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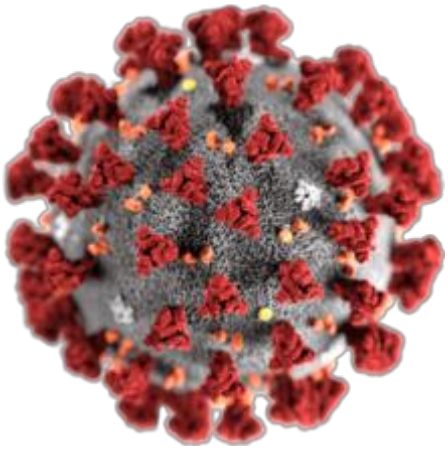

COVID-19 Science Report: Diagnostics

NUS Saw Swee Hock School of Public Health
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Contents

Diagnostics

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

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 is a summary of the latest non-commercial laboratory diagnostic protocols listed on WHO's COVID-19 webpage, available or upcoming commercial, non-commercial diagnostics, and summary of approaches for laboratory diagnostics of coronaviruses by Zhang et al (2020,[3] as well as the gene targets and specimen sample types tested with polymerase chain reaction (PCR) as reported in publications on clinical cases of COVID-19. Diagnostics that can be used for point-of-care testing have been noted in Table 2 in the first column.

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.[4] The WHO webpage has since been updated with a different URL and with additional guidance documents.[5] A seventh protocol from Institut Pasteur in Paris, France, was added on WHO's webpage in March 2020.[6]

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.[7]

The first validated diagnostic test was designed by Prof Christian Drosten's group from Charité Institute of Virology in Berlin, Germany.[1,8] 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 Wuhan 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.[9,10] 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.[10]

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.[11,12] 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).[13] 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 shipped US CDC diagnosis kits, however, quality control issues were found with reagents pertaining to the third step N3 gene assay for universal detection of SARS-like coronaviruses.[14] As such, US CDC is 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.[15,16] An investigation has also been launched, with major concerns raised in the preliminary stages.[17,18] 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 the only EUA-approved US CDC) before the FDA has completed the EUA review.[17,19] As of 17 March 2020, six companies have obtained EUA approvals from US FDA for their commercial RT-PCR diagnostics: Roche,[20] Thermo Fisher Scientific,[21] Hologic,[22,23] LabCorp,[23] Quidel,[24] and Quest Diagnostics.[25] IDT[26] and LGC, Biosearch Technologies[27] also have specific lots of their RT-PCR diagnostic kits approved for EUA by US FDA.

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.

Serological Testing

For diagnosis of acute infections, there is a lag period as antibodies specifically targeting the virus would normally appear between 7-14 days after the illness onset. However, serological tests can be used to assess both active and historical infection within the community. 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.[28,29] This test for the antibodies for SARS-CoV-2 was developed by Prof Wang Linfa's group in Duke-NUS Medical School.

Rapid IgM antibody test strips have been developed by Guangzhou Medical University under the guidance of famed researcher Dr Zhong Nanshan and are already in use in China.[7,30] Guangzhou Wondfo Biotech and Innovita Biological Technology have already received EUA approvals from the China National Medical Products Administration for their antibody test kits.[31-34] 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.[35,36] Pharmact AG from Germany,[37] Zhejiang Orient Gene Biotech,[38,39] and SD Biosensor[40] 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,[41] Shenzhen Tisenc Medical Devices,[42] and Nankai University[43] 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.[41] 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.[44] 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.[45] BioMedomics is seeking to obtain EUA approval from US FDA.[46,47]

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.[7] China had previously announced that they would include in the count of COVID-19 cases, those that were diagnosed using chest CT Scans.[48] 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.[49,50] 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.[51-53] 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.[54]

Issues with Diagnosis Approaches

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.[55]

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.[56,57] This is one key characteristic that may be similar to SARS-CoV-2.

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.[58] However, initial rapid guidelines from China only indicated the use of throat swabs.[59]

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.[60] 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.

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.[60] 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.[60] 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.

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

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.[61] 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. 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 samples from potential cases with COVID-19.[62] 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.

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.

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. 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.

Appendix A

Table 1. Non-Commercial Laboratory Protocols

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,63]	13 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay Additional confirmatory assay: N gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. Additional confirmatory assay **Technical LOD:** 8.3 RNA copies/reaction, at 95% hit rate; **95% CI:** 6.1-16.3 RNA copies/reaction.	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,8]	17 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. (Preliminary experiment compared single probe assay for SARS-CoV with single probe assay for SARS-CoV-2.)	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control. • Synthetic control RNA for SARS-CoV-2 E gene assay is available via EVAg. • Synthetic control for SARS-CoV-2 RdRp is expected to be available via EVAg from Jan 21st onward.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**School of Public Health, The University of Hong Kong** (HKU) [9,10]	16 Jan 2020	**Primer and Probe** Assay 1 (Target: ORF1b-nsp14 gene) Assay 2 (Target: N gene)	Positive control using SARS-CoV RNA Wide dynamic range of 2^{-4} to 2000 $TCID_{50}$/reaction.	Exclusivity Negative results against all of these preparations: • RNA extracted from cultured viruses • RNA from retrospective human clinical specimens previously tested positive for other infections • RNA from control human clinical specimens	Available • Positive control (Available from HKU) Primers and probes: • HKU-ORF1b-nsp14F • HKU- ORF1b-nsp14R • HKU-ORF1b-nsp141P • HKU-NF	28 min 40 sec of cycle time for each assay	(no info)

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
						• HKU-NR • HKU-NP		
rRT-PCR	**Chinese Center for Disease Control and Prevention**, Beijing, China[64]	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[65]	Jan 2020	**With gel electrophoresis**	(no info)	(no info)	Available Primers: • NbatCoV_F1 • NbatCoV_R1	107 min of cycle time	(no info)
RT-PCR	**National Institute of Infectious Diseases**, Japan[66]	23 Jan 2020	**With gel electrophoresis** (Nested RT-PCR) **Primer and Probe** (Real-time RT-PCR)	(no info)	(no info)	Available Primers and probes: • NIID_2019-nCOV_N_F2 • NIID_2019-nCOV_N_R2 • NIID_2019-nCOV_N_P2	81 min for Nested RT-PCR 95 min for Real-time RT-PCR	(no info)
rRT-PCR	**Centers for Disease Control and Prevention**, Atlanta, USA[11,12]	24 Jan 2020	**Primer and Probe** 3 N gene targets 1 human RNase P gene control	(no info)	(no info)	Available Primers and probes: • 2019-nCOV_N1_F • 2019-nCOV_N1_R • 2019-nCOV_N1_P • 2019-nCOV_N2_F • 2019-nCOV_N2_R • 2019-nCOV_N2_P • 2019-nCOV_N3_F • 2019-nCOV_N3_R • 2019-nCOV_N3_P • RP_F • RP_R • RP_P	43 min 45 sec of cycle time for each assay	(no info)
rRT-PCR	**Institut Pasteur**, Paris, France[6]	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	61 min of cycle time for each assay	(no info)

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
						• E_Sarbeco_R2 • E_Sarbeco_P1		

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. Upcoming/Available Diagnostics

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Genesig[67,68] UK	Jan 2020	**Real-Time PCR COVID-19 (CE)** *[Previously Coronavirus (Strain 2019-nCoV) Easy/Standard Kit]*	(no info)	(no info)	Commercially available. Received CE Mark for IVD.	(no info)	(by quote)
RT-PCR	Bioperfectus Technologies[69] China	14 Jan 2020	**RT-PCR test kit**	(no info)	(no info)	Available as scientific research product – does not require registration[69]	(no info)	(no info)
Genome sequencing	Oxford Nanopore[70,71] UK	22 Jan 2020	Works with public health labs globally to support rapid sequencing of SARS-CoV-2 through sharing of methods / workflows. Nanopore sequencing workflows can provide a consensus viral genome from sample within a day.	(no info)	(no info)	Available.	(no info)	(no info)
End-to-end solution of sample processing to epidemiological info generation	Oxford Nanopore[70,72] UK	22 Jan 2020	**ARTIC project** A 'lab-in-a-suitcase' solution for processing samples from viral outbreaks, to generating real-time epidemiological information interpretable and actionable by public health bodies. Deployable to remote/resource-limited locations. Based on viral genome data generated prospectively during similar outbreaks (eg. MERS, SARS etc). Relies on direct amplification of the virus using tiled, multiplexed primers.	Not stated but described to have high sensitivity compared to metagenomic approaches.[73]	(no info)	(no info)	(no info)	(no info)
RT-PCR	Co-Diagnostics[74,75] USA	23 Jan 2020	**Logix Smart Coronavirus COVID-19 test** RT-PCR kit with lower false positive	Stated to be high but with no accompanying statistics.	No specific statistics but claims to have ability to reliably and accurately differentiate between	Commercially available for sale on 10 Feb 2020.[75]	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
					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.[74,76]	Received CE Mark 24 Feb 2020.[77]		
RT-PCR	altona Diagnostics[78] Germany	23 Jan 2020	**Commercial Kit** RT-PCR kit	(no info)	(no info)	(no info)	(no info)	(no info)
RT-PCR	BGI[79] Pathomics Health (distributor) China	23 Jan 2020	**Fluorescent RT-PCR kit** In vitro RT-PCR combining fluorescent probing.[80]	(no info)	(no info)	Available. Received CE Mark for IVD 28 Feb 2020.[81] Currently used in hospitals and local disease control centres in China. BGI is also engaged with relevant organizations in Hong Kong, Taiwan, Brunei, Thailand, Nigeria, South Africa, to supply the test kits.[79] Passed emergency approval procedure of the National Medical Products Administration.	No data stated but described as 'can issue results in a few hours'.	(no info)
Combination of RT-PCR and meta-genomics detection	BGI[79] Pathomics Health (distributor)[82] China	23 Jan 2020	**2019-nCoV PMseq Kit** A metagenomics sequencing kit based on combinatorial Probe Anchor Sythesis. Faster SARS-CoV-2 virus detection, and able to detect both known and novel microorganisms, enabling	(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	SARS-CoV-2 detection stated to be faster than Fluorescent RT-PCR kit. For detection of unknown pathogens, Within 5 hours,	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			monitoring of evolution during transmission.			the National Medical Products Administration.	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	
Microfluidic	Veredus Laboratories[83-85] 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.[86]	Stated to be high but with no accompanying statistics.[86]	Available for RUO since Jan 2020. Provisional approval for IVD by Singapore's Health Sciences Authority since Mar 2020.[85] Used for testing of swab samples from Singapore's land, sea and air checkpoints since Mar 2020.[87]	2 hours[88]	(no info)
CRISPR-based diagnostics	Sherlock Biosciences[89-92] (Plus collaboration with Cepheid)[92] 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.[92]	(no info)	(no info)	Protocol published 14 Feb 2020.[93,94]	(no info)	(no info)
Microfluidic	Lexagene[95] 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)
Real-time RT-PCR	Liferiver Biotech[96,97] China	29 Jan 2020	**Fluorescent PCR**[97]	(no info)	(no info)	Commercially available.	(no info)	€ 991[98]
Real-time RT-PCR	Liferiver Biotech[96,99] China	29 Jan 2020	**Multiplex RT-PCR**[99]	(no info)	(no info)	Commercially available.	(no info)	€ 1347[100]
Real-time RT-PCR	GenScript[96,101,102]	29 Jan 2020	**qRT-PCR**	"This assay is RUO and has not been tested on	"This assay may have cross-reactivity with other	Commercially available for RUO.	(no info)	(by quote)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	USA		Targets RdRP gene, N gene and E gene in Wuhan-Hu-1 genome (GenBank sequences NC_045512.2) [same as Charite's first protocol]	clinical samples. We make no claims on the performance of this assay."[101]	coronavirus family members such as causative agents of the Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS)."[101]			
NGS	IDbyDNA[103,104] USA	29 Jan 2020	Next-generation sequencing-based metagenomics, allows enhanced pathogen detection and profiling in comparison to conventional PCR testing.[104]	(no info)	(no info)	Commercially available.	(no info)	(by quote)
Real-time RT-RAA	Beijing Ditan Hospital[105] 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 analyze 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)
CRISPR-based diagnostics	Mammoth Biosciences[89,106,107] (Partnering with UCSF Researchers) USA	30 Jan 2020	**CRISPR**: Using the smaller Cas14 protein instead of usual Cas9 protein. Theoretically, the Cas14 "breaks apart a "reporter molecule," which can then change the color of the solution, indicating a positive or negative test result."[107]	(no info)	(no info)	In development as of 6 Feb 2020	(no info)	(no info)
Real-time RT-PCR	CerTest Biotec[108] Spain	30 Jan 2020	**VIASURE 2019-nCoV Real Time PCR Kit** Amplification of a fragment of the S gene.[109]	(no info)	(no info)	Available. Received CE Mark for IVD for the version adapted for the BD MAX™ System.[109]	(no info)	(no info)
PCR-based genotyping	Genomica[110,111] Spain	30 Jan 2020	**CLART COVID-19** Based on Genomica's CLART technology of PCR-based genotyping with low-density microarray.	(no info)	(no info)	Available. Received CE Mark 6 Mar 2020.[112]	< 5 hr	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
qPCR	Novacyt[113,114] (molecular diagnostics division Primerdesign) France/UK	31 Jan 2020	**qPCR[114]** Can run on multiple molecular testing platforms, including Primerdesign's own genesig® q16 and q32 instrument	(no info)	(no info)	Commercially available. Received CE Mark for IVD 17 Feb 2020.[115,116] Submitted to US FDA for EUA.[115]	< 2 hr	
RT-PCR	Roche[20,117,118] Switzerland	31 Jan 2020	**Cobas SARS-CoV-2 Test** Runs on the Cobas 6800/8800 systems.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 13 Mar 2020.[20] CE Mark for IVD.	3 hr 30 min	(no info)
RT-PCR	A*STAR[119,120] (Manufactured by Singapore's MiRxes which has a nonexclusive license)[121] Singapore	1 Feb 2020	**A*STAR Fortitude 2.0** Supports 188 tests per kit	(no info)	(no info)	Available but not for commercial sale yet. Provisional authorization for clinical use from Singapore's Health Sciences Authority.[120,121]	(no info)	(no info)
Real-time RT-PCR	GeneFirst[122] 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[122] 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)
(no info)	TCM Biosciences[123] South Korea	3 Feb 2020	**TCM-Q Corona Ⅲ**	(no info)	(no info)	Developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	(no info)	(no info)
Real-time RT-PCR	Kogene Biotech[123,124] 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.[124,125]	(no info)	(no info)
(no info)	PCL[123] South Korea	3 Feb 2020	**Multiplex diagnostic kit**	(no info)	(no info)	Developed as of 3 Feb 2020.	(no info)	(no info)
(no info)	Bioneer[123] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Assumed developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
(no info)	Lab Geneomics[123] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Undergoing commercialisation as of 6 Feb 2020	(no info)	(no info)
(no info)	CEVI[123] (Partnership with Wells Bio) South Korea	3 Feb 2020	(no info)	(no info)	(no info)	In development as of 6 Feb 2020	(no info)	(no info)
Enzyme-assisted nanocomplex	iHealthtech[84,126] (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)
RT-PCR	Biomeme[127,128] 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
Conventional and Real Time RT-PCR	Genekam[129,130] Germany	4 Feb 2020	5 options: 1. Conventional PCR 2. Real Time PCR for nCoV only[131] 3. Multiplex Real Time PCR for nCoV + other Bat CoV[132] 4. Multiplex Real Time PCR for nCoV + other Bat CoV + MERS[133] 5. Multiplex Real Time PCR for nCoV + Influenza A[134]	(no info)	(no info)	In development as of 6 Feb 2020	126 min 15 s[131,133] or 120 min[132,134] of cycle time	€ 599[130] € 699[130] € 799[130] € 999[130] € 899[130]
Real-time RT-PCR	Thermo Fisher Scientific[21,127,135] USA	4 Feb 2020	**TaqPath COVID-19 Combo Kit (previously TaqMan 2019-nCoV Assay Kit)** Real-time RT-PCR kit assays specifically target all 44 complete genomes currently available at GISAID, and do not target any of the 2,116 complete genomes of other coronaviruses currently	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 13 Mar 2020.[21]	(no info)	(by quote)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			available at NCBIm covering orf1ab, spike (S) gene, nucleocapsid (N) gene)					
Real-time RT-PCR	US CDC[13] 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 N gene targets and 1 human RNase P gene control	(no info)	Quality control issues with reagents pertaining to detection of the N3 assay for universal detection of SARS-like coronaviruses.[14]	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)
RT-PCR	Livzon[136]	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 National Medical Products Administration on 27 Jan 2020	(no info)	(no info)
IgM/IgG antibody immunoassay (ELISA)	Livzon[136] (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 National Medical Products Administration on 28 Jan 2020.	(no info)	(no info)
IgM/IgG antibody immunoassay (colloidal gold)	Livzon[136] (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 National Medical Products Administration on 2 Feb 2020.	15 min	(no info)
qPCR	Coyote Bioscience[91,127] China	4 Feb 2020	**2019-nCoV Prep Free QPCR Assay**	(no info)	(no info)	Available. Reportedly being used in China in over 30 hospitals, 16	1 hr	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Runs on the Mini8 Portable Molecular Diagnostic QPCR Station (CFDA approved)			local CDC offices, and 8 airports.		
Microfluidic	Shenzhen Shineway Technology[137,138] (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.[138] Device already has CE Mark and is qualified for export to all European Union (EU) countries as well as Hong Kong.[137]	40 min	(no info)
RT-PCR	Acumen Research Laboratories[139] Singapore	7 Feb 2020	**RT-PCR** With specific gene targets.	(no info)	(no info)	Prototype developed.	About 2 hr	(no info)
Microfluidic	Qiagen[140] The Netherlands	10 Feb 2020	**QiaStat-Dx Respiratory Panel [Plus]** Tests for two gene targets: ORF1b recommended by the Chinese CDC and N recommended by the US CDC.	(no info)	(no info)	Expected to be developed by Feb 2020.	Would be faster than RT-PCR.	(no info)
(no info)	Public Health England[141] UK	10 Feb 2020	(no info)	(no info)	(no info)	Available (non-commercially) to 12 labs across the UK.	(no info)	(no info)
RT-PCR [Point-of-Care]	Cepheid[142] (Plus collaboration with Sherlock Biosciences)[92] USA	10 Feb 2020	**GeneXpert system** Cartridge-based nucleic acid amplification test	(no info)	(no info)	In development.	30 min	(no info)
Real-time PCR and microarray technologies [Point-of-Care]	Mobidiag[143] (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.	(no info)	(no info)	In development.	30 min	(no info)
Immunoassay [Point-of-Care]	Sona Nanotech[144]	10 Feb 2020	Proprietary nanotechnology lateral flow test using antigens specific to SARS-CoV-2	(no info)	(no info)	In development.	5-15 min	<$50

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	(collaboration with The Native Antigen Company)[145] Canada		produced at Native's Oxford facility using proprietary mammalian VirtuE expression system.					
LAMP [Point-of-Care]	HiberGene Diagnostics[146,147] (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)[147]	(no info)
(no info) [Point-of-Care]	QuantuMDx[91] UK	12 Feb 2020	(no info)	(no info)	(no info)	(no info)	(no info)	(no info)
qPCR [Point-of-Care]	Molbio Diagnostics[91] India	12 Feb 2020	Potentially real-time PCR then detection of wavelengths of fluorescent signal.	(no info)	(no info)	In development using existing TrueLab System.	55 min	(no info)
qPCR [Point-of-Care]	OnSiteGene[91] (San Diego-based subsidiary of Singapore's Star Array) USA	12 Feb 2020	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.	(no info)	(no info)	In development.	10 min	(no info)
CLIA	Shenzhen Tisenc Medical Device[42] (collaboration with Shenzhen University and Shenzhen No.3 People's Hospital) China	12 Feb 2020	Chemiluminescence antibody test kit using serum or plasma.	(no info)	(no info)	Developed and tested but not commercially available yet.	22 min (unclear if serum/plasma extraction time included or not)	(no info)
RT-PCR	TIB-Molbiol[118,148] (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 for RUO.	(no info)	(no info)
IgM antibody immunoassay [Point-of-Care]	Guangzhou Medical University[7,30] (Dr Zhong Nanshan) China	15 Feb 2020	IgM antibody detection kit.	(no info)	(no info)	Available for use in China but not commercially	15 min (unclear if serum/plasma extraction time included or not)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgM/IgG antibody immunoassay	Nankai University[43] China	17 Feb 2020	**Novel Coronavirus (2019-nCoV) IgM/IgG antibody detection kit**	(no info)	(no info)	Developed but not commercially available yet.	15 min (unclear if serum/plasma extraction time included or not)	(no info)
RT-PCR	Seegene[149,150] South Korea	18 Feb 2020	**Allplex 2019-nCoV Assay** Single-tube assay that tests for three gene targets: E, RdRP, and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean FDA 12 Feb 2020.[124,151] Product already has CE Mark for IVD.	(no info)	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	Guangzhou Wondfo Biotech[31-35] 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 the China National Medical Products Administration. Received CE Mark Mar 2020.[35,36]	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgG and IgA antibody immunoassay	EUROIMMUN AG[152-154] Germany	21 Feb 2020	ELISA for IgG and IgA antibody detection.	(no info)	(no info)	Commercially available. Not available as IVD in the EU.[152]	(no info)	(no info)
IgG and IgM antibody immunoassay [Point-of-Care]	BioMedomics / Jiangsu Medomics Medical Technology[41,44,45] 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 positive out of 397 positive cases: - 256 both IgG and IgM - 72 IgG - 24 IgM	**90.63%** 12 positive 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.[45] Submitted to US FDA for EUA approval.[46,47]	15 min	(no info)
IgM antibody immunoassay	Innovita Biological Technology[31] China	23 Feb 2020	IgM antibody detection.	(no info)	(no info)	Available. Approved by the China National Medical Products Administration.	(no info)	(no info)
(RT-PCR)	CapitalBio[32] (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 the China National Medical Products Administration.	1 hr 30 min	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgM or IgG antibody immunoassay	Duke-NUS Medical School[28,29] (Prof Wang Linfa) Singapore	26 Feb 2020	IgM or IgG antibody detection.	(no info)	(no info)	Available (not commercially).	(no info)	(no info)
Real-time RT-PCR	SolGent[124,151,155] South Korea	28 Feb 2020	**DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit** Tests for two gene targets: Orf1a and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 27 Feb 2020.[124,151] Received CE Mark for IVD.	2 hr PCR	(no info)
Real-time RT-PCR	SD Biosensor[124,151] South Korea	28 Feb 2020	**STANDARD M n-CoV Real-Time Detection Kit** Tests for two gene targets: E and RdRP.	(no info)	(no info)	Available. Obtained EUA approval from Korean CDC 27 Feb 2020.[124,151]	6 hr	(no info)
CLIA for IgM and IgG antibody	Snibe Diagnostic[156,157] China	28 Feb 2020	**Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits** Fully automated CLIA using 10µL sample volume of serum or plasma.	(no info)	(no info)	Available. Have been distributed in China and will soon be in Italy. Received CE Mark 19 Feb 2020.[157]	30 min	(no info)
RT-PCR	Osang Healthcare[158,159] (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.	(no info)	(no info)	Available. Received CE Mark for IVD.	(no info)	(no info)
Real-time RT-PCR	Integrated DNA Technologies (IDT)[26,160] 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[26] for 500 rxn
Real-time RT-PCR	Genomica[112,161] Spain	6 Mar 2020	**qCOVID-19** Real-time RT-PCR	Reported **100%.**[161] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Reported **100%.**[161] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Available. Received CE Mark 6 Mar 2020.[112]	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgM and IgG antibody immunoassay [Point-of-Care]	Pharmact AG[37] 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
IgM and IgG antibody immunoassay [Point-of-Care]	Zhejiang Orient Gene Biotech[38,39] 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.	2-10 min	(no info)
Real-time RT-PCR	Wadsworth Center, New York State Department of Public Health[162] USA	10 Mar 2020	**New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel**	(no info)	(no info)	Available. Obtained EUA approval from US FDA for use in Wadsworth Center, New York State Public Department of Health, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories.	(no info)	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	SD Biosensor[40] 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.	(no info)	**95%** (95/100)	Available.	10 min	(no info)
RT-PCR	LGC Biosearch Technologies[27,163]	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[163]
RT-PCR	GenMark Diagnostics[164]	11 Mar 2020	**ePlex SARS-CoV-2**	(no info)	(no info)	Submitted to US FDA for EUA Approval.	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	USA							
RT-PCR	Fulgent Genetics[165] USA	11 Mar 2020	(no info)	Reported 95% sensitivity.	(no info)	Submitted to US FDA for EUA Approval.	(no info)	(no info)
NGS	Fulgent Genetics[165] 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)
Microfluidic	Fluidigm[166] 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)
RT-PCR	Hologic[22,23] USA	16 Mar 2020	**Panther Fusion SARS-CoV-2 Assay**	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020.	(no info)	(no info)
RT-PCR	LapCorp (Laboratory Corporation of America)[23] USA	16 Mar 2020	**COVID-19 RT-PCR Test**	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 16 Mar 2020.	(no info)	(no info)
RT-PCR	Quidel[24] USA	17 Mar 2020	**Lyra SARS-CoV-2 Assay**	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	(no info)	(no info)
RT-PCR	Quests Diagnostics[25] USA	17 Mar 2020	**Quest SARS-CoV-2 rRT-PCR**	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 17 Mar 2020.	(no info)	(no info)

RT-PCR: reverse transcription polymerase chain reaction
NGS: next generation sequencing
LAMP: loop-mediated isothermal amplification
CLIA: chemiluminescence immunoassay
IgM: Immunoglobulin M

IgG: Immunoglobulin G
IgA: Immunoglobulin A
RUO: Research Use Only
IVD: In Vitro Diagnostics
EUA: emergency use assessment
CE Mark: Conformitè Europëenne (CE) Mark – European Union's mandatory conformity marking for regulating goods sold in European Economic Area
rxn: reactions

Table 3. Approaches for Coronavirus Diagnostics

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

RT-PCR: reverse transcription polymerase chain reaction
rRT-PCR: real-time reverse transcription polymerase chain reaction
RT-LAMP: reverse transcription loop-mediated isothermal amplification
RT-LAMP-VF: reverse transcription loop-mediated isothermal amplification with a vertical flow visualization strip
upE: envelope gene
ORF1a: open reading frame 1a
ORF1b: open reading frame 1b

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

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
Ong et al (2020)[167]	RdRp E	81 min 15 sec	3 cases* Singapore	Surface environment, personal protective equipment, and air samples.
Chan et al (2020)[168]	RdRp S	200 min	6 cases Shenzhen, China	Nasopharyngeal and throat swabs, and stool and urine samples.
Huang C et al (2020)[169]	E	51 min 45 sec	41 cases Wuhan, China	Nasal and pharyngeal swabs, bronchoalveolar lavage fluid, sputum, or bronchial aspirates.
Phan et al (2020)[170]	(no info)	(no info)	2 cases Ho Chi Minh, Vietnam	Throat swab.
Chen Z et al (2020)[171]	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)[172]	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)[173]	(no info)	(no info)	1 case Lanzhou, China	Sputum.
Liu P et al (2020)[174]	(no info)	(no info)	1 case Hunan, China	Throat swab.
Chang et al (2020)[175]	(Testing by Beijing CDC)	(no info)	13 cases Beijing, China	Throat swabs.
Fang Y et al (2020a)[176]	(no info)	(no info)	2 cases Linhai, China	Sputum.
Liu K et al (2020)[177]	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)[52]	(no info)	(no info)	1 case Wuhan, China	Sputum.
Wang D et al (2020)[178]	ORF1ab N	60 min	138 cases Wuhan, China	Throat swab.
Liu Y et al (2020)[179]	ORF1ab N (GeneoDx test kit)	(Chinese CDC protocol)	12 cases Shenzhen, China	Throat swabs and bronchoalveoar lavage fluid.
Wang Z et al (2020)[180]	E (same as Huang et al)	51 min 45 sec	4 cases	Throat swab.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Shanghai, China	
Bastola et al (2020)[181]	(Testing by WHO lab in Hong Kong)	(no info)	1 case Nepal	Throat swab.
Chen H et al (2020)[182]	ORF1ab N (Biogerm test kit)	51 min 45 sec	9 cases (pregnant women) Wuhan, China	Throat swab.
Duan et al (2020)[183]	(no info)	(no info)	1 case Guangzhou, China	Pharyngeal swab.
Huang P et al (2020)[184]	(no info)	(no info)	1 case Zhuhai, China	Sputum.
Li X et al (2020)[185]	(no info)	(no info)	1 case Hefei, China	Sputum.
Liu Y et al (2020)[186]	[cited Corman et al (2020) – assume E and RdRP genes]	(no info)	1 case Taiwan	Throat swab.
Liu T et al (2020)[187]	(no info)	(no info)	3 cases Zhuhai, China	Sputum.
Ng et al (2020)[188]	[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)[189]	(no info)	(no info)	1 case Toronto, Canada	Mid-turbinate and throat swabs.
China CDC (2020)[190]	(no info)	(no info)	72,314 cases China	Throat swabs.
Wei M et al (2020)[191]	(no info)	(no info)	9 cases (infants under 1 yr) China	Nasopharyngeal swab.
Wu Y et al (2020)[192]	(no info)	(no info)	1 case Wuhan, China	Nasopharyngeal swab.
Van Cuong et al (2020)[193]	(sample ran by National Institute of Hygiene and Epidemiology)	(no info)	1 case Hanoi, Vietnam	Nasopharyngeal swab.
Xu Z et al (2020)[194]	(Testing by Beijing CDC)	(no info)	1 case Beijing, China	Throat swab.
Fang Y et al (2020b)[195]	(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) [196]	(Testing by Taiwan CDC)	(no info)	2 cases Taichung, Taiwan	Nasopharyngeal swab.
Zou et al (2020)[197]	N ORF1b	(no info)	18 cases Zhuhai, China	Nasal and throat swabs.
Xu X et al (2020a)[198]	(no info)	(no info)	62 cases 7 hospitals in Zhejiang province, China	Throat swabs and sputum samples.
Bernheim et al (2020)[50]	(Test kits by Sansure Biotech, Shanghai Zhijiang Biotechnology, or Da An Gene)	(no info)	121 cases China	Nasopharyngeal or oropharyngeal swab, bronchoalveolar lavage fluid, or endotracheal aspirate.
Zhu N et al (2020)[199]	RdRp	41 min 50 sec	3 cases Wuhan, China	Bronchoalveolar lavage fluid.
Pan et al (2020)[200]	(no info)	(no info)	2 cases Beijing, China	Throat swabs, sputum, urine, and stool samples.
Shi et al (2020b)[52]	E	(no info)	81 cases Wuhan, China	Throat swabs.
Wei J et al (2020)[201]	(no info)	(no info)	1 case Nanchang, China	Sputum.
Yang W et al (2020)[202]	(no info)	(no info)	149 cases Wenzhou, China	Nasal and pharyngeal swabs, sputum.
Lan et al (2020)[203]	ORF1ab N (Biogerm test kit) [cited Wang D et al (2020)]	60 min [cited Wang D et al (2020)]	4 cases Wuhan, China	Throat swabs.
Cai et al (2020)[204]	ORF1ab N	(no info)	10 cases (children) China	Nasopharyngeal and throat swabs, urine and serum samples.
Guan at al (2020)[205]	(no info)	(no info)	1099 cases China	Nasal and pharyngeal swabs.
Kam et al (2020)[206]	N ORF1ab	89 min 10 sec 72 min 30 sec	1 case Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Lillie et al (2020)[207]	(no info)	(no info)	2 cases UK	Nasopharyngeal, nose and throat swabs.
Ling et al (2020)[208]	(no info)	(no info)	66 cases	Oropharyngeal swabs or stool samples.

Paper	Gene Targets	Cycle Time	Number of Confirmed Cases	Sample Type Tested with PCR
			Shanghai, China	
Tian et al (2020)[209]	(no info)	(no info)	2 cases Wuhan, China	Pharyngeal swab.
Li K et al (2020)[210]	(no info)	(no info)	83 cases Chongqing and Jinan, China	Throat swabs or lower respiratory tract samples.
Wu J et al (2020)[211]	N ORF1ab (Biogerm test kit)	48 min 20 sec	80 cases 3 hospitals across Jiangsu province, China	Nose and/or throat swabs.
Xiong et al (2020)[212]	(no info)	(no info)	42 cases Wuhan, China	Nasopharyngeal or oropharyngeal swabs.
Young et al (2020)[213]	N ORF1ab S	89 min 10 sec 72 min 30 sec 72 min 30 sec	18 cases Singapore	Nasopharyngeal swabs, blood, stool, and urine samples.
Zhu et al (2020)[214]	(no info)	(no info)	6 cases Guangzhou, China	Oropharyngeal swabs.
Fan et al (2020)[215]	(Testing by NCID)	(no info)	69 cases Singapore	Respiratory samples.
Hu et al (2020)[216]	(Test kit by BGI Genomics)	(no info)	24 cases Nanjing, China	Pharyngeal swabs.
Li Y et al (2020) [217]	(no info)	(no info)	51 cases Wuhan, China	Oropharyngeal swabs.
Yan et al (2020)[218]	N ORF1ab	(no info)	2 cases Singapore	Nasopharyngeal swabs.
Liu Y et al (2020)[219]	(no info)	(no info)	18 cases (pregnant women) China	Oropharyngeal swabs.
Wang et al (2020)[220]	(Testing by Henan CDC)	(no info)	18 cases Zhengzhou, China	Throat swabs.
Xia et al (2020)[221]	(no info)	(no info)	20 cases (children) Wuhan, China	Pharyngeal swabs.
Zhou et al (2020)[222]	(no info)	(no info)	62 cases Wuhan, China	Respiratory samples.

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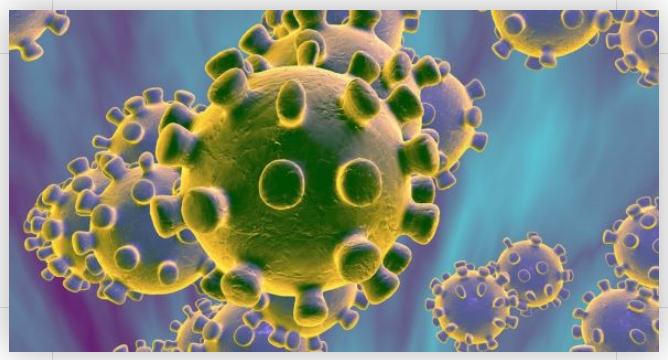
SARS-COV-2 DIAGNOSTIC PIPELINE



We are collating an overview of all SARS-CoV-2 tests commercially available or in development for the diagnosis of COVID-19. We cannot guarantee that this is a fully comprehensive list. The below is information directly submitted by test suppliers or obtained from publicly available sources, and is not independently verified. If you have queries or updates, please contact us.

SUBMISSION FORM TO ADD A TEST TO THIS TRACKER

MOLECULAR ASSAYS

Commercialized

Manual NAT

1drop Inc., *1copy™ COVID-19 qPCR Kit* (CE-IVD) Contact

AB ANALITICA, Contact

REALQUALITY RQ-2019-nCoV (manual; lab-based NAT; CE-IVD)

REALQUALITY RQ-SARS-CoV-2 (manual; lab-based NAT; RUO)

A*ccelerate, *A*STAR Fortitude Kit 2.0* (Singapore HSA) Contact

Acumen Research Laboratories Pte. Ltd. Contact

Acu-Corona (RUO)

Acu-Corona 2.0 (RUO)

ADT Biotech, *LyteStar 2019-nCoV RT-PCR Kit 1.0* (RUO) Contact

altona Diagnostics, *RealStar® SARS-CoV-2 RT-PCR Kit* (RUO) Contact

Atila BioSystems, Inc., *iAMP COVID-19 Detection Kit* (RUO) Contact

Beijing Applied Biological Technologies Co., Ltd., *Multiple Real-Time PCR Kit for Detection of 2019-nCoV* (manual & automated lab-based) (China FDA–EUA; CE-IVD) Contact

Beijing Genskey Medical Technology Co., Ltd, *SARS-CoV-2 Nucleic Acid Detection Kit (RT-qPCR with Taqman-Probe)* (RUO) Contact

Beijing Kewei Clinical Diagnostic Reagent Inc., *Kewei COVID-19 Nucleic Acid Test Kit* (CE-IVD) Contact

Beijing Kinhawk Pharmaceutical Co., Ltd, *2019-nCoV ORF1ab/N Gene Detection Kit (Fluorescence PCR Method)* (RUO) Contact

Beijing NaGene Diagnosis Reagent Co., Ltd, *Multiple Real-Time PCR kit for Detection of 2019-nCoV* (RUO) Contact

Beijing Wantai Biological Pharmacy Enterprise Co.,Ltd, *Wantai SARS-CoV-2 RT-PCR Kit* (RUO) Contact

BGI Health (HK) Co. Ltd., *Real-time fluorescent RT-PCR kit for detecting 2019 nCoV* (China-FDA EUA) Contact

Boditech Inc, *ExAmplar COVID-19 real-time PCR kit (L)* (RUO) Contact

bioMérieux SA, *SARS-COV-2 R-GENE®* (manual & automated lab-based) (RUO) Contact

Cancer Rop Co., Ltd., *Q-Sens® 2019-nCoV Detection Kit* (CE-IVD) Contact

CellSafe, *Qplex COVID-19 RT-qLAMP Assay* (RUO) Contact

CerTest Biotec, S.L., Contact

VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit (CE-IVD)

VIASURE SARS-CoV-2 Real Time PCR Detection Kit (CE-IVD)

Chaozhou Hybribio Biochemistry Ltd., *COVID-19 Real-Time PCR Kit (*manual & automated lab-based) (CE-IVD) Contact

ChromaCode, Inc., *ChromaCode COVID-19 Six Target Single Well Assay* (RUO) Contact

Clonit, *quanty-CONV-19* (CE-IVD) Contact

Co-Diagnostics, *Logix Smart Coronavirus disease 2019 (COVID-19)* (CE-IVD) Technical contact; Regulatory contact

CTK Biotech, Inc., *Aridia COVID-19 Real Time PCR Test* (CE-IVD) Contact

Daan Gene Co., Ltd. of Sun Yat-sen University, *Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR kit* (China-FDA EUA; CE-IVD) Contact-1; Contact-2

Dynamiker Biotechnology (Tianjin) Co., Ltd., *Novel Coronavirus(2019-nCov)RT-PCR Kit* (RUO) Contact

Edinburgh Genetics Limited, *COVID-19 Real-time PCR Testing Kit* (China-FDA EUA; CE-IVD) Contact

Eurobio Scientific, *EurobioPlex SARS-CoV-2 Multiplex* (CE) Contact

EUROIMMUN AG, *EURORealTime SARS-CoV-2* (RUO) Contact

Gene Biosystems, *Gene Bio COVID-19 Qualitative Real Time PCR Kit Ver. 1.0* (RUO) Contact

Gencurix Inc. Contact

GenePro COVID-19 Detection Test (CE-IVD)

GenePro COVID-19 Detection Test v2 (CE-IVD)

GeneFirst Ltd Contact

The Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit (RUO)

Respiratory Pathogen Panel (RUO)

Genesystem, Co. Ltd, *SMARTCHECK SARS-CoV2 Detection Kit* (RUO) Contact

Genetic Signatures Limited, *EasyScreen™ Pan-Coronavirus/SARS-CoV-2 Detection Kit* (RUO) Contact

Genomictree, Inc., *AccuraTect RT-qPCR SARS-CoV-2* (RUO) Contact

GenScript, *2019-nCoV qRT-PCR Detection Assay* (RUO) Contact

Getein Biotech, Inc., *Novel Coronavirus (2019-nCoV) Real-time RT-PCR Kit* (CE-IVD) Contact

Guangdong Huayin Medicine Science Co,. Ltd, *Detection Kit for 2019-nCoV RNA (RT-PCR Fluorescence Probing) (Lyophilised)* (RUO) Contact

GuangZhou HEAS BioTech Co.,Ltd. *2019 Novel Coronavirus (2019-nCoV) RNA ASSAY (PCR Fluorescent Probe Method)* (RUO) Contact

Guangzhou Supbio Biotechnologies, Inc., *Supbio SARS-CoV-2 (ORF1ab/N) Nucleic Acid Detection Kit* (PCR-Fluorescent Probing) (RUO) Contact

Guangzhou Wondfo Biotech Co., Ltd, *Wondfo SARS-CoV-2 Nucleic Acid Detection Kit* (RUO) Contact

Hangzhou Matridx Biotechnology Co., Ltd, *2019-nCov Rapid Test Kit* (RUO) Contact

ICBFM, *LAMP kit for qualitative detection of SARS-CoV-2* (RUO) Contact

Innovita (Tangshan) Biological Technology Co., Ltd., *Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit* (Multiple Fluorescence PCR) (RUO) Contact

Jiangsu Bioperfectus Technologies Co. Ltd Contact

PerfectLyo SARS-COV-2 Real Time PCR kit (RUO)

PerfectQ COVID-19 Coronavirus Real Time PCR Kit (RUO)

JN Medsys, *ProTect Covid-19 RT-qPCR kit* (RUO) Contact

KH Medical Co. Ltd, *RADI COVID-19 Detection Kit and RADI COVID-19 Triple Detection Kit*

(CE-IVD) Contact

KogeneBiotech Co. Ltd, *PowerChekTM 2019-nCoV Real-time PCR Kit*, (Korea MFDS–EUA; CE-IVD) Contact

Liferiver, *Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCRT kit* (China-FDA EUA; CE-IVD)

Liming Bio-Products Co., Ltd, *SrongStep®Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit* (CE-IVD) Contact

Luminex Corp., *NxTAG CoV Extended Panel* (RUO) Contact

Mabsky Bio-Tech Co., Ltd Real-Time PCR Method Contact

COVID-19 virus (2019-nCoV) Dual-Detection Kit (RUO)

Influenza A virus, Influenza B virus & COVID-19 virus (2019-nCoV) Triple-Detection Kit (RUO)

Medical Innovation Ventures Sdn Bhd. *GenoAmp® Real-Time RT-PCR SARS-CoV-2* (RUO) Contact

Mikrogen GmbH, *ampliCube Coronavirus Panel* (RUO) Contact

Nanjing Vazyme Medical Technology Co., LTD., *2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit* (CE-IVD) Contact

NanoBio Lab, A*STAR Research Entities, *Isothermal Exponential Amplification for COVID-19 Detection* (RUO) Contact

National Institute for Control of Vaccines and Biologicals, *Accupid nCoV 2019 Detection Kit* (RUO) Contact

Ningbo Health Gene Technologies Co. Ltd. *SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)* (RUO) Contact

Norgen Biotek Corp, *2019-nCoV TaqMan RT-PCR Kit (Catalog# TM67100)* (RUO) Contact

Novacyt/Primerdesign Ltd, *genesig Real-Time PCR COVID-19* (US-FDA EUA; CE-IVD) Contact

PaxGen Bio Co. Ltd, *PaxView COVID-19* real time RT-PCR (RUO) Contact

PerkinElmer Inc., *PerkinElmer® SARS-CoV-2 Realtime RT-PCR Assay* (CE-IVD) Contact

Pishtaz Teb, *COVID-19 Onestep RT-PCR Dual Target Gene* (Iran-FDA) Contact

Promis Diagnostics, *SensDtect RT-qPCR SARS CoV-2* (RUO) Contact

R-Biopharm AG, *RIDA®GENE SARS-CoV-2* (RUO) Contact

Sansure Biotech, Inc., *Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)* (China-FDA EUA; CE-IVD) Contact

SD BIOSENSOR Inc., *STANDARD M nCoV Real-Time Detection Kit* (Korea-MFDS EUA; CE-IVD) Contact

Sentinel CH, *STAT-NAT® Covid-19 HK and STAT-NAT® Covid-19 B* (RUO) Contact

Shaanxi Lifegen Co., Ltd., *Novel coronavirus (COVID-19) nucleic acid detection kit*

(fluorescent PCR method) (CE-IVD) Contact

SunStar Joint Stock Company, *LAMP-COVID-19* (RUO) Contact

Shanghai Fosun Long March Medical Science Co.,Ltd., *2019-Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit* (RUO) Contact

Shanghai GeneoDx Biotechnology Co., LTD., *Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Fluorescent PCR Method)* (China-FDA EUA) Contact

Shanghai Kehua Bio-engineering Co., Ltd, *SARS-CoV-2 Nucleic Acid Test* (RUO) Contact

Shenzhen Puruikang Biotech Co., Ltd, *Detection Kit for 2019-Novel Coronavirus RNA* (RT-PCR-Fluorescence Probing) (CE-IVD) Contact

Shenzhen Tailored Medical Ltd, *New Coronavirus (SARS-CoV-2) Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method)* (CE-IVD) Contact

SunStar Joint Stock Company, *LAMP-COVID-19* (RUO) Contact

TargetingOne, *Novel Coronavirus (SARS-CoV-2) nucleic acid detection kit* (Digital PCR method) (RUO) Contact

Thermo Fisher Scientific, *TaqMan™ SARS-CoV-2 Assay Kit v2* (US-FDA EUA) Contact

TIB Molbiol/Roche Diagnostics

- *LightMix Modular SARS and WuHan CoV E-gene* (RUO)
- *LightMix Modular SARS and WuHan CoV N-gene* (RUO)
- *LightMix Modular WuHan CoV RdRp-gene* (RUO)

US CDC, *2019 nCoV Real-Time RT-PCR Diagnostic Panel* (US-FDA EUA)

Vircell, S.L., *SARS-COV-2 REALTIME PCR KIT* (CE-IVD) Contact

Wuhan Easydiagnosis Biomedicine Co., Ltd, *SARS-CoV-2 nucleic acid test kit* (China-FDA EUA; CE-IVD) Contact

Wuhan HealthCare Biotechnology Co., Ltd., *Corona Virus Disease 2019 (COVID-19) Nucleic Acid Detection Kit* (CE-IVD) Contact

Xiamen Zeesan Biotech Co., Ltd., *SARS-CoV-2 Test Kit* (manual; lab-based; CE-IVD) Contact-1 Contact-2

Xi'an Tianlong Science and Technology Co.,Ltd., *COVID-19 ORF1ab/N Gene PCR Detection Kit* (RUO) Contact

Zhuhai Haitai Biological Pharmaceutical Co., LTD, *Novel Coronavirus (2019-nCoV)/Flu A/Flu B Real-time Multiplex RT-PCR Kit* (manual & automated lab-based) (RUO) Contact

Automated lab-based, near-POC NAT or POC NAT

3D Medicine Science & Technology Co., Ltd., *ANDiS® SARS-CoV-2 RT-qPCR Detection Kit* (US-FDA EUA; CE-IVD)

AITbiotech, *abTES COVID-19 qPCR I Kit* (lab-based; CE-IVD) Contact

Anatolia Geneworks, *Bosphore Novel Coronavirus (2019-nCoV) Detection Kit* (lab-based; CE-IVD) Contact

Anbio (Xiamen) Biotechnology Co., Ltd., *COVID-19 Hybrid Capture Fluorescence Immunoassay Test* (China-FDA EUA) Contact-1 Contact-2

AusDiagnostics, *SARS-CoV-2, Influenza and RSV 8-well* (RUO) Contact

Bai-care, *Multiplex Nucleic Acid Detection Kit for Respiratory Pathogens* (Microfluidic Chip-PCR Fluorescent Probes) (CE-IVD) Contact

Beijing Bohui Innovation Biotechnology, *Automated SarS-CoV-2 NAT* (RUO) Contact

Beijing Microread Genetics Co.,Ltd, *COVID-19 (SARS-CoV-2) Detection Kit (LAMP)* (lab-based or near-POC; CE-IVD) Contact

Biomeme, *COVID-19 Go Strips* (RUO)

BIONEER Corporation, *AccuPower® 2019-nCoV Real Time RT-PCR Kit* (manual kit: NCV-2122; CE-IVD/lab-based automated kit: NCV-1111; CE-IVD) Contact

CapitalBio Technology, *Respiratory Virus Nucleic Acid Detection Kit (Isothermal Amplification Chip Method)* (automated near-POC NAT; China-FDA) Contact

Cepheid, *Xpert Xpress SARS-CoV-2* (US-FDA EUA) Contact

CerTest Biotec, S.L., *VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit adapted for BD MAX™ System* (CE-IVD) Contact

FIND

Because diagnosis matters

Search

COVID-19 Viral Antigen Test Kit (ELISA) (RUO)

COVID-19 IgG Antibody Test Kit (ELISA) (RUO)

COVID-19 IgM Antibody Test Kit (ELISA) (RUO)

Beijing Savant Biotechnology Co., Ltd., *SARS-Cov-2 Antigen Fluorescence Rapid Detection Kit* (CE-IVD) Contact

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. Contact

Wantai SARS-CoV-2 IgM ELISA (RUO)

Wantai SARS-CoV-2 Ab ELISA (RUO)

BluSense Diagnostics ApS, *ViroTrack COVID IgA+IgM/IgG/Total Ig Ab* (RUO) Contact

Bio-Techne, *Ella / Simple Plex COVID-19 16×4 Standard Panel* (RUO) Contact

Boditech Med, Inc. Contact

AFIAS COVID-19, Viral Antigen (automated; RUO)

AFIAS COVID-19 Ab, IgM/IgG (automated; RUO)

Ichroma COVID-19, viral antigen (manual; RUO)

Ichromia COVID-19 Ab, IgM/IgG (manual; RUO)

Creative Biolabs Contact

SARS-CoV-2 (2019-nCoV) Spike Protein ELISA Kit (Manual; automated; RUO)

SARS-CoV-2 (2019-nCoV) Nucleoprotein Protein ELISA Kit (manual; automated; RUO)

Creative Diagnostics, Contact

SARS-CoV-2 IgG ELISA Kit (RUO)

SARS-CoV-2 IgM ELISA Kit (RUO)

SARS-CoV-2 Antigen ELISA Kit (RUO)

Eagle Biosciences, Inc. Contact

COVID-19 IgG ELISA Assay (RUO)

COVID-19 IgM ELISA Assay (RUO)

Epitope Diagnostics, Inc. Contact

EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit (CE-IVD)

EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit (CE-IVD)

EUROIMMUN AG Contact

Anti-SARS-CoV-2 ELISA (IgA) (manual; automated; CE-IVD)

Anti-SARS-CoV-2 ELISA (IgG) (manual; automated; CE-IVD)

GenBody, Inc. *GenBody FIA COVID-19 IgM/IgG* (manual; RUO) Contact

Guangzhou Darui Biotechnology Co.,Ltd Contact

2019 Novel Coronavirus (2019-nCoV) IgM Antibody Detection Kit (ELISA Method) (RUO)

2019 Novel Coronavirus (2019-nCoV) IgG Antibody Detection Kit (ELISA Method) (RUO)

Novel Coronavirus 2019-nCoV IgM Antibody Detection Kit (Colloidal Gold Method) (RUO)

Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO)

Guangzhou Wondfo Biotech Co., Ltd, *Finecare SARS-CoV-2 Antibody Test* (manual; RUO) Contact

Liming Bio-Products Co., Ltd, *COVID-19 Antigen Rapid Test Device* (CE-IVD) Contact

LOMINA AG., *SARS-CoV-2(COVID19)IgM/IgG Antibody Fast Detection Kit* (CE-IVD) Contact

SD BIOSENSOR, Inc., *STANDARD F COVID-19 Ag FIA* (manual; CE-IVD) Contact

Shanghai Combio Biotech Co. Ltd, *Combio Human IgM & IgG antibodies detection kit of COVID-19 (ELISA)* (manual; RUO) Contact

Shenzhen Yhlo Biotech Co. Ltd Contact

iFlash-SARS-CoV-2 IgM (CE-IVD)

iFlash-SARS-CoV-2 IgG (CE-IVD)

Snibe Co., Ltd. (Shenzhen New Industries Biomedical Engineering Co., Ltd) Contact

MAGLUMI 2019-nCoV IgG (CLIA) (automated IA, CE-IVD)

MAGLUMI 2019-nCoV IgM (CLIA) (automated IA, CE-IVD)

Sophonix Co., Ltd., *SARS-CoV-2 IgG antibody test kit SARS-CoV-2 IgM antibody test kit* (automated IA, RUO) Contact

Sugentech, Inc. Contact

SGTi-flex COVID-19 IgM/IgG (manual, CE-IVD)

SGTi-flex COVID-19 IgM (manual, CE-IVD)

SGTi-flex COVID-19 IgG (manual, CE-IVD)

Taizhou ZECEN Biotech Co., Ltd., Contact

SARS-CoV-2 IgM (CE-IVD)

SARS-CoV-2 IgG (CE-IVD)

Tetracore Inc., *Multiplex detection and differentiation SARS-Cov-2 Serology Assay* (manual; RUO) Contact

Zhengzhou Humanwell Biocell Biotechnology Co., Ltd Contact

BIOCELL COVID-19 IgM ELISA test (RUO)

BIOCELL COVID-19 IgG ELISA test (RUO)

Rapid diagnostic tests

AmonMed Biotechnology Co., Ltd. Contact

COVID-19 IgM/IgG test kit (Rare Earth Nano Fluorescence Immunochromatography) (CE-IVD)

COVID-19 IgM/IgG test kit (Colloidal Gold) (CE-IVD)

COVID-19/Influenza A virus/Influenza B virus IgM combo test kit (Rare Earth Nano Fluorescence Immunochromatography) (CE-IVD)

COVID-19/Influenza A virus/Influenza B virus test kit (Rare Earth Nano Fluorescence Immunochromatography) (CE-IVD)

COVID-19 Antigen Test Kit (Rare Earth Nano Fluorescence Immunochromatography) (CE-IVD)

Anhui Deep Blue Medical Technology Co., Ltd., *Colloidal gold strip for SARS-CoV-2 IgG & IgM* (RUO) Contact

Avioq Bio-Tech Co.,Ltd., *Novel Coronavirus (2019-nCov) Antibody IgG/IgM Assay Kit* (Colloidal Gold) (RUO) Contact

Beijing Abace Biology Co., Ltd., Contact

COVID-19 Viral Antigen Test Kit (Colloidal Gold Immunochromatography) (RUO)

COVID-19 Antibody (IgG/IgM)Test Kit (Colloidal Gold Immunochromatography) (CE-IVD)

Beijing Diagreat Biotechnologies Co., Ltd., Contact

2019-nCoV IgG Antibody Determination Kit (CE-IVD)

2019-nCoV IgM Antibody Determination Kit (CE-IVD)

Beijing Kewei Clinical Diagnostic Reagent Inc. Contact

Kewei COVID-19 IgM ELISA Test Kit (CE-IVD)

Kewei COVID-19 IgG ELISA Test Kit (CE-IVD)

Kewei COVID-19 IgG/IgM Fluorescence Rapid Test Kit (CE-IVD)

Kewei COVID-19 Antigen ELISA Test Kit (Nasal/Throat Swab) (CE-IVD)

Kewei COVID-19 Antigen Fluorescence Rapid Test Kit (Nasal/Throat Swab) (CE-IVD)

Beijing Tigsun Diagnostics Co.,Ltd., *Tigsun COVID-19 Combo IgM/IgG Rapid Test* (Lateral Flow Method) (CE-IVD) Contact

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. *Wantai SARS-CoV-2 Ab Rapid Test* (RUO) Contact

BIOMAXIMA S.A., *2019-nCoV IgG/IgM Rapid Test Cassette* (CE-IVD) Contact

BioMedomics, Inc. *COVID-19 IgM-IgG Dual Antibody Rapid Test* (CE-IVD) Contact

BTNX Inc., *Rapid Response COVID-19 IgG/IgM Test Cassette* (Whole Blood/Serum/Plasma) (RU) Contact

Cellex, Inc., *Cellex qSARS-CoV-2 IgGIgM Cassette Rapid Test* (CE-IVD) Contact

Changsha Sinocare Inc., *SARS-CoV-2 Antibody Test Strip* (Colloidal Gold Method) (CE-IVD) Contact

Core Technology Co., Ltd., *COVID-19 IgM/IgG Ab Test* (CE-IVD) Contact-1 Contact-2

Coris BioConcept, *COVID-19 Respi-Strip* (RUO) Contact

CTK Biotech, Inc., *OnSite COVID-19 IgG/IgM Rapid Test* (CE-IVD) Contact

Dynamiker Biotechnology (Tianjin) Co., Ltd., *2019 nCOV IgG/IgM Rapid Test* (CE-IVD) Contact-1 Contact-2

Edinburgh Genetics Limited, *Watmind 2019 nCoV novel coronavirus antibody detection reagent* (Colloidal gold) (CE-IVD) Contact

GenBody, Inc., Contact

GenBody COVID-19 IgM/IgG (CE-IVD)

GenBody COVID-19 IgM/IgG DUO (RUO)

Getein Biotech, Inc., *One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)* (CE-IVD) Contact

Guangzhou Fenghua Bioengineering , Co. LTD, *Combined Detection Kit for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody* (RUO) Contact

Hanghzhou AllTest Biotech Co., Ltd, *2019-nCoV Antigen Rapid Test Cassette* (Swab/Sputum) (CE-IVD) Contact

Hangzhou Biotest Biotech Co.,Ltd., *COVID-19 IgG/IgM Rapid Test Cassette* (Whole Blood/Serum/Plasma) (CE-IVD) Contact

Humasis, *Humasis COVID-19 IgG/IgM Test* (RUO) Contact

Hunan Lituo Biotechnology Co., Ltd., *COVID-19 IgG/IgM Detection Kit (Colloidal Gold)* (CE-IVD) Contact

Hunan Yonghe-Sun Biotechnology Co., Ltd., SARS-COV-2 specific antibody test kit (Immunochromatography) (RUO) Contact

Innovita Biological Technology Co. Ltd, *2019-nCoV Ab Test (Colloidal Gold)* (IgM/IgG Whole Blood/Serum/Plasma Combo) (China-FDA EUA; CE-IVD) Contact

InTec Products, Inc., Contact-1; Contact-2

Rapid SARS-CoV-2 Antibody (IgM/IgG) Test (RUO)

Rapid SARS-CoV-2 Antibody Test (RUO)

Jiangsu Bioperfectus Technologies Co. Ltd, Contact

PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (CE-IVD)

PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit (CE-IVD)

Jiangsu Superbio Biomedical Technology (Nanjing) Co., Ltd., *Fast SARS-CoV-2 IgM/IgG Antibody Detection Kit* (Colloidal Gold) (RUO) Contact

Liming Bio-Products Co., Ltd, *COVID-19 IgG/IgM Combo Rapid Test Device* (CE-IVD) Contact

MedicalSystem Biotechnology Co., Ltd., *COVID-19 IgM/IgG Rapid Test Cassette* (CE-IVD) Contact

Mei Ning Kang Cheng China Biotechnology R&D Center, Inc., *Corona Virus Disease 2019 (COVID-19) IgM/IgG Detection Kit* (RUO) Contact

Nantong Egens Biotechnology Co., LTD, *EGENS COVID-19 IgG/IgM Rapid Test Kit* (CE-IVD; RUO) Contact

Nirmidas Biotech, Inc., *Rapid COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit* (RUO) Contact

PerGrande BioTech Development Co., Ltd., *SARS-CoV-2 Antibody Detection Kit* (Colloidal Gold Immunochromatographic assay) (CE-IVD) Contact

RayBiotech, *Coronavirus (SARS-CoV-2) IgM/IgG Test Kit* (Colloidal Gold) (US-FDA; CE-IVD) Contact

SD BIOSENSOR, Inc., Contact

- *STANDARD Q COVID-19 IgM/IgG Duo* Test (CE-IVD)
- *STANDARD Q COVID-19 Ag Test* (CE-IVD)

SensingSelf, Pte, Ltd, Singapore, *EDR COVID 19 Rapid Test Kit* (IgM/IgG) (CE-IVD) Contact

servoprax GmbH, *Cleartest Corona, Covid-19* (CE-IVD) Contact-1; Contact-2

Shanghai Chemtron Biotech Co. Ltd., 2019-nCoV IgM Antibody Diagnostic Kit (Colloidal gold) (China-FDA; CE-IVD) Contact

ShanXi Medical University, *SARS-COV-2 IgM/IgG antibody test* (Colloidal Gold) (RUO) Contact

Shenzhen Bioeasy Biotechnology Co., Ltd., Contact

- *Bioeasy 2019-nCoV Fluorescence Antigen Rapid Test* (CE-IVD)
- *Bioeasy 2019-nCov Colloidal Gold Antigen Rapid Test* (CE-IVD)
- *Bioeasy 2019-nCoV IgG/IgM detection kit (colloidal gold immunochromatography)* (CE-IVD)
- *Bioeasy 2019-nCoV Ag Fluorescence Rapid Test Kit (Time-Resolved Fluorescence)* (CE-IVD)

Shenzhen Tailored Medical Ltd., *Novel Coronavirus (SARS-CoV-2) IgM/IgG Antibody Assay Kit* (Colloidal Gold Method) (CE-IVD) Contact

Sugentech, Inc., Contact

- *SGTi-flex COVID-19 IgM/IgG* (CE-IVD)
- *SGTi-flex COVID-19 IgM* (CE-IVD)
- *SGTi-flex COVID-19 IgG* (CE-IVD)

Sure Bio-Tech (USA) Co., Ltd. Contact

- *SARS-CoV-2 IgM Ab Rapid Test* (CE-IVD)
- *SARS-CoV-2 IgG Ab Rapid Test* (CE-IVD)
- *SARS-CoV-2 IgM/IgG Ab Rapid Test* (CE-IVD)

Tianjin Jianbo Biological Co., Ltd, *SARS-CoV-2 Specific IgM and IgG Test Kit* (Coillodal Gold) (RUO) Contact

Tianjin MNCHIP Technologies Co., Ltd., *Anti-COVID-19 virus IgM/IgG rapid test kit (Colloidal gold assay)* (CE-IVD) Contact

VivaChek Biotech (Hangzhou) Co., Ltd, *VivaDiag COVID-19 IgM/IgG Rapid Test* (CE-IVD) Contact

Wuhan EasyDiagnosis Biomedicine Co.,Ltd Contact

Novel Coronavirus IgM antibody test kit (colloidal gold method) (CE-IVD)

Novel Coronavirus IgG antibody test kit (colloidal gold method) (CE-IVD)

Xiamen Biotime Biotechnology Co., Ltd., *SARS-CoV-2 IgG/IgM Rapid Qualitative Test Kit* (CE-IVD) Contact

Xiamen Wiz Biotech Co., Ltd., *Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-COV-2* (RUO) Contact

Zhuhai Livzon Diagnostics Inc., *Diagnostic Kit for IgM Antibody to Corona Virus(nCoV-2019)* (Colloidal Gold) (China-FDA) Contact

In development

Manual or automated immunoassays

Attomarker Ltd, *Quantitative Immuno-kinetic assay for Covid-19 IgG+IgM+IgA for a multiantigen panel with CRP* (automated; proof of concept) Contact

Beijing Shengkun Kangru Medical Equipment Co., Ltd., *2019-nCoV Detection kit (quantum dot immunofluorescence method)* (validated) Contact

BluSense Diagnostics ApS, *ViroTrack COVID IgA+IgM/IgG/Total Ig Ab* (automated; proof of concept) Contact

DART Diagnostics, *DART COVID-19* (manual; concept) Contact

InDevR Inc., *COVID Serology Kit: Multiplexed Immunoassay* (manual; concept) Contact

Kephera Diagnostics, *KDx COVID-19 IgG and IgM ELISA* (manual; proof of concept) Contact

St. Petersburg Research Institute of Vaccines and Sera (FSUE SPbSRIVS FMBA), *SARS-CoV-2 Tru-EIA* (manual; concept) Contact

Zalgen Labs, LLC, Contact

ReSARS CoV-2 Antigen ELISA Kit (manual; proof of concept)

ReSARS Pan-Corona Antigen ELISA Kit (manual; proof of concept)

ReSARS CoV-2 IgM ELISA Kit (manual; proof of concept)

ReSARS Pan-Corona IgM ELISA Kit (manual; proof of concept)

Rapid diagnostic tests

Absea Biotechnology Ltd., *The non-invasive MEGA test of SARS-CoV-2* (mucosal swabs) (validated) Contact-1 Contact-2

Academia Sinica Contact

Anti-SARS-CoV-2 nucleocapsid protein human IgM/IgG rapid detection kit

SARS-CoV-2 Nucleocapsid Protein Rapid Detection Kit

Alfa Scientific Designs, Inc., *DrivenFlow COVID-19* Contact

Baiya Phytopharm, Co, Ltd., *Baiya Rapid COVID-19 IgM/IgG test kit* (proof of concept) Contact

Denka Seiken Co. Ltd., *QuickNavi-COVID19* (tentative) (concept) Contact-1 Contact-2

FemtoDx, *COVID-19 Antibody Test* (proof of concept) Contact

Great Basin – Vela Operations, *SARS-CoV-2 Direct Test* (concept) Contact

Hangzhou AllTest Biotech Co. Ltd., *2019-nCOV Antigen Rapid Test Cassette* (proof of concept) Contact

Kephera Diagnostics, Contact

KDx COVID-19 IgG/IgM Rapid Detection Test Kit (proof of concept)

KDx COVID-19 Antigen Detection Rapid Test (proof of concept)

Lifeassay Diagnostics Pty. Ltd., *Test-it COVID-19 IgM/IgG Lateral Flow Assay* (proof of concept) Contact

Luminostics, Inc., *CLIP-COVID19* (smartphone-read out high sensitivity antigen detection test) (concept) Contact

Mologic Ltd., *Mologic COVID-19 Rapid Test* (proof of concept) Contact

Nanjing BioPoint Diagnostics, *BioPoint SARS-CoV-2 dIgA/total antibody rapid test* (concept) Contact

Nanotech (concept)

Pinpoint Science Inc., *Pinpoint Covid-19 Screening Assay* (proof of concept) Contact

Predigen, Inc., *HR-PreV* (validated) Contact

Qingdao Hightop Biotech Co., Ltd., *Hightop COVID-19 IgM/IgG Ab Rapid Test Kit* (proof of concept) Contact

RapiGEN Inc. Contact

BIOCREDIT COVID-19 IgG+IgM Duo (proof of concept)

BIOCREDIT COVID-19 Ag (proof of concept)

Sona Nanotech, *Sona-COVID-19 LFA* (proof of concept) Contact

Zalgen Labs, LLC, Contact

ReSARS CoV-2 Antigen Rapid Test (proof of concept)

ReSARS Pan-Corona Rapid Test (proof of concept)

DIGITAL SOLUTIONS

Beijing Infervision Technology Co. Ltd, *InferRead CT Pneumonia* (validated) Contact

Canary Health Technologies, *AiroStotleCV19 (Breath VOCs)* (proof-of-concept) Contact

SAMPLE COLLECTION / INACTIVATION

AcouSort AB, *Blood plasma separation using ultrasound* (RUO) Contact

CanaryQ, *Simple Blood & Saliva Separation* (proof-of-concept; RUO) Contact

FABPulous/DTwist BV *DTwist* Contact

University of Washington, *Tongue swab diagnosis of SARS-CoV-2* (proof of concept) Contact

OTHER DIAGNOSTICS

Ativa Medical, *Early Recognition Enhanced Screening Complete Blood Count* Contact-1 Contact-2

Pinpoint Science Inc., *Pinpoint Covid-19 Screening Assay – Electrical detection of SARS-CoV-2 nucleocapsid protein using nanosensors and aptamer* (proof of concept) Contact

RetroVirox Inc., *SARS-CoV-2 Pseudovirus assay for neutralizing antibodies* (RUO) Contact

Twist Bioscience, *NGS-based target capture for SARS-CoV-2 detection and screening* (proof of concept) Contact

CE-IVD – conformité européenne (EU certification)-*in vitro* diagnostics
EUA – Emergency Use Authorization
HSA – Health and Safety Authority/Health and Sciences Authority
MFDS – Ministry of Food and Drug Safety
NRA – National Regulatory Authority
RUO – Research Use Only

MORE INFORMATION

For more information please contact us.

Laboratory testing for coronavirus disease (COVID-19) in suspected human cases

Interim guidance
19 March 2020

World Health Organization

Background

This document provides interim guidance to laboratories and stakeholders involved in COVID-19 virus laboratory testing of patients.

It is based in part on the interim guidance on laboratory testing for Middle East Respiratory Syndrome (MERS) coronavirus.[1-6] Information on human infection with the COVID-19 virus is evolving and WHO continues to monitor developments and revise recommendations as necessary. This document will be revised as new information becomes available. Feedback is welcome and can be sent to WHElab@who.int.

The virus has now been named SARS-CoV-2 by the International Committee of Taxonomy of Viruses (ICTV)[7] (2). This virus can cause the disease named coronavirus disease 2019 (COVID-19). WHO refers to the virus as COVID-19 virus in its current documentation.

Laboratory testing guiding principles for patients who meet the suspect case definition.

The decision to test should be based on clinical and epidemiological factors and linked to an assessment of the likelihood of infection. PCR testing of asymptomatic or mildly symptomatic contacts can be considered in the assessment of individuals who have had contact with a COVID-19 case. Screening protocols should be adapted to the local situation. The case definitions are being regularly reviewed and updated as new information becomes available. For the WHO suspected case definition see: Global Surveillance for human infection with coronavirus disease (COVID-2019).[8]

Rapid collection and testing of appropriate specimens from patients meeting the suspected case definition for COVID-19 is a priority for clinical management and outbreak control and should be guided by a laboratory expert. Suspected cases should be screened for the virus with nucleic acid amplification tests (NAAT), such as RT-PCR.

If testing for COVID-19 is not yet available nationally, specimens should be referred. A list of WHO reference laboratories providing confirmatory testing for COVID-19 and shipment instructions are available.

If case management requires, patients should be tested for other respiratory pathogens using routine laboratory procedures, as recommended in local management guidelines for community-acquired pneumonia. Additional testing should not delay testing for COVID-19. As co-infections can occur, all patients that meet the suspected case definition should be tested for COVID-19 virus regardless of whether another respiratory pathogen is found.

In an early study in Wuhan, the mean incubation period for COVID-19 was 5.2 days among 425 cases, though it varies widely between individuals.[9-11] Virus shedding patterns are not yet well understood and further investigations are needed to better understand the timing, compartmentalization, and quantity of viral shedding to inform optimal specimen collection. Although respiratory samples have the greatest yield, the virus can be detected in other specimens, including stool and blood.[12,14] Local guidelines on informed consent should be followed for specimen collection, testing, and potentially future research.

Specimen collection and shipment

Safety procedures during specimen collection

Ensure that adequate standard operating procedures (SOPs) are in use and that staff are trained for appropriate specimen collection, storage, packaging, and transport. All specimens collected for laboratory investigations should be regarded as potentially infectious.

Ensure that health care workers who collect specimens adhere rigorously to infection prevention and control guidelines. Specific WHO interim guidance has been published.[16]

Box 1. Biosafety practices in the laboratory

Testing on clinical specimens from patients meeting the suspected case definition should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures. National guidelines on laboratory biosafety should be followed in all circumstances. There is still limited information on the risk posed by COVID-19, but all procedures should be undertaken based on a risk assessment. Specimen handling for molecular testing would require BSL-2 or equivalent facilities. Attempts to culture the virus require BSL-3 facilities at minimum.

For more information related to COVID-19 risk assessment, see: WHO interim guidance for laboratory biosafety related to 2019-nCoV. Samples that are potentially infectious materials (PIM) for polio need to be handled and stored as described in WHO document Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance) . For general laboratory biosafety guidelines, see the WHO Laboratory Biosafety Manual, 3rd edition before the 4th edition is released.

Specimens to be collected

At minimum, respiratory material should be collected:

- upper respiratory specimens: nasopharyngeal and oropharyngeal swab or wash in ambulatory patients
- and/or lower respiratory specimens: sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease. (Note high risk of aerosolization; adhere strictly to infection prevention and control procedures).

Additional clinical specimens may be collected as COVID-19 virus has been detected in blood and stool, as had the coronaviruses responsible for SARS and MERS.[12,14,17-19] The duration and frequency of shedding of COVID-19 virus in stool and potentially in urine is unknown. In case of patients who are deceased, consider autopsy material including lung tissue. In surviving patients, paired serum (acute and convalescent) can be useful to retrospectively define cases as serological assays become available.

Further recommendations on materials to collect, including the testing of asymptomatic individuals, can be found in Table 1.

Packaging and shipment of clinical specimens

Specimens for virus detection should reach the laboratory as soon as possible after collection. Correct handling of specimens during transportation is essential. Specimens that can be delivered promptly to the laboratory can be stored and shipped at 2-8°C. When there is likely to be a delay in specimens reaching the laboratory, the use of viral transport medium is strongly recommended. Specimens may be frozen to - 20°C or ideally -70°C and shipped on dry ice if further delays are expected (see Table 2). It is important to avoid repeated freezing and thawing of specimens.

Transport of specimens within national borders should comply with applicable national regulations. International transport of potentially COVID-19 virus containing samples should follow the UN Model Regulations, and any other applicable regulations depending on the mode of transport being used. More information may be found in the WHO Guidance on regulations for the Transport of Infectious Substances 2019-2020[22] and WHO interim guidance for laboratory biosafety related to coronavirus disease.[16]

Ensure good communication with the laboratory and provide needed information.

Alerting the laboratory before sending specimens encourages proper and timely processing of samples and timely reporting. Specimens should be correctly labelled and accompanied by a diagnostic request form (template provided in Annex I).

Laboratory testing for COVID-19 virus

Laboratories undertaking testing for COVID-19 virus should adhere strictly to appropriate biosafety practices.

Nucleic acid amplification tests (NAAT) for COVID-19 virus.

Routine confirmation of cases of COVID-19 is based on detection of unique sequences of virus RNA by NAAT such as real-time reverse-transcription polymerase chain reaction (rRT-PCR) with confirmation by nucleic acid sequencing when necessary. The viral genes targeted so far include the N, E, S and RdRP genes. Examples of protocols used may be found here. RNA extraction should be done in a biosafety cabinet in a BSL-2 or equivalent facility. Heat treatment of samples before RNA extraction is not recommended.

Laboratory confirmation of cases by NAAT in areas with no known COVID-19 virus circulation.

To consider a case as laboratory-confirmed by NAAT in an area with no COVID-19 virus circulation, one of the following conditions need to be met:

- A positive NAAT result for at least two different targets on the COVID-19 virus genome, of which at least one target is preferably specific for COVID-19 virus using a validated assay (as at present no other SARS-like coronaviruses are circulating in the human population it can be debated whether it must be COVID-19 or SARS-like coronavirus specific); OR
- One positive NAAT result for the presence of betacoronavirus, and COVID-19 virus further identified by sequencing partial or whole genome of the virus as long as the sequence target is larger or different from the amplicon probed in the NAAT assay used.

When there are discordant results, the patient should be resampled and, if appropriate, sequencing of the virus from the original specimen or of an amplicon generated from an appropriate NAAT assay, different from the NAAT assay initially used, should be obtained to provide a reliable test result. Laboratories are urged to seek confirmation of any surprising results in an international reference laboratory.

Laboratory-confirmed case by NAAT in areas with established COVID-19 virus circulation.

In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which, for example, screening by rRT-PCR of a single discriminatory target is considered sufficient.

One or more negative results do not rule out the possibility of COVID-19 virus infection. A number of factors could lead to a negative result in an infected individual, including:

- poor quality of the specimen, containing little patient material (as a control, consider determining whether there is adequate human DNA in the sample by including a human target in the PCR testing).
- the specimen was collected late or very early in the infection.
- the specimen was not handled and shipped appropriately.

- technical reasons inherent in the test, e.g. virus mutation or PCR inhibition.

If a negative result is obtained from a patient with a high index of suspicion for COVID-19 virus infection, particularly when only upper respiratory tract specimens were collected, additional specimens, including from the lower respiratory tract if possible, should be collected and tested.

Each NAAT run should include both external and internal controls, and laboratories are encouraged to participate in external quality assessment schemes when they become available. It is also recommended to laboratories that order their own primers and probes to perform entry testing/validation on functionality and potential contaminants.

Serological testing

Serological surveys can aid investigation of an ongoing outbreak and retrospective assessment of the attack rate or extent of an outbreak. In cases where NAAT assays are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples (in the acute and convalescent phase) could support diagnosis once validated serology tests are available. Serum samples can be stored for these purposes.

Cross reactivity to other coronaviruses can be challenging,[22] but commercial and non-commercial serological tests are currently under development. Some studies with COVID-19 serological data on clinical samples have been published.[23,24]

Viral sequencing

In addition to providing confirmation of the presence of the virus, regular sequencing of a percentage of specimens from clinical cases can be useful to monitor for viral genome mutations that might affect the performance of medical countermeasures, including diagnostic tests. Virus whole genome sequencing can also inform molecular epidemiology studies. Many public-access databases for deposition of genetic sequence data are available, including GISAID, which is intended to protect the rights of the submitting party.[25]

Viral culture

Virus isolation is not recommended as a routine diagnostic procedure.

Reporting of cases and test results

Laboratories should follow national reporting requirements. In general, all test results, positive or negative, should be immediately reported to national authorities. States Parties to the IHR are reminded of their obligations to share with WHO relevant public health information for events for which they notified WHO, using the decision instrument in Annex 1 of the IHR (2005).[26]

Research toward improved detection of COVID-19 virus.

Many aspects of the virus and disease are still not understood. A better understanding will be needed to provide improved guidance. For example:

Viral dynamics: optimal timing and type of clinical material to sample for molecular testing-

- Dynamic of immunological response
- Disease severity in various populations, e.g. by age.
- The relationship between viral concentration and disease severity.
- The duration of shedding, and relation to clinical picture (e.g. clinical recovery occurs with viral clearing, or shedding persists despite clinical improvement).
- Development and validation of useful serological assays.
- Comparative studies of available molecular and serological assays.
- Optimal percentage of positive cases that requires sequencing to monitor mutations that might affect the performance of molecular tests.
- WHO encourages the sharing of data to better understand and thus manage the OVID-19 outbreak, and to develop countermeasures.

Table 1. Specimens to be collected from symptomatic patients and contacts

	Test	Type of sample	Timing
Patient	NAAT	Lower respiratory tract - sputum - aspirate - lavage Upper respiratory tract - nasopharyngeal and - oropharyngeal swabs - nasopharyngeal wash/nasopharyngeal aspirate. Consider stools, whole blood, urine, and if diseased, material from autopsy.	Collect on presentation. Possibly repeated sampling to monitor clearance. Further research needed to determine effectiveness and reliability of repeated sampling.
Patient	Serology	Serum for serological testing once validated and available.	Paired samples are necessary for confirmation with the initial sample collected in the first week of illness and the second ideally collected 2-4 weeks later (optimal timing for convalescent sample needs to be established).
Contact in health-care centre associated outbreaks or other settings where contacts have symptoms, or where asymptomatic contacts have had high-intensity contact with a COVID-19 case.	NAAT	Nasopharyngeal and oropharyngeal swabs.	Within incubation period of last documented contact.
	Serology	Serum for serological testing once validated and available.	Baseline serum taken as early as possible within incubation period of contact and convalescent serum taken 2-4 weeks after last contact (optimal timing for convalescent sample needs to be established).

Table 2. Specimen collection and storage (adapted from[4, 27, 28])

Specimen type	Collection materials	Storage temperature until testing in-country laboratory	Recommended temperature for shipment according to expected shipment time
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Bronchoalveolar lavage	Sterile container *	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
(Endo)tracheal aspirate, nasopharyngeal or nasal wash/aspirate	Sterile container *	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
Sputum	Sterile container	2-8 °C	2-8 °C if ≤2 days –70 °C (dry ice) if >2 days
Tissue from biopsy or autopsy including from lung.	Sterile container with saline or VTM.	2-8 °C	2-8 °C if ≤24 hours –70 °C (dry ice) if >24 hours
Serum	Serum separator tubes (adults: collect 3-5 ml whole blood).	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Whole blood	Collection tube	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Stool	Stool container	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days
Urine	Urine collection container	2-8 °C	2-8 °C if ≤5 days –70 °C (dry ice) if >5 days

* For transport of samples for viral detection, use viral transport medium (VTM) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens. If VTM is not available sterile saline may be used instead (in which case, duration of sample storage at 2-8 °C may be different from what is indicated above).

Aside from specific collection materials indicated in the table also assure other materials and equipment are available: e.g. transport containers and specimen collection bags and packaging, coolers, and cold packs or dry ice, sterile blood-drawing equipment (e.g. needles, syringes and tubes), labels and permanent markers, PPE, materials for decontamination of surfaces, etc.

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication

Annex I

COVID-19 VIRUS LABORATORY TEST REQUEST FORM[1]

Submitter information				
NAME OF SUBMITTING HOSPITAL, LABORATORY, or OTHER FACILITY*				
Physician				
Address				
Phone number				
Case definition:[2]	☐ Suspected case ☐ Probable case			
Patient info				
First name		Last name		
Patient ID number		Date of Birth		Age:
Address		Sex	☐ Male ☐ Female ☐ Unknown	
Phone number				
Specimen information				
Type	☐ Nasopharyngeal and oropharyngeal swab ☐ Bronchoalveolar lavage ☐ Endotracheal aspirate ☐ Nasopharyngeal aspirate ☐ Nasal wash ☐ Sputum ☐ Lung tissue ☐ Serum ☐ Whole blood ☐ Urine ☐ Stool ☐ Other: ….			
All specimens collected should be regarded as potentially infectious and you must contact the reference laboratory before sending samples. All samples must be sent in accordance with category B transport requirements.				
Please tick the box if your clinical sample is post mortem ☐				
Date of collection		Time of collection		
Priority status				
Clinical details				
Date of symptom onset:				
Has the patient had a recent history of travelling to an affected area?	☐ Yes ☐ No	Country		
		Return date		
Has the patient had contact with a confirmed case?		☐ Yes ☐ No ☐ Unknown ☐ Other exposure:		
Additional Comments				

WHO reference number: WHO/COVID-19/laboratory/2020.5

[1] Form in accordance with ISO 15189:2012 requirements

[2] World Health Organization. Global Surveillance for human infection with coronavirus disease (COVID-19)