirmed to be SARS-CoV-2 positive with PCR. ³⁹¹	100% (400/400) 400 presumed SARS-CoV-2 negative samples from healthy blood donors serving as negative controls. ³⁹¹	Available. Obtained EUA approval from US FDA 14 Apr 2020. Date of Provisional Authorisation from HSA: 8 May 2020 ³⁹³	48 min (Up to 150 samples per hour)	(no info)
2.2.2 IgG/IgM antibody immunoassay								
IgG/IgM antibody immunoassay (ELISA)	Livzon ¹³⁵ (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. ³⁹⁴	(no info)	(no info)
IgG/IgM antibody immunoassay (colloidal gold) [Point-of-Care]	Mobidiag (in collaboration with Autobio Diagnostics) ¹⁹⁹ 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)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgG/IgM antibody immunoassay (colloidal gold)	Livzon ¹³⁵ (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 ³⁹⁵ 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)
IgG/IgM antibody immunoassay (CLIA)	Shenzhen Tisenc Medical Device ⁵⁵ (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) ³⁹⁶	(no info)	Available. Received CE certification on 6 March 2020 ³⁹⁶	22 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG/IgM antibody immunoassay (CLIA)	Snibe Diagnostic ^{397,398} 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) ³⁹⁹	(no info)	Available. Have been distributed in China and will soon be in Italy. Received CE Mark 19 Feb 2020. ³⁹⁸	30 min	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgG/IgM antibody immunoassay	GenBody Inc (South Korea) ²¹⁴		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. ²¹⁴	Sensitivity : 50% at Day 1-6, 91.7% at after Day 7 ²¹⁴	Specificity : 97.5% ²¹⁴	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) ⁴⁰⁰		COVID-19 Antibody Rapid Detection Kit⁴⁰⁰ 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)
IgG/IgM antibody immunoassay	PCL		PCL COVID19 IgG/IgM Rapid Gold¹³² 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. ¹³²	10 minutes	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	BioMedomics / Jiangsu Medomics Medical Technology ^{54,57,58} 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. ⁵⁸ Submitted to US FDA for EUA approval. ^{59,60}	15 min	(no info)
IgG/IgM antibody immunoassay	Shenzen YHLO Biotech Co. Ltd (China) ⁴⁰¹		iFlash 8000 CLIA analyser⁴⁰² Fully Automated chemiluminescent immunoassay for anti-	Sensitivity: 81.5% for IgM, 100% for IgG ⁴⁰²	Specificity: 88.1% for IgM, 92.8% for IgG ⁴⁰²	(no info)	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			SARS-CoV-2 IgM and IgG antibodies.					
IgG/IgM antibody immunoassay	Biolidics Limited ⁴⁰³ 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 ⁴⁰⁴ 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)
IgG/IgM antibody immunoassay	Grit Overseas Pte Ltd ⁴⁰⁵		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 ⁴⁰⁶ 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. ¹⁴³	10 minutes	(no info)
IgG/IgM antibody immunoassay	Qingdao Hightop Biotech Co Ltd ⁴⁰⁷ 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. ¹⁴³	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	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
						143		
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 detection of IgG and IgM antibodies to SARS-CoV-2	IgM – 87.01% (67/77) IgG – 99.42% (75/77) ⁴⁰⁸	IgM – 98.89% (89/90) ⁴⁰⁸	Available. Received CE mark. ⁴⁰⁸ Approved for inclusion into the Australian Register of Therapeutic Goods on 26 March 2020 ¹⁴³	(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 and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma	IgG – 100% (75/75) IgM – 91.8% (78/85) ⁴⁰⁹	IgG – 99.5% (369/371); IgM – 99.2% (368/371) ⁴⁰⁹	Available. Received CE mark. Approved for inclusion into the Australian Register of Therapeutic Goods on 4 April 2020. ¹⁴³	(no info)	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Guangzhou Wondfo Biotech ⁴⁴⁻⁴⁸ 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. ^{48,49} Obtained HSA provisional approval on 9 April 2020, supplied through SkyQuest Pte Ltd. ⁴¹⁰ Approved for inclusion on the Australian Register of Therapeutic Goods on 25 March 2020. ¹⁴³	15 min (unclear if serum/plasma extraction time included or not)	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
						Date of Provisional Authorisation from HSA: 27 April 2020 ⁴¹¹		
IgG/IgM antibody immunoassay [Point-of-Care]	Hangzhou AllTest Biotech ^{81,412,413} 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. ⁸¹ Used in study by Lee et al (2020). ⁴¹⁴	10 min	(by quote)
IgG/IgM antibody immunoassay [Point-of-Care]	Pharmact AG ⁵⁰ 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
IgG/IgM antibody immunoassay [Point-of-Care]	Zhejiang Orient Gene Biotech ^{51,52} 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. ⁸¹	2-10 min	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	SD Biosensor ⁵³ 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) ⁵³	Specificity at 96.7% (29/30)	Available.	10 min	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgG/IgM antibody immunoassay [Point-of-Care]	Chembio Diagnostic Systems ⁴¹⁵⁻⁴¹⁷ 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-authorized RT-PCR test. ⁴¹⁶	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-authorized RT-PCR test. ⁴¹⁶	Commercially available. Obtained EUA approval from US FDA 14 Apr 2020.	10-15 min	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Cellex ^{61,358} 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 presentation and the results of other laboratory tests." ⁶¹ Can be used with serum, plasmas, or whole blood from venepuncture (not fingerstick).	93.8% (120/128) Tested with 98 positive serum or plasma samples collected from individuals who tested positive with RT-PCR and 30 samples from hospitalised individuals who were clinically confirmed positive and exhibited severe symptoms. ⁶¹	96.0% (240/250) Tested with negative serum or plasma samples collected prior to September 2019. ⁶¹	Commercially available. Obtained EUA approval from US FDA 1 Apr 2020. Approved for inclusion in Australia's ARTG 31 Mar 2020. ⁸¹	15-20min	(no info)
IgG/IgM antibody immunoassay	Nankai University ⁵⁶ (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 ⁴¹⁸	(no info)	Available non-commercially in China. ⁴¹⁸	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 ⁴¹⁹ 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. ¹⁴³	Within 10 min	\$20 per test kit
IgG/IgM antibody immunoassay	Shanghai LiangRun ⁴²⁰ China	27 April 2020	LionRun Diagnostic Kit for Antibody IgM-IgG of Novel Coronavirus COVID-19	(no info)	(no info)	Date of Provisional Authorisation from HSA: 27 April 2020	(no info)	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			An in vitro diagnostic test for the qualitative and differential detection of IgM and IgG antibodies against SARS-CoV-2					
IgG/IgM antibody immunoassay	Grey Solutions Pte Ltd ⁴²¹		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)	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Innovation Scientific Pty Ltd (Australia) ³¹⁴		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)	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	MP Biomedicals Asia Pacific Pte Ltd ⁴²²		MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test Qualitative in vitro immunochromatographic test to detect and differentiate IgG/IgM antibodies against SARS-CoV-2 in human plasma, serum or whole blood with anti-coagulants	(no info)	(no info)	Date of Provisional Authorisation from HSA: 8 May 2020	(no info)	(no info)
IgG/IgM antibody immunoassay	Xiamen Boson Biotech Co. ⁴²³		Xiamen Boson Rapid 2019-nCoV IgG/IgM Combo Test Card Immunochromatography for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019- nCoV, SARS-CoV- 2) in human serum, plasma, or whole blood	(no info)	(no info)	Date of Provisional Authorisation from HSA: 14 May 2020, supplied by Trans Sahara Corporation Pte Ltd ⁴²⁴	15 mins	(no info)
IgG/IgM antibody immunoassay [Point-of-Care]	Atlaslink Beijing Technology Co Ltd (China) ⁴²⁵		NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold) Qualitative detection of IgG/IgM antibodies to	(no info)	(no info)	Approved for inclusion into the Australian Register of Therapeutic Goods on 18 May 2020	10 mins	(no info)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			SARS-CoV-2 in human serum, plasma or whole blood.					
IgG/IgM antibody immunoassay [Point-of-Care]	Healthgroup Medical Pte Ltd (Singapore)		HealthGroup Medical V-CODE Sars-CoV-2 (COVID-19) IgG/IgM Rapid Test Lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus (SARS-CoV-2) in human whole blood, serum or plasma.	(no info)	(no info)	HSA provisional authorisation approved on 18 May 2020 ⁴²⁶	(no info)	(no info)
2.2.3 IgM Antibody Immunoassay								
IgM antibody immunoassay [Point-of-Care]	Guangzhou Medical University ^{11,43} (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 ^{427, 57}	88.66% (352/397) Evaluated using blood samples from 397 clinically confirmed (including PCR test) SARS-CoV-2-infected patients. ⁵⁷	90.63% (116/128) Evaluated using blood samples from 128 non-SARS-CoV-2-infected patients. ⁵⁷	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 ⁴⁴ China	23 Feb 2020	2019-nCoV Antibody Test (colloidal gold) IgG and IgM antibody detection from venous whole blood/ plasma/ serum samples	87.3% ⁴²⁸	100% ⁴²⁸	Available commercially. Approved by China's NMPA. Approved for inclusion on the Australian Register of Therapeutic Goods. ⁸¹ CE-IVD approved. ³ Partnered with Scanwell Health to be distributed in US, together with an accompanying smartphone app,	(no info)	Projected to be \$70 as distributed by Scanwell Health ⁴²⁸

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
						pending US FDA EUA approval. ⁴²⁸ Date of Provisional Authorisation from HSA: 27 April 2020		
IgM antibody immunoassay	Epitope Diagnostics		EDI Novel Coronavirus COVID-19 IgM ELISA Kit Qualitative detection of human anti-COVID-19 IgG antibody in human serum using ELISA.	73.8% (34/42)	100% (153/153)	HSA provisional authorisation approved on 15 May 2020. ⁴²⁹ CE marked. ⁴³⁰ Pending EUA approval from US FDA.	90 minutes	(no info)
2.2.4 IgG Antibody Immunoassay								
IgG antibody immunoassay	Abbott Laboratories Inc. ^{431,432} 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) ⁴³³	Specificity: 100% (73/73) ⁴³³	Commercially available. FDA EUA issued on 23/04/2020 Date of Provisional Authorisation from HSA: 30 April 2020 ⁴³⁴	(100-200 tests per hour)	(no info)
IgG Antibody immunoassay	Mount Sinai Laboratory ⁴³⁵		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)

Serological tests (Antibody immunoassay test)								
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgG Antibody detection	Ortho-Clinical Diagnostics, Inc. ⁴³⁶		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. ⁴³⁷		LIAISON SARS-CoV-2 S1/S2 IgG	25% (Less than 5 days from diagnosis), 89.8% (6-14 days from diagnosis), 97.56% (More than 15 days from diagnosis)	99.3% (1082/1090)	FDA EUA issued on 24/4/2020	(no info)	(no info)
IgG Antibody detection	Epitope Diagnostics		EDI Novel Coronavirus COVID-19 IgG ELISA Kit Qualitative detection of human anti-COVID-19 IgG antibody in human serum using ELISA.	98.4% (184/187)	99.8% (623/624)	HSA provisional authorisation approved on 15 May 2020. ⁴³⁸ CE marked. ⁴³⁰ Pending EUA approval from US FDA.	90 minutes	(no info)
2.2.5 IgA/IgG antibody immunoassay								
IgA/IgG antibody immunoassay	EUROIMMUN AG ⁴³⁹⁻⁴⁴¹ 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. ⁴⁴²	Sensitivity: 90% (27/30) Specificity: 100% (80/80) ⁴⁴³	IgG – 99% IgA – approximately 90%, not recommended for screening ⁴⁴⁴	Commercially available. CE-marked since 25 March 2020 ²⁶²	2 hours ⁴⁴⁵	(no info)
2.2.6 Neutralising Antibodies Test								
Neutralising Antibodies test	Genscript Biotech (Singapore) Pte Ltd, in collaboration with Duke-NUS Medical School ^{40,41} (Professor Wang Linfa) and A*Star DxD Hub ⁴⁴⁶	26 Feb 2020	SARS-CoV-2 Neutralization Antibody Detection Kit Blocking assay intended for the qualitative detection of neutralization antibodies against SARS-CoV-2 in human serum	At a cutoff inhibition of 20%: 100% (evaluated using 77 COVID-19 patients in Singapore), 98% (evaluated using 50 COVID-19 patients in Nanjing, China) At a cutoff inhibition of 40%: 95.6% (evaluated using 77 COVID-19 patients in Singapore), 96% (evaluated using 50	100% (75/75 in cohort done in Singapore; 50/50 in cohort done in Nanjing, China)	Date of Provisional Authorisation from HSA: 8 May 2020 ⁴⁴⁷	1-2 hours	(no info)

Serological tests (Antibody immunoassay test)									
Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs	
				COVID-19 patients in Nanjing, China)					

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: Conformité Européenne (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	<u>AccuPower (Bioneer, Korea)</u> Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	<u>Anyplex (Seegene, Korea)</u> 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	<u>DiaPlexQ (SolGent, Korea)</u> 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	<u>LightMix (Roche Molecular Diagnostics, Switzerland)</u> Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	<u>UltraFast kits (Nanobiosys, Korea)</u> Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	<u>PowerChek (Kogene Biotech, Korea)</u> 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 <u>ORF1b</u> 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) ⁴⁴⁸	RdRp E	81 min 15 sec	3 cases* Singapore	Surface environment, personal protective equipment, and air samples.
Chan et al (2020) ³⁶¹	RdRp S	200 min	6 cases Shenzhen, China	Nasopharyngeal and throat swabs, and stool and urine samples.
Huang C et al (2020) ⁴⁴⁹	E	51 min 45 sec	41 cases Wuhan, China	Nasal and pharyngeal swabs, bronchoalveolar lavage fluid, sputum, or bronchial aspirates.
Phan et al (2020) ⁴⁵⁰	(no info)	(no info)	2 cases Ho Chi Minh, Vietnam	Throat swab.
Chen Z et al (2020) ⁴⁵¹	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) ⁴⁵²	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) ⁴⁵³	(no info)	(no info)	1 case Lanzhou, China	Sputum.
Liu P et al (2020) ⁴⁵⁴	(no info)	(no info)	1 case Hunan, China	Throat swab.
Chang et al (2020) ⁴⁵⁵	(Testing by Beijing CDC)	(no info)	13 cases Beijing, China	Throat swabs.
Fang Y et al (2020a) ⁴⁵⁶	(no info)	(no info)	2 cases Linhai, China	Sputum.
Liu K et al (2020) ⁴⁵⁷	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) ⁷²	(no info)	(no info)	1 case Wuhan, China	Sputum.
Wang D et al (2020) ⁴⁵⁸	ORF1ab N	60 min	138 cases Wuhan, China	Throat swab.
Liu Y et al (2020) ⁴⁵⁹	ORF1ab N (GeneoDx test kit)	(Chinese CDC protocol)	12 cases Shenzhen, China	Throat swabs and bronchoalveolar lavage fluid.
Wang Z et al (2020) ⁴⁶⁰	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) ⁴⁶¹	(Testing by WHO lab in Hong Kong)	(no info)	1 case Nepal	Throat swab.
Chen H et al (2020) ⁴⁶²	ORF1ab N (Biogerm test kit)	51 min 45 sec	9 cases (pregnant women) Wuhan, China	Throat swab.
Duan et al (2020) ⁴⁶³	(no info)	(no info)	1 case Guangzhou, China	Pharyngeal swab.
Huang P et al (2020) ⁴⁶⁴	(no info)	(no info)	1 case Zhuhai, China	Sputum.
Li X et al (2020) ⁴⁶⁵	(no info)	(no info)	1 case Hefei, China	Sputum.
Liu Y et al (2020) ⁴⁶⁶	[cited Corman et al (2020) – assume E and RdRp genes]	(no info)	1 case Taiwan	Throat swab.
Liu T et al (2020) ⁴⁶⁷	(no info)	(no info)	3 cases Zhuhai, China	Sputum.
Ng et al (2020) ⁴⁶⁸	[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) ⁴⁶⁹	(no info)	(no info)	1 case Toronto, Canada	Mid-turbinate and throat swabs.
China CDC (2020) ⁴⁷⁰	(no info)	(no info)	72,314 cases China	Throat swabs.
Wei M et al (2020) ⁴⁷¹	(no info)	(no info)	9 cases (infants under 1 yr) China	Nasopharyngeal swab.
Wu Y et al (2020) ⁴⁷²	(no info)	(no info)	1 case Wuhan, China	Nasopharyngeal swab.
Van Cuong et al (2020) ⁴⁷³	(sample ran by National Institute of Hygiene and Epidemiology)	(no info)	1 case Hanoi, Vietnam	Nasopharyngeal swab.
Xu Z et al (2020) ⁴⁷⁴	(Testing by Beijing CDC)	(no info)	1 case Beijing, China	Throat swab.
Fang Y et al (2020b) ⁴⁷⁵	(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) ⁴⁷⁶	(Testing by Taiwan CDC)	(no info)	2 cases	Nasopharyngeal swab.
			Taichung, Taiwan	
Zou et al (2020) ⁴⁷⁷	N ORF1b	(no info)	18 cases	Nasal and throat swabs.
			Zhuhai, China	
Xu X et al (2020a) ⁴⁷⁸	(no info)	(no info)	62 cases	Throat swabs and sputum samples.
			7 hospitals in Zhejiang province, China	
Bernheim et al (2020) ⁷⁰	(Test kits by Sansure Biotech, Shanghai Zhijiang Biotechnology, or Da An Gene)	(no info)	121 cases	Nasopharyngeal or oropharyngeal swab, bronchoalveolar lavage fluid, or endotracheal aspirate.
			China	
Zhu N et al (2020) ⁴⁷⁹	RdRp	41 min 50 sec	3 cases	Bronchoalveolar lavage fluid.
			Wuhan, China	
Pan et al (2020) ⁴⁸⁰	(no info)	(no info)	2 cases	Throat swabs, sputum, urine, and stool samples.
			Beijing, China	
Shi et al (2020b) ⁷²	E	(no info)	81 cases	Throat swabs.
			Wuhan, China	
Wei J et al (2020) ⁴⁸¹	(no info)	(no info)	1 case	Sputum.
			Nanchang, China	
Yang W et al (2020) ⁴⁸²	(no info)	(no info)	149 cases	Nasal and pharyngeal swabs, sputum.
			Wenzhou, China	
Lan et al (2020) ⁴⁸³	ORF1ab N (Biogerm test kit) [cited Wang D et al (2020)]	60 min [cited Wang D et al (2020)]	4 cases	Throat swabs.
			Wuhan, China	
Cai et al (2020) ⁴⁸⁴	ORF1ab N	(no info)	10 cases (children)	Nasopharyngeal and throat swabs, urine and serum samples.
			China	
Guan at al (2020) ⁴⁸⁵	(no info)	(no info)	1099 cases	Nasal and pharyngeal swabs.
			China	
Kam et al (2020) ⁴⁸⁶	N ORF1ab	89 min 10 sec 72 min 30 sec	1 case	Nasopharyngeal swabs, blood, stool, and urine samples.
			Singapore	
Lillie et al (2020) ⁴⁸⁷	(no info)	(no info)	2 cases	Nasopharyngeal, nose and throat swabs.
			UK	
Ling et al (2020) ⁴⁸⁸	(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
Tian et al (2020) ⁴⁸⁹	(no info)	(no info)	Shanghai, China 2 cases	Pharyngeal swab.
Li K et al (2020) ⁴⁹⁰	(no info)	(no info)	Wuhan, China 83 cases	Throat swabs or lower respiratory tract samples.
Wu J et al (2020) ⁴⁹¹	N ORF1ab (Biogerm test kit)	48 min 20 sec	Chongqing and Jinan, China 80 cases	Nose and/or throat swabs.
Xiong et al (2020) ⁴⁹²	(no info)	(no info)	3 hospitals across Jiangsu province, China 42 cases	Nasopharyngeal or oropharyngeal swabs.
Young et al (2020) ⁴⁹³	N ORF1ab S	89 min 10 sec 72 min 30 sec 72 min 30 sec	Wuhan, China 18 cases	Nasopharyngeal swabs, blood, stool, and urine samples.
Zhu et al (2020) ⁴⁹⁴	(no info)	(no info)	Singapore 6 cases	Oropharyngeal swabs.
Fan et al (2020) ⁴⁹⁵	(Testing by NCID)	(no info)	Guangzhou, China 69 cases	Respiratory samples.
Hu et al (2020) ⁴⁹⁶	(Test kit by BGI Genomics)	(no info)	Singapore 24 cases	Pharyngeal swabs.
Li Y et al (2020) ⁴⁹⁷	(no info)	(no info)	Nanjing, China 51 cases	Oropharyngeal swabs.
Yan et al (2020) ⁴⁹⁸	N ORF1ab	(no info)	Wuhan, China 2 cases	Nasopharyngeal swabs.
Liu Y et al (2020) ⁴⁹⁹	(no info)	(no info)	Singapore 18 cases (pregnant women)	Oropharyngeal swabs.
Wang et al (2020) ⁵⁰⁰	(Testing by Henan CDC)	(no info)	China 18 cases	Throat swabs.
Xia et al (2020) ⁵⁰¹	(no info)	(no info)	Zhengzhou, China 20 cases (children)	Pharyngeal swabs.
Zhou et al (2020) ⁵⁰²	(no info)	(no info)	Wuhan, China 62 cases	Respiratory samples.
			Wuhan, China	

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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