

Supporting Information

ASSAY TECHNIQUES AND TEST DEVELOPMENT FOR COVID-19 DIAGNOSIS

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Supporting Information

Statement

This supporting information includes: (1) descriptions of selected molecular genetic tests for COVID-19 diagnosis, (2) tables S1 and S2 highlight over 200 of the currently available molecular, serological and immunological diagnostic tests, (3) highlights of patented technology for diagnosis of related coronavirus such as SARS-CoV and MERS-CoV, and (4) selected patents with SARS-CoV-related sequences for potential applications in diagnostics.

Supporting Information I. Descriptions of selected molecular genetic tests for COVID-19 diagnosis

LabCorp COVID-19 RT-PCR test (US FDA 3/16/20), is a 1-step real-time RT-PCR test which uses a TaqPath 1-step RT-PCR master mix for qualitative detection of RNA from SARS-CoV-2 in upper and lower respiratory specimens. This test uses three DNA primer and probe sets to detect three regions in the virus nucleocapsid (N) gene and one control primer-probe set to detect human RNase P in a clinical sample. During the amplification phase, the probe anneals to a specific target sequence located between the forward and reverse primers. During the subsequent extension phase of the PCR cycle, the 5'-nuclease activity of Taq polymerase degrades the bound probe, causing a reporter dye (FAM) to separate from a quencher dye (BHQ1) and generate a fluorescent signal, the intensity of which is monitored at each PCR cycle.¹ On April 20, 2020, LabCorp's at home COVID-19 test (called Pixel) received EUA approval from the US FDA. This test includes a nasal swab that allows individuals to collect a sample from the comfort of their home and a shipping package to be used to return the sample to the lab for testing.²

CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (US FDA 2/4/20) contains full instructions for the CDC RT-PCR-based diagnostic test for detection and diagnosis of SARS-CoV-2 along with oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan) and control material used in rRT-PCR of respiratory specimens. In addition, the CDC maintains a list of primers and probes intended for

SARS-CoV-2 Real-Time RT-PCR diagnostic testing, distributed by the International Reagent Resource.³

ThermoFisher-Applied Biosystems TaqPath COVID-19 Combo Kit (US FDA 3/13/20) consists of both the TaqPath RT-PCR COVID-19 Kit and the TaqPath COVID-19 Control Kit. The TaqPath RT-PCR COVID-19 Kit is a multiplex real-time RT-PCR that includes three primers and one probe sets designed to detect the nucleocapid (N) and spike (S) genes of SARS-CoV-2. In addition to the primers and probes, the TaqPath RT-PCR COVID-19 Kit contains MS2, an internal positive control. The TaqPath COVID-19 Control Kit contains an external positive RNA control that contains in vitro transcribed RNA specific for N, S and ORF1ab regions of SARS-CoV-2.⁴

Seegene Allplex 2019-nCoV Assay (CE mark 2/22/20 and Korea MFDS 2/12/20 and US FDA 4/21/20) is a real-time RT-PCR assay for simultaneous detection and identification of three target genes (RdRP and N genes of SARS-CoV-2 and E gene from Sarbecovirus which includes SARS-CoV-2) in a single assay. The assay uses FAM to label the E gene-specific probe, Cal Red 610 to label the RdRP gene-specific probe and Quasar 670 to label the N gene-specific probe.⁵

cobas SARS-CoV-2 (Australia 2/20/20, CE mark 2020, and US FDA 3/12/20) is a real-time RT-PCR that amplifies a specific target unique to SARS-CoV-2 along with a conserved region of the E gene. It includes fully automated sample preparation (nucleic acid extraction and purification) followed by reverse transcription, PCR amplification and detection on the cobas 6800/8800 system, or other authorized instruments.⁶

ID NOW COVID-19 (US 3/27/20) is an automated assay that utilizes isothermal nucleic acid amplification technology for detection of SARS-CoV-2 RdRP gene. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets. To perform the assay, the Sample Receiver and Test base are inserted into the ID NOW™ Instrument. The test delivers high-quality molecular positive results in as little as 5 minutes.^{7, 8}

Table S1. Examples of molecular diagnostic tests used to detect viral genetic material in SARS-CoV-2⁹⁻¹¹

No.	Test Name	Test Type	Manufacturer/ Organization Name	Sample Source	Gene or Region detected	Test result time/ Additional Information	Country of approval
1	2019-nCoV RT-qPCR	real-time RT-PCR	3DMed 3D Biomedicine Science & Technology Co. Ltd	nasopharyngeal and oropharyngeal swabs	ORF1ab, and E and N genes	one-step real-time RT-PCR. N and E gene-specific probes labeled with FAM and ORF1ab region-specific probe labeled with ROX	United States
2	ID NOW COVID-19	isothermal nucleic acid amplification technology	Abbott Diagnostics Scarborough, Inc. D2	nasal, nasopharyngeal and throat swabs	RdRP gene	positive results in ~ 5 minutes and negative results in 13 minutes, approved for use outside of lab	United States
3	Abbott RealTime SARS-CoV-2 assay	real-time RT-PCR	Abbott Molecular Inc. (USA) Abbott Laboratories Pte Ltd (Singapore)	nasal, nasopharyngeal and oropharyngeal swabs	N and RdRP genes	The Abbott RealTime SARS-CoV-2 assay in combination with the realTime m2000 system, testing volumes (24-96 samples) and up to 470 patient samples in 24 hours	Brazil Canada Singapore United States
4	AcuCorona 2.0	real-time RT-PCR	Acumen Research Laboratories	nasopharyngeal or oropharyngeal swabs, sputum and bronchoalveolar lavage fluid	E and RdRP genes	The design is targeted at achieving high-throughput testing, reduced manual steps and cold-chain logistics, and overall robust results	Singapore
5	SARS-CoV-2 Test	real-time RT-PCR	AIT laboratory	nasopharyngeal and oropharyngeal swabs, and sputum	E, N and RdRP genes		United States
6	abTES COVID-19 qPCR I Kit	qualitative (real-time) RT-PCR	AITbiotech Pte Ltd	nasopharyngeal and throat swabs, sputum and serum	N gene (N1 and N2 regions)	lab-on-chip platform	Singapore
7	RealStar SARS-CoV-2 RT-PCR Kits U.S.	real-time RT-PCR	altona Diagnostics GmbH	nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate swabs, and nasal washes/aspirates			
8	Nucleic Acid reagent test kit for novel coronavirus	hybridization capture immunofluorescence	Anbio (Xiamen) Biotechnology Co., Ltd.	oropharyngeal swabs, sputum	ORF1ab, and E and N genes	rapid pathogen detection	China

	2019-nCoV (hybridization capture immunofluorescence)						
9	iAMP COVID-19 Detection Kit	real-time RT isothermal amplification	Atila BioSystems, Inc.	nasal, nasopharyngeal, and oropharyngeal swabs	ORF1ab and/or N gene	results in < 1.5 hours	United States
10	AusDiagnostics respiratory virus panel (including SARS-CoV-2) test	multiplexed tandem PCR	AusDiagnostics Pty Ltd (Australia)	respiratory samples	ORF1a and ORF8	extracts within a 3-hour timeframe	Australia
11	AvellinoCoV 2 test	real-time RT-PCR	Avellino Lab USA, Inc.	nasopharyngeal and oropharyngeal swabs	N gene (two regions)	results in 1.5-3 hours	United States
12	COVID-19 RT-PCR Test	real-time RT-PCR	Baptist Hospital Miami Pathology/Laboratory Medicine Lab	nasopharyngeal and oropharyngeal swabs	RdRP and N genes		United States
13	SARS-CoV-2 S gene for BD Max	real time RT-PCR	Becton Dickinson Surgical Industries, LTD.	nasopharyngeal and oropharyngeal swabs	S gene	results for up to 24 samples in < 3 hours	Brazil
14	BD SARS-CoV-2 Reagents for BD MAX System	real time RT-PCR	Becton, Dickinson and Company (BD)	nasal, nasopharyngeal and oropharyngeal swabs	N gene (N1 and N2 regions)		United States
15	BioGX SARS-CoV-2 Reagents for BD MAX System	real-time RT-PCR	Becton, Dickinson, BioGx	nasopharyngeal and oropharyngeal swabs	N gene (N1 and N2 regions)	results in ~2-3 hours, each BD MAX™ System can process 24 samples simultaneously	United States
16	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Beijing Applied Biological Technologies Co., Ltd	oropharyngeal swabs, sputum	ORF1ab, and E and N genes	rapid pathogen detection	China
17	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	BGI Biotechnology (Wuhan) Co., Ltd.	oropharyngeal swabs, bronchoalveolar lavage fluid	ORF1ab		China
18	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe anchor	RT-PCR and metagenomic sequencing	BGI Biotechnology (Wuhan) Co., Ltd.	oropharyngeal swabs, bronchoalveolar lavage fluid	SARS-CoV-2 RNA	results in a few hours	China

	synthesis sequencing)						
19	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	fluorescent RT-PCR	BGI Genomics Co. Ltd	bronchoalveolar lavage fluid and throat swabs	ORF1ab	results within 3 hours, detects as low as 100 viral copies/mL for BALF samples	United States
20	BioFire COVID-19 Test	multiplexed real-time RT-PCR	BioFire Defense, LLC bioMerieux	nasopharyngeal swabs	ORF1ab and ORF8	results in ~ 45 minutes	United States
21	VIASURE SARS-CoV-2 Real-Time PCR Detection Kit	real-time RT-PCR	Biomedical Equipment and Supplies, Hospitalares Ltda	nasopharyngeal swabs	ORF1ab and N genes		Brazil
22	Real-Q 2019- nCoV Detection Kit	one-step real-time RT-PCR	BioSewoom Inc.	sputum, oropharyngeal and nasopharyngeal swabs	E and RdRP genes		South Korea
23	Kit for Novel Coronavirus (2019-nCoV) RNA (Isothermal Amplification -Real Time Fluorescence Assay)	isothermal amplification n-real-time fluorescence assay	Biowalker Pte Ltd	oropharyngeal swabs and sputum	viral RNA	results within 3 hours, detects as low as 100 viral copies/mL for BALF samples	Singapore
24	Childrens-Altona-SARS-CoV-2 assay	real-time RT-PCR	Boston Children's Hospital Infectious Diseases Diagnostic Laboratory (IDDL)	nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate swabs, and sputum specimens	E and S genes		United States
25	CDC 2019- Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	real-time RT-PCR	CDC-US	nasopharyngeal or oropharyngeal aspirates/washes /swabs and bronchoalveolar lavage fluid, tracheal aspirates, and sputum	N gene	human RNase P gene used as control	United States
26	Xpert Xpress SARS-CoV-2 test	real-time RT-PCR	Cepheid	nasopharyngeal, nasal, and mid-turbinate swabs	E and N2 genes	results in ~ 45 minutes with < 1 minute of hands-on time	Australia Canada Singapore United States
27	CRISPR-based tests for SARS-CoV-2	CRISPR-based lateral flow assay isothermal	Cepheid Sherlock Biosciences	respiratory samples		combines Sherlock's Cas12 and Cas13 enzymes for nucleic acid detection with Cepheid's GeneXpert	United States

		amplification				test-processing instruments	
28	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	real-time RT-PCR	CerTest Biotec SL (Spain)	respiratory samples	ORF1ab and N gene	results in 2 hours	Australia
29	VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit	real-time RT-PCR	CerTest Biotec SL (Spain)	respiratory samples	S gene	results in 2 hours	Australia
30	SARS-CoV-2 RT-PCR test	real-time RT-PCR	Children's Hospital of Philadelphia Infectious Disease Diagnostics Laboratory	nasopharyngeal and tracheal aspirates	N2 gene		United States
31	CIRRUSDx SARS-COV-2 Assay	real-time RT-PCR	CirrusDx Laboratories	nasopharyngeal, oropharyngeal, and nasal swabs, and bronchoalveolar lavage fluid	E, N, and RdRP genes		United States
32	Logix Smart Coronavirus Disease 2019	single-step real-time RT-PCR	CoDiagnostics, Inc.	bronchoalveolar lavage fluid, sputum, tracheal aspirate, nasopharyngeal fluids, and nasal swabs	RdRP gene	results in 63-90 minutes	United States
33	VitaPCR SARS-CoV-2 Assay	real-time PCR	Credo Diagnostics Biomedical Pte Ltd	nasal and oropharyngeal swabs	viral RNA	results in 20 minutes with 1 minute of hands-on time	Singapore
34	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Da An Gene Co., Ltd. - website unavailable	oropharyngeal swabs, sputum	ORF1ab and N gene	rapid pathogen test	China
35	QuantiVirus SARS-CoV-2 Test kit	real-time RT-PCR	DiaCarta, Inc.	nasopharyngeal and oropharyngeal swabs, sputum	ORF1ab and E and N genes	results < 2 hours on most qPCR machines, sensitivity is 100 copies per mL	United States
36	LYRA SARS-CoV-2 ASSAY	real-time RT-PCR	Diagnostic Hybrids, Inc. Quidel Corporation	nasopharyngeal and oropharyngeal swabs	pp1ab	results in < 75 minutes after extraction	Canada
37	SARS-Cov-2 Assay	real-time RT-PCR	Diagnostic Molecular Laboratory – Northwestern Medicine	nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swabs, and bronchoalveolar lavage fluid	N1 and RdRP genes	results in < 1 hour without manual RNA extraction	United States

38	FORTITUDE KIT 2.0	real-time RT-PCR	Diagnostics Development Hub (DxD)	nasopharyngeal swabs	viral RNA genes less prone to mutation	results in 90 minutes, 96 samples in 1 run, 100,000 test kits/wk	Singapore
39	Simplexa COVID-19 Direct	real-time RT-PCR	DiaSorin Molecular LLC	nasopharyngeal swabs	ORF1ab and S gene	results in ~ 1 hour, no RNA extraction	United States
40	SARS-CoV-2 RT-PCR Assay	nested, end-point PCR followed by hybridization	Diatherix Eurofins Laboratory	nasal swabs, nasopharyngeal, oropharyngeal and throat swabs/washes, bronchial aspirates, and sputum	viral RNA		
41	Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus	real-time RT-PCR	DSO National Laboratories	nasopharyngeal swabs	polymerase gene		Singapore
42	Loopamp Novel Coronavirus 2019 (SARSCoV-2) Detection Kit	real-time RT-PCR	Eiken Chemical Co., Ltd.	swabs and bronchoalveolar lavage fluid	ORF1ab and S gene	results in ~ 25 minutes	Japan
43	SARS-CoV-2 Test	real-time RT-PCR	Exact Sciences Laboratories	nasopharyngeal, oropharyngeal, and nasal swabs	E, N and RdRP genes		United States
44	Fosun COVID-19 RT-PCR Detection Kit	real-time RT-PCR	Fosun Pharma USA Inc.	upper and lower respiratory specimens	ORF1b and N and E genes	ORF1b detected using FAM, N gene detected using JOE, and E gene detected using ROE	United States
45	ePlex SARS-CoV-2 Test	RT-PCR	GenMark Diagnostics, Inc.	nasopharyngeal swabs	RNA	< 2 minutes hands-on time and results in < 2 hours	United States
46	GS COVID-RT-PCR Kit	real-time RT-PCR	GenoSensor, LLC	nasopharyngeal, oropharyngeal, nasal, and mid-turbinate nasal swabs	ORF1ab and E and N genes		United States
47	Gnomegen COVID-19 RT-Digital PCR Detection Kit	digital RT-PCR	Gnomegen LLC	upper respiratory tract specimens	N gene	limit of detection of 2.5 copies per reaction, results in ~ 3 hours	United States
48	SARS-CoV-2 Real-Time RT-PCR Assay	real-time RT-PCR	Guangzhou Wondfo Biotech Co., Ltd	respiratory samples	ORF1ab and N gene	limit of detection of 2.5 copies per reaction, results in ~ 3 hours	China
49	CDI Enhanced COVID-19 Test	real-time RT-PCR	Hackensack University Medical Center Molecular Pathology Lab	nasopharyngeal, oropharyngeal, nasal, and mid-turbinate nasal swabs	E and N genes		United States
50	Panther Fusion SARS-CoV-2	real-time RT-PCR	Hologic Inc. (USA)	nasopharyngeal and	ORF1ab regions 1 and 2	each Panther Fusion system can provide results in < 3 hours and	Australia

	Assay (Panther Fusion System)			oropharyngeal swabs		process up to 1,150 coronavirus tests in 24-hour period	United States
51	Smart Detect SARS-CoV-2 rRT-PCR Kit	real-time RT-PCR	InBios International, Inc.	nasopharyngeal, anterior nasal and mid-turbinate nasal swabs	E, N, and RdRP genes	results in ~ 4 hours	United States
52	SARS-CoV-2 RT-PCR test	real-time RT-PCR	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	nasopharyngeal aspirates, nasopharyngeal, nasal and mid-turbinate nasal swabs, and tracheal aspirates and bronchoalveolar lavage specimens	N2 gene	testing limited to the hospital's CLIA-certified Infectious Disease Diagnostics Laboratory	United States
53	SARS-CoV-2 Test	real-time RT-PCR	Integrity Laboratories	nasopharyngeal, nasal and oropharyngeal swabs	N gene (N1, N2 regions)		United States
54	COV-19 IDx assay	real-time RT-PCR	Ipsium Diagnostics, LLC	nasopharyngeal and oropharyngeal swabs	N gene		United States
55	ProTect COVID-19 RT-qPCR Kit	one-step RT-qPCR	JN Medsys Pte Ltd	sputum, nasopharyngeal and oropharyngeal swabs, and bronchoalveolar lavage fluid, tracheal aspirates, and serum	N gene (N1, N2, N3 regions)	results in < 2 hours	Singapore
56	PowerCheck T M2019-nCoV RT PCR kit	real-time RT-PCR	Kogene Biotech	respiratory samples	E and RdRP genes		South Korea
57	Curative-Korva SARS-CoV-2 assay	real-time RT-PCR	KorvaLabs Inc.	nasopharyngeal, oropharyngeal, nasal swabs and oral fluid specimen			United States
58	COVID-19 RT-PCR Test	real-time RT-PCR	LabCorp Laboratory Corporation of America	nasopharyngeal and oropharyngeal swabs/washes/aspirates and sputum and bronchoalveolar lavage fluid	N gene	results in 2-4 days	United States
59	Pixel, COVID-19 At Home Kit	real-time RT-PCR	LabCorp Laboratory Corporation of America	nasal swabs	N gene		United States

60	1copy COVID-19 qPCR Kit	real-time RT-PCR	Luminarie Canada Inc. (South Korea)/1Drop Inc.	swabs	E and RdRP genes	results in < 2 hours, sensitivity- limit of detection 4 copies/reaction	Canada
61	ARIES SARS CoV-2 Assay	real-time RT-PCR	Luminex Corporation	nasopharyngeal swabs	ORF1ab and N gene	minimal hands-on time and an automated workflow delivers results in ~ 2 hours	United States
62	NxTAG CoV Extended Panel Assay	RT-PCR	Luminex Molecular Diagnostics, Inc. (Canada)	nasopharyngeal swabs	ORF1ab and E and N genes	highly scalable, cost-effective solution that can process up to 96 samples in ~ 4 hours	Canada United States
63	SARS-CoV-2 fluorescent PCR Kit	real-time RT-PCR	Maccura Biotechnology (USA) LLC	upper respiratory tract specimens			United States
64	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Maccura Biotechnology Co., Ltd	oropharyngeal swabs, sputum	ORF1ab and E and N genes		China
65	SARS-CoV-2 DETECTR	CRISPR-based lateral flow assay isothermal amplification	Mammoth Biosciences	respiratory samples	E and N genes	CRISPR Cas12a-based lateral flow assay results in 30-40 minutes	United States
66	MGH COVID-19 qPCR assay	quantitative real-time RT-PCR	Massachusetts General Hospital	nasal, nasopharyngeal and oropharyngeal swabs and bronchoalveolar lavage specimens	N gene (N1 and N2 regions)		United States
67	SARS-CoV-2 Molecular Detection Assay	real-time RT-PCR	Mayo Clinic Laboratories, Rochester, MN	upper and lower respiratory specimens	ORF1ab and N gene		United States
68	Accula SARSCov-2 Test	PCR and lateral flow technologies	Mesa Biotech Inc.	throat and nasal swabs specimens combined	N gene	results in 30 minutes, palm-sized device can be used in physician's office or patient's home	United States
69	MiRXES FORTITUDE KIT 2.0	real-time RT-PCR	MiRXES Pte Ltd	nasopharyngeal swabs	viral RNA genes less prone to mutation	results in 90 minutes, 96 samples in one run, produces 100,000 test kits/wk	Singapore
70	XGEN MASTER COVID-19 KIT - Master Kit for Detection of the SARS-CoV-2 Coronavirus	RT-quantitative PCR	Mobius Life Science (Brazil)	nasal and oropharyngeal swabs	ORF1ab and N gene		Brazil

71	NeuMoDx SARS-CoV-2 Assay	real-time RT-PCR	NeuMoDx Molecular, Inc.	nasopharyngeal, oropharyngeal and nasal swabs	N genes	results in ~ 1 hour	United States
72	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	real-time RT-PCR	New York Department of Health	respiratory samples			United States
73	SARS-CoV-2 Assay	real-time PCR	Northwestern Medicine Diagnostic Molecular Laboratory	respiratory samples			United States
74	Orig3n 2019 Novel Coronavirus (COVID-19) Test	real-time RT-PCR	Orig3n, Inc.	oropharyngeal, nasopharyngeal, anterior nasal, and mid-turbinate nasal swabs	N gene (N1, N2 regions), N3 SARS-like coronavirus uses gene	results in 24-36 hours from receipt of specimens in Orig3n's Boston laboratory	United States
75	GeneFinder COVID-19 Plus RealAmp Kit	real-time RT-PCR	OSANG Healthcare	oropharyngeal, nasopharyngeal, nasal, mid-turbinate nasal swabs and bronchoalveolar lavage fluid	E, N and RdRP genes		United States
76	MOLECULAR SARS-CoV-2 (E/P1) kit	real-time RT-PCR	Oswaldo Cruz Foundation	nasopharyngeal aspirates and triple swabs	E, P1 and RdRP genes		Brazil
77	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	real-time RT-PCR	PerkinElmer, Inc.	oropharyngeal and nasopharyngeal swabs	ORF1ab and N gene	detection limit = 20 copies/mL	United States
78	Primer design Ltd COVID19 genesig Real-Time PCR assay	real-time RT-PCR	Primerdesign Ltd	nasopharyngeal and oropharyngeal swabs, sputum	viral RNA		United States
79	QIAstat-Dx Respiratory SARS-CoV-2 Panel	multiplex real-time RT-PCR	Qiagen GmbH	nasopharyngeal swabs	E and RdRP genes	results in ~ 1 hour, by differentiating novel coronavirus from 21 other bacterial and viral respiratory pathogens	United States
80	Quest SARSCoV-2 rRTPCR	real-time RT-PCR	Quest Diagnostics Infectious Disease, Inc.	nasopharyngeal and oropharyngeal swabs bronchoalveolar lavage fluid/wash,	viral RNA	results in < 2 days	United States

				nasopharyngeal aspirate/wash, tracheal aspirate, or sputum sample			
81	Lyra SARS-CoV-2 Assay	real-time RT-PCR	Quidel Corp.	nasopharyngeal and oropharyngeal swabs	pp1ab	results in < 75 minutes after extraction	United States
82	Cobas SARS-CoV-2	real-time RT-PCR	Roche Molecular Systems, Inc. Roche Diagnostics K.K. Roche Diagnostics Asia Pacific Pte Ltd	nasopharyngeal and oropharyngeal swabs	viral RNA	results in ~ 3.5 hours, instruments can process up to 384 results (cobas 6800 System) and 1056 results (cobas 8800 System) in 8 hours	Australia Brazil Canada Japan Singapore United States
83	ThermoFisher - Applied Biosystems TaqPath COVID-19 Combo Kit	multiplex real-time RT-PCR	Rutgers Clinical Genomics Laboratory- Rutgers University	oropharyngeal, nasopharyngeal, anterior nasal, mid-turbinate nasal swabs and saliva specimens	ORF1ab and N and S genes		United States
84	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence probing)	real-time RT-PCR	Sansure Biotech Inc.	nasopharyngeal and oropharyngeal swab, serum, blood and feces	ORF1ab and N gene	results in 30 minutes	China
85	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RTqPCR) Detection Kit	real-time RT-PCR	ScienCell Research Laboratories	nasopharyngeal and oropharyngeal aspirates/swabs/washes and bronchoalveolar lavage fluid, tracheal aspirates, and sputum	N gene		United States
86	STANDARD M nCoV RT Detection kit	real-time RT-PCR	SD BIOSENSOR	oropharyngeal swabs	E and RdRP genes	results within 90 minutes	South Korea United States
87	Allplex 2019-nCoV Assay	multiplex real-time RT-PCR	Seegene	nasopharyngeal, nasopharyngeal aspirates, throat swabs, and bronchoalveolar lavage fluid	E, N and RdRP genes	results in < 2 hours after extraction	Australia South Korea Singapore
88	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Shanghai BioGerm Medical Biotechnology Co., Ltd	nasopharyngeal and oropharyngeal swabs, and sputum	ORF1ab and N gene		China

89	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Shanghai Fosun Long March Medical Science Co., Ltd.	oropharyngeal swabs, sputum	ORF1ab and E and N genes	results for 96 samples within 2 hours	China
90	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Shanghai GeneDx Biotechnology Co., Ltd Also known as GeneDx	nasopharyngeal swabs, sputum	ORF1ab and N gene		China
91	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method)	RNA capture probe method	Shanghai Rendu Biotechnology Co., Ltd	oropharyngeal swabs, sputum	ORF1ab	results within 90 minutes	China
92	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	multiplex real-time RT PCR	Shanghai ZJ Bio-Tech Co. Ltd (China) Also known as LifeRiver	nasopharyngeal extracts, deep cough sputum, bronchoalveolar lavage fluid	E, N and RdRP genes	results within 15 minutes	Australia
93	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Shanghai ZJ Bio-Tech Co., Ltd.	oropharyngeal swabs, sputum, bronchoalveolar lavage fluid	ORF1ab and E and N genes	rapid pathogen detection	China
94	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	real-time RT-PCR	SolGent Co., Ltd (represented by JK Toxpert) (South Korea)	nasopharyngeal and oropharyngeal swabs, sputum	E and RdRP genes	results within 2 hours after extracting RNA	Canada
95	DiaPlexQ TMN Coronavirus Detection kit	real-time RT-PCR	SolGent Co.,Ltd.	nasopharyngeal and oropharyngeal swabs, sputum	Orf1a and N gene	results within ~120 minutes	South Korea
96	COVID-19 Key Assay	real-time RT-PCR	Southwest Regional PCR laboratory LLC MicroGen DX	nasal, nasopharyngeal, mid-turbinate, oropharyngeal swabs and sputum	N gene (N, N2 regions)		United States
97	Cepheid Xpert Xpress SARSCoV-2	real-time RT-PCR	SPD Scientific Pte Ltd	nasopharyngeal, nasal, and mid-turbinate swabs	N2 and E genes	results with ~ 45 minutes, with < 1 minute hands-on time	Singapore
98	SDI SARS-CoV-2 Assay	real-time RT-PCR	Specialty Diagnostic (SDI) Laboratories	nasopharyngeal and oropharyngeal swabs	ORF1ab		United States
99	Stanford SARS-CoV-2 assay	RT-PCR	Stanford Health Care Clinical Virology Laboratory	nasopharyngeal swabs	N gene	results able to test 2,000/day	United States

100	2019-nCoV Fluorescence Detection	fluorescence combined with real-time RT-PCR	Sysmex Corporation	throat swabs and bronchoalveolar lavage fluid	ORF1ab region		Japan
101	TaqPath COVID-19 Combo Kit	multiplex real-time RT-PCR	Thermo Fisher Scientific, Inc. (USA) Life Technologies Holdings Pte Ltd	nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), and bronchoalveolar lavage fluid	ORF1ab and N and S genes	complete workflow from viral RNA extraction from up to 94 specimens and genetic analysis using real-time PCR to generate diagnostic report under 3 hours	Australia Canada Singapore Taiwan United States
102	Phoenix Dx 2019-CoV	real-time RT-PCR	Trax Management Services, Inc.	nasal, nasopharyngeal and oropharyngeal swabs, and bronchoalveolar lavage fluid	E and N genes		United States
103	UDX SARS-CoV-2 Molecular Assay	real-time RT-PCR	Ultimate Dx Corp	nasal, nasopharyngeal and oropharyngeal swabs	ORF1ab		United States
104	UNC Health SARS-CoV-2 real-time RT-PCR test	real-time RT-PCR	University of North Carolina Medical Center	nasopharyngeal and oropharyngeal specimens, tracheal aspirates, bronchoalveolar lavage fluid and nasopharyngeal aspirates/washings	E gene	testing is limited to university lab, 24-hour turn-around	United States
105	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification real time fluorometric PCR)	isothermal amplification real-time fluorometric PCR	Ustar Biotechnologies (Hangzhou) Ltd.	oropharyngeal swabs, sputum	ORF1ab and N gene		China
106	VereCoV Detection Kit	multiplex RT-PCR combined with microarray	Veredus Laboratories Pte Ltd	nasopharyngeal, nasal, throat swabs and throat aspirates	ORF1ab and N and S genes	results in ~ 2 hours after extraction, lab-on-chip platform	Singapore
107	Viracor SARS-CoV-2 assay	real-time RT-PCR	Viracor Eurofins Clinical Diagnostics	nasopharyngeal, nasal, oropharyngeal washes/swabs and bronchoalveolar lavage fluid	N gene	results the same day, 12-18 hours from receipt of specimen	United States

108	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	real-time RT-PCR	Wadsworth Center, NYSDOH	nasopharyngeal/ oropharyngeal swabs and sputum	Various genes		United States
109	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	fluorometric PCR	Wuhan Easy Diagnosis Biomedicine Co., Ltd.	oropharyngeal and nasopharyngeal swabs, sputum	ORF1ab and N gene	rapid pathogen detection	China
110	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay)	RNA isothermal amplification lateral flow assay	Wuhan Zhongzhi Biotechnologies Inc.	oropharyngeal swabs, sputum	ORF1ab and E gene		China
111	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification)	RNA isothermal amplification lateral flow assay	Wuhan Zhongzhi Biotechnologies Inc.	oropharyngeal swabs, sputum	ORF1ab and E gene	rapid pathogen detection	China
112	SARS-CoV-2 PCR test	real-time RT-PCR	Yale New Haven Hospital, Clinical Virology Laboratory	respiratory swabs	N gene (N, N2 regions)	can complete 500 tests/day	United States

Table S2. Examples for serological and immunological diagnostic tests for the detection of viral proteins or antibodies to SARS-CoV-2 virus⁹⁻¹¹

No.	Test Name	Test Type	Manufacturer/ Organization Name	Sample Source	Ig or Protein detected	Test result time/ Additional Information	Country of approval
1	m2000 SARS-CoV-2	chemiluminescent microparticle immunoassay	Abbott Laboratories Core Laboratory	serum/plasma/whole blood	IgG	runs up to 100-200 test/hour	United States
2	COVID-19 IgG/IgM LF	lateral flow immunoassay	Advagen Biotech	serum/plasma/whole blood	IgG/IgM	results in 10 minutes	Brazil
3	RapCov™ Rapid COVID-19 Test	lateral flow immunoassay	Advaita	blood sample	IgG/IgM	research use only	United States
4	COVID-19 IgG/IgM Point of Care Rapid test	lateral flow immunoassay	Aytu Biosciences/Orient Gene Biotech	serum/plasma/whole blood	IgG/IgM	results in 2-10 minutes	China United States
5	Wantai SARS-CoV-2	chromatographic lateral flow assay	Beijing Wantai Biological Pharmacy	serum/plasma/whole blood	N protein, S1 and S2 subunits of S protein	results in 15 minutes	Australia
6	Wantai SARS-CoV-2 Ab Rapid Test kit	ELISA	Beijing Wantai Biological Pharmacy Enterprise Co. Ltd. (China)	serum/whole blood	IgG/IgM		Australia
7	OnSite COVID-19 IgG/IgM Rapid Test	lateral flow immunoassay	Bio Advance Diagnostics	serum/plasma/whole blood	IgG/IgM	results in 15 minutes	Brazil
8	Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit also marketed as Biolidics 2019-nCoV IgG/IgM Detection Kit	lateral flow immunoassay	Biolidics Limited	serum/plasma/whole blood	IgG/IgM	results within 10 minutes	Singapore
9	COVID-19 IgM/IgG Rapid Test	lateral flow immunoassay	BioMedomics	serum/plasma/whole blood	IgG/IgM	results within 15 minutes	United States
10	IgG Antibody test kit for novel coronavirus 2019-nCoV	magnetic particle-based chemiluminescence immunoassay	Bioscience (Chongqing) Diagnostic Technology Co., Ltd.	serum	IgG		China
11	IgM Antibody test kit for novel coronavirus 2019-nCoV	magnetic particle-based chemiluminescence immunoassay	Bioscience (Chongqing) Diagnostic Technology Co., Ltd.	serum	IgM		China

12	SARS-CoV-2 IgG/IgM kit	colloidal gold lateral flow immunoassay	Biotime	serum/plasma/whole blood	IgG/IgM	results within 10-15 minutes	China
13	One Step COVID-2019 Test	lateral flow immunoassay	Celer Biotechnologia	serum/plasma/whole blood	IgG/IgM	results in 15 minutes	Brazil
14	qSARS-CoV-2 IgG/IgM Rapid Test	lateral flow immunoassay	Cellex Inc.	serum/plasma/whole blood	IgG/IgM	results in 15-20 minutes	Australia United States
15	COVID-19 IgG/IgM	lateral flow immunoassay	Cepalab Laboratorios Ltda	serum/plasma/whole blood	IgG/IgM		Brazil
16	DPP COVID-19 IgM/IgG System	lateral flow immunoassay	ChemBio Diagnostics	serum/plasma/whole blood	IgG/IgM	results within 15 minutes	Brazil
17	COVID-19 Ag Respi-Strip	lateral flow immunoassay (dipstick)	Coris Bioconcept	nasal mucus swabs	viral antigen	results in 15 minutes	Belgium
18	DEIASL019 SARS-CoV-2 IgG ELISA kit	ELISA	Creative Diagnostics	serum/plasma	IgG	tests for patients IgG specific for N protein	United States
19	DEIASL020 SARS-CoV-2 IgM ELISA kit	ELISA	Creative Diagnostics	serum/plasma	IgM		United States
20	OnSite COVID-19 IgG/IgM Rapid Test	lateral flow immunoassay	CTK Biotech Inc. (USA)	serum/plasma/whole blood	IgG/IgM	results in 10 minutes	Australia
21	CORONAVIR US RAPID TEST	lateral flow immunoassay	Diagnostica Industria E Comercio Ltda	serum/plasma/whole blood	IgG/IgM	results within 15 minutes	Brazil
22	Diazyme DZ-Lite SARS-CoV-2 IgG test	luminescent immunoassay	Diazyme Laboratories	blood sample	IgG		United States
23	Diazyme SARS-CoV-2 IgM CLIA test	luminescent immunoassay	Diazyme Laboratories	blood sample	IgM		United States
24	2019 nCoV IgG/IgM Rapid test DNK-1419-1	lateral flow immunoassay	Dynamiker	serum/plasma/whole blood	IgG/IgM	NMPA approved, reaction time 10 minutes	China
25	Coronavirus COVID-19 IgG ELISA Assay Kit KT-1032	ELISA	Eagle Biosciences	serum	IgG	incubation time of 1.5 hours	United States
26	Coronavirus COVID-19 IgM ELISA Assay Kit KT-1033	ELISA	Eagle Biosciences	serum	IgM	incubation time of 1.5 hours	United States
27	CORONAVIR US IgG/IgM (COVID-19)	chromatographic rapid qualitative immunoassay	Ebram Productos Laboratoriais	serum/plasma/whole blood	IgG/IgM	results in 10-20 minutes	Brazil
28	COVID-19 IgG/IgM ECO Test	chromatographic rapid	Eco Diagnostica Ltda	serum/plasma/whole blood	IgG/IgM	results in 10-15 minutes	Brazil

		qualitative immunoassay					
29	COVID-19 Ag ECO Test	Immunoassay	Eco Diagnostica Ltda	nasopharyngeal or oropharyngeal swab	SARS-CoV-2 antigen	results in 10-15 minutes	Brazil
30	ECO F COVID-19 Ag	fluorescent immunoassay	Eco Diagnostica Ltda	nasopharyngeal or oropharyngeal swabs	SARS-CoV-2 antigen		Brazil
31	COVID-19 Ag ECO Teste	immunochromatographic assay enhanced with colloidal gold	Eco Diagnostica Ltda	nasopharyngeal or oropharyngeal swabs	SARS-CoV-2 antigen	results in 10-15 minutes	Brazil
32	KT-1032 EDI Novel Coronavirus COVID-19 ELISA Kit	ELISA	Epitope Diagnostics	serum	IgG/IgM		United States
33	KT-1033 EDI Novel Coronavirus COVID-19 ELISA Kit	ELISA	Epitope Diagnostics	serum	IgG/IgM		United States
34	Anti-SARSCoV-2 ELISA IgA EI 2606-9601 A	ELISA	EUROIMMUN	blood serum or plasma	IgA	results in several hours	Brazil
35	Anti-SARSCoV-2 IgG ELISA EI 2606-9601 G	ELISA	EUROIMMUN	blood serum or plasma	IgG	results in several hours	Brazil
36	VivaDiag COVID-19 IgM/IgG Rapid Test	lateral flow immunoassay	Everest Links Pte Ltd.	serum/plasma/whole blood	IgG/IgM	results in 15 minutes	Singapore
37	FIA COVID-19 IgM/IgG (COVI025)	lateral flow immunoassay	GenBody	blood sample	IgG/IgM	research use only, results within 15 minutes	South Korea
38			Gold Standard Diagnostics				
39		lateral flow immunoassay	Guangdong Hecin	serum/blood	IgM	NMPA approved	China
40	Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	lateral flow immunoassay	Guangzhou Wondfo Biotech Co., Ltd.	serum/blood	IgG/IgM	approved for diagnosis	China
41	Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Immunoassay	Guangzhou Wondfo Biotech Co., Ltd.	serum/plasma/whole blood	IgG/IgM	no distinguishing between IgM and IgG	China
42	Finecare SARS-CoV-2 Antibody Test	Immunoassay	Guangzhou Wondfo Biotech Co., Ltd.	serum/blood	IgG/IgM	using with Finecare series, multiple parameters can be detected simultaneously, such as CRP, PCT,	China

						SAA, IL-6, Myo, cTn I, cTn T, D-dimer	
43	2019-n-CoV IgG/IgM Rapid Test Cassette	lateral flow immunoassay	Hangzhou Alltest Biotech Co. Ltd. (China)	serum/whole blood	IgG/IgM	results in 15-20 minutes	Australia
44	COVID-19 IgG/IgM Rapid Test Cassette	lateral flow immunoassay	Hangzhou Biotest Biotech Co. Ltd. (China)	serum/whole blood	IgG/IgM	results in 15-20 minutes	Australia
45	COVID-19 IgG/IgM Rapid Test Cassette	lateral flow immunoassay	Hangzhou Clonegene Biotech Co. Ltd. (China)	serum/plasma/whole blood	IgG/IgM	results in 10-15 minutes per test	Australia
46	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test	lateral flow immunoassay	Hangzhou Laihe Biotech Co. Ltd. (China)	serum/whole blood	IgG/IgM	results in 15 minutes	Australia
47	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	lateral flow immunoassay	Hangzhou Laihe Biotech Co. Ltd. (China)	whole blood, serum, plasma or cell culture media	IgG/IgM		Australia
48	One Step SARS-CoV-2 (COVID-19) IgG/IgM Test	lateral flow chromatographic immunoassay	Hangzhou Testsealabs Biotechnology	serum/plasma/whole blood	IgG/IgM	results in 15 minutes	China
49	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	lateral flow immunoassay	Healgen Scientific	serum/plasma/whole blood	IgG/IgM	results in 10 minutes, do not interpret after 15 minutes	United States
50	IgM antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Immunoassay	Hecin Scientific, Inc.	serum/plasma	IgM		China
51	2019-nCoV Ab Test (Colloidal Gold)	lateral flow immunoassay	Innovita (Tangshan) Biological Technology Co. Ltd. (China)	serum/whole blood	IgG/IgM	results between 10-20 minutes	Australia
52	Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	immunoassay	Innovita (Tangshan) Biological Technology Co., Ltd.	serum/plasma/blood	IgG/IgM	results in 15 minutes	China

53	Novel Coronavirus (SARS-CoV-2) IgM/IgG Rapid Test Kit	lateral flow immunoassay	Jiangsu bioPerfectus Technologies	blood sample	IgG/IgM		China
54	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit	ELISA	Jiangsu bioPerfectus Technologies	nasal swabs	viral proteins		China
55	SARS-CoV-2 rapid IgG-IgM combined antibody test	lateral flow immunoassay	Jiangsu Medomics Medical Technologies	blood sample	IgG/IgM	results in 15 minutes	China
56	Anti COVID19 IgG/IgM Rapid Test	Immunoassay	Labtest Diagnostica S.A.		IgG/IgM		Brazil
57	COVID-19 IgG/IgM Combo Rapid Test Device	lateral flow immunoassay	Liming Bio	serum/plasma/blood	IgG/IgM		China
58	COVID-19 Antibody test IgM/IgG	lateral flow immunoassay	Livzon Diagnostics	serum/plasma/blood	IgG/IgM	antibodies specific to N protein, results by 15 minutes	China
59	LUMIRATEK COVID-19 (IgG/IgM)	Immunoassay	LumiraDX Healthcare Ltda		IgG/IgM		Brazil
60		ELISA	Mayo Clinic University of Minnesota			for clinical use	United States
61	Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit	lateral flow immunoassay	Medical Systems Biotechnology	serum/plasma/whole blood	IgG/IgM	results within 5-10 minutes	China
62		lateral flow immunoassay	Mologic				United Kingdom
63	COVID-19 ELISA IgG Antibody Test	ELISA	Mount Sinai Labs	serum/plasma	IgG	plates coated with receptor-binding domain (RBD) of S protein	United States
64	SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit		Nanjing Liming Bioproducts Co. Ltd.	blood samples	IgG/IgM		China
65	IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	colloidal gold immunochromatography	Nanjing Vazyme Medical Technology Co., Ltd.	blood serum/plasma	IgG/IgM	results in 10 minutes	China
66	NanoMedicina SARS-CoV-2 IgM/IgG Antibody Rapid Test		NanoResearch	blood samples	IgG/IgM		

67	(2019-nCoV) New coronavirus Antibody Test (Colloidal Gold)		Nantong Diagnos Biotechnology	blood samples			China
68	pGOLD COVID-19 High Accuracy IgG/IgM assay kits	colloidal gold immunochrom atography	Nirmidas Biotech, Inc.	serum/plasma/whole blood	IgG/IgM/Ig A	results ~ 2 hours, can run 48 samples with controls in each run	United States
69	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	colloidal gold immunochrom atography	Nirmidas Biotech, Inc.	serum/plasma/whole blood	IgG/IgM	results within 15 minutes	United States
70	VITROS-Immunodiagn ostics Products Anti-SARS-CoV-2 Total Reagent Pack	ELISA	Ortho-Clinical Diagnostics	blood serum/plasma	IgG/IgM	can't distinguish between IgG/IgM	United States
71	VITROS immunodiagn ostic products Anti-SARS-CoV-2 IgG Reagent pack	ELISA	Ortho-Clinical Diagnostics	blood serum/plasma	IgG		United States
72	TR DPP COVID-19 IGM/IGG - BioManguinho	Immunochrom atography	Oswaldo Cruz Foundation	whole blood	IgG/IgM		Brazil
73	CANARY Biosensor	Immunosensor	Path sensors	environment/air	SARS-CoV-2 antigen	results < 5 minutes	United States
74	COVID19 IgG/IgM Rapid Gold		PCL Inc.		IgG/IgM		
75	COVID19 IgG/IgM Rapid Test	lateral flow immunoassay	Phamatech	serum/plasma/whole blood	IgG/IgM	results in 10 minutes	United States
76	SARS-COV-2 Rapid Test	lateral flow immunoassay	PharmACT	whole blood/serum	IgG/IgM	results after 20 minutes, N protein, and S1 and S2 subunits used as antigens	Germany
77	COVID-19 IgG/IgM Rapid Test Cassette	lateral flow immunoassay	Premier Biotech	blood sample	IgG/IgM	results in 10 minutes and remain valid for 20 minutes	United States
78	SARS-CoV-2 IgM/IgG Antibody Rapid Test	lateral flow immunoassay	Qingdao Hightop Biotech Co. Ltd. (China)	serum/whole blood	IgG/IgM		Australia
79	SARS-CoV-2 IgM/IgG	lateral flow immunoassay	Qingdao Hightop Biotech Co. Ltd. (China)	serum/whole blood	IgG/IgM		Australia

	Antibody Rapid Test						
80	COVID-19 IgG/IgM Rapid Test (total blood/serum/plasma)	lateral flow immunoassay	QR Consulting, Import and Distribution of Medical products	blood/serum/plasma	IgG/IgM	results within 15 minutes	Brazil
81	2019-nCoV IgG/IgM Cassette Rapid Test (blood/serum/plasma)	lateral flow immunoassay	QR Consulting, Import and Distribution of Medical products	blood/serum/plasma	IgG/IgM	results within 15 minutes	Brazil
82	Coronavirus (COVID-19) IgM/IgG Rapid test	lateral flow immunoassay	RayBiotech	serum/whole blood	IgG/IgM	antibodies specific to N protein	United States
83	SARS-CoV-2 Antibody Test Strip	colloidal gold lateral flow immunoassay	Sannuo Biotech (Sinocare)	blood/serum/plasma	IgG/IgM	results within 15-20 minutes	China
84	Standard Q COVID-19 IgM/IgG Duo	lateral flow immunoassay	SD BIOSENSOR	blood/serum/plasma	IgG/IgM	results within 10 minutes	South Korea
85	Standard Q COVID-19 Ag	chromatographic immunoassay	SD BIOSENSOR	nasopharyngeal swabs	viral antigen	results within 30 minutes	South Korea
86	Standard F COVID-19 Ag FIA	fluorescent immunoassay	SD BIOSENSOR	nasopharyngeal swabs	N protein	results within 30 minutes	South Korea
87	Covid-19 Rapid IgG/IgM combined with Antibody assay Prescreening test kit	lateral flow immunoassay	sensing.self	serum/whole blood	IgG/IgM	designed for home use	Singapore
88	BIOEASY 2019-nCoV IgG/IgM GICA Rapid test	lateral flow immunoassay	Shenzhen Bioeasy Biotechnology Co., Ltd.	serum/whole blood	IgG/IgM		China United States
89	BIOEASY 2019-nCoV IgG/IgM Ab GICA Rapid test	colloidal gold enhanced immunoassay	Shenzhen Bioeasy Biotechnology Co., Ltd.	serum/whole blood	IgG/IgM		China United States
90	BIOEASY 2019-Novel Coronavirus (2019-nCoV) Fluorescence Ag Rapid Test	Immunoassay	Shenzhen Bioeasy Biotechnology Co., Ltd.	oropharyngeal swabs and sputum	viral antigen		China United States
91	COVID-19 IgG/IgM Rapid Test Device		Shenzhen Landwind Medical				
92	iFLASH-SARS-CoV-2-IgG	Immunoassay	Shenzhen Yhlo Biotech Company	blood/serum/plasma	IgG		China

93	iFLASH-SARS-CoV-2-IgM	Immunoassay	Shenzhen Yhlo Biotech Company	blood/serum/plasma	IgM		China
94	MAGLUMI IgG de 2019-nCoV	chemiluminescence immunoassay	Snibe Diagnostic (China)	whole blood	IgG	results-600 tests per hour	Brazil
95	MAGLUMI IgM de 2019-nCoV	chemiluminescence immunoassay	Snibe Diagnostic (China)	whole blood	IgM	results-600 tests per hour	Brazil
96	MAGLUMI IgM de 2019-nCoV (CLIA)	chemiluminescence immunoassay	Snibe Diagnostic (China)	blood serum/plasma	IgM	results in 30 minutes	Brazil
97	MAGLUMI IgG de 2019-nCoV (CLIA)	chemiluminescence immunoassay	Snibe Diagnostic (China)	blood serum/plasma	IgG	results in 30 minutes	Brazil
98	Rapid SARS-CoV-2 antigen detection test	antigen-based LFIA	Sona Nanotech	nasal or oropharyngeal swabs	S1 domain of Spike protein		Canada Nova Scotia
99	SGTi-flex COVID-19 IgM/IgG	gold nanoparticle-based immunochromatography	Sugentech	whole blood/serum/plasma	IgG/IgM	results in 10-15 minutes	South Korea
100	SARS-CoV-2 IgM/IgG Antibody Rapid Test VC012103	lateral flow immunoassay	Sure Biotech	whole blood/serum/plasma	IgG/IgM	results in 15 minutes, tests for IgM and IgG also exist separately	China United States
101	SARS-CoV-2 IgG/IgM Rapid Qualitative Test		Telepoint Medical Services		IgG/IgM		
102	VivaDiag COVID-19 IgM/IgG Rapid Test	lateral flow immunoassay	VivaChek Biotech (Hangzhou) Co. Ltd. (China)	serum/whole blood	IgG/IgM	results after 15 minutes	Australia
103	Smart Test Covid-19 Vyttra	Immunochromatography	Vyttra Diagnosticos	blood serum/plasma	IgG/IgM	results in 10 minutes	Brazil
104	New Coronavirus (2019-nCoV) IgM/IgG detection kit	lateral flow immunoassay	Wuhan Easy Diagnosis Biomedicine Co., Ltd.	whole blood/serum/plasma	IgG/IgM		
105	Antibody test kit for novel coronavirus 2019-nCoV(Chemiluminescence microparticle immunoassay)	chemiluminescence microparticle immunoassay	Xiamen Innodx Biotech Co., Ltd.	serum/plasma	anti-Covid-19 total antibody		China
106	COVID-19 IgG/IgM Rapid Test Cassette	lateral flow immunoassay	Zhejiang Orient Gene Biotech Co. Ltd. (China)	whole blood/serum/plasma	IgG/IgM	results should appear within 10 minutes and are invalid after 15 minutes	Australia

107	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Colloidal Gold)	colloidal gold immunochromatography	Zhuhai Livzon Diagnostics Inc.	blood serum/plasma	IgG/IgM	results in 150 seconds	China
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Supporting information II. Highlights of patented technology for diagnosis of related coronavirus such as SARS-CoV and MERS-CoV

(1) Selected patents from the CAS content collection related to molecular genetic assays for detection of SARS-CoV and MERS-CoV

Patent applications WO2005025407 and WO2005025408 by Becton, Dickinson and Company (BD) disclose primers and probes specific for SARS-CoV nucleocapsid and replicase genes, and the use of these primers in real-time RT-PCR assays for virus detection. The sequences of the primers and probes used in the detection of SARS-CoV were disclosed. On April 3, 2020 BD in collaboration with BioGX Inc. announced that the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for a new diagnostic test (BioGX SARS-CoV-2 Reagents for BD MAX System) which will enable hospitals to screen for COVID-19 on-site and get their results in under 3 hours.¹² The assay is based on the same viral RNA targeting sequences and real-time PCR detection method as the test developed by the U.S. Centers for Disease Control and Prevention (CDC). BD and BioGX report that test will help to rapidly screen patients and healthcare workers.¹³

Patent application CN1598580 by Da An Gene Co. disclosed RNA-dependent RNA polymerase gene-specific primers and probes for early detection of SARS-CoV and their use in real-time PCR. The sequences of the forward and reverse primers were 5'-gacgagttcgtggtggtgac-3' (CAS RN 875025-39-1) and 5'-aagcttctgggccagttcct-3' (CAS RN 875025-40-4), respectively. The sequence of the probe used was 5'-caaatgaaagagctcagccccagatg-3' (CAS RN 875025-41-5). Using technologies found in this patent, Da An Gene developed a fluorescent PCR test [(Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)) that targets the ORF1ab region and N gene of SARS-CoV-2].¹⁴

Patent application CN108060266 by Beijing Applied Biological Technology Co. discloses primers and fluorescent probes for detecting SARS-CoV and MERS-CoV using fluorescent reverse transcription-recombinase polymerase amplification (RT-RPA). The invention relates that RT-RPA does not need to convert the RNA into cDNA for the amplification reaction. In collaboration with the Institute of Pathogen Biology of Chinese Academy of Medical Sciences, the company developed a multiple real-time PCR kit [Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)] for detection of 2019-nCoV, attaining NMPA certification on February 27, 2020.¹⁵

Patent applications WO2020050852 and US10072309 by Dr. Dougbeh-Chris Nyan disclose a multiplex real-time RT-LAMP for detecting pathogen bacteria and viruses. The inventions relate that the method utilizes 2 to 3 pairs of pathogen-specific oligonucleotides, including fluorogenic oligonucleotides that produce real-time nucleic acid amplification results representing different pathogens or different genotypes/species of a particular pathogen. The sequences of an extensive list of pathogen-specific RT-LAMP oligonucleotides/primers are disclosed, including those specific for SARS-CoV and MERS. Dr. Nyan discloses that the multiplex real-time RT-LAMP can detect up to 7 different viruses in less than one hour.¹⁶

Patent application WO2011146629 (Qiagen Gaithersburg) discloses the use of sequence-specific purification and multiplex amplification for detection of pathogens. Qiagen subsequently developed the QIAstat-Dx Respiratory SARS-CoV-2 Panel test that can differentiate SARS-CoV-2 from 20 other serious respiratory infections in about 1 hour. This is a multiplex nucleic acid test and the new panel includes two genes specific for SARS-CoV-2.¹⁷

(2) Selected patents from the CAS content collection related to serological and immunological assays for detection of SARS-CoV and MERS-CoV

Patent CN105510596 reports a multiplex assay that was developed for the detection of antibodies to respiratory virus antigens. The assay was constructed using a microscope slide substrate to provide a matrix array of immobilized viral antigens that included adenovirus, respiratory syncytial virus, parainfluenza virus, SARS virus, and influenza A viruses. Colorimetric or luminescent detection of bound anti-viral antibodies was assessed using biotin-conjugated secondary antibodies and streptavidin-labeled alkaline phosphatase (AP) or horseradish peroxidase (HRP).

Patent SG152020 reports that a dot-blot enzyme immunoassay (EIA) was utilized for the detection of serum antibodies to SARS coronavirus. In the protocol, heat-inactivated virus is absorbed to a nitrocellulose membrane and the antigen-dotted membrane is probed with diluted serum. Detection of bound antibodies is assessed using rabbit anti-human IgG-HRP and DAB (3, 3'-diaminobenzidine) substrate and the results interpreted visually.

Patent US20060188519 reports that a lateral rapid test strip was developed for the detection of serum IgM and IgG antibodies to SARS virus. The assay device comprises a nitrocellulose membrane having SARS test peptide(s) and control (Ig) lines. A glass fiber pad overlay contains gold-conjugated goat anti-human IgG and anti-IgM. A diluted or undiluted serum sample is allowed to flow laterally through the strip for 10 minutes and the results are assessed visually.

Patent WO2005047308 reports that an ELISA with improved sensitivity was developed by using antigenic peptides of SARS-CoV S, M, and N proteins and immunologically functional analogs in a 96-well micro-titer plate format. Horseradish peroxidase-conjugated goat antihuman IgG was used as a labeled tracer to bind the immune complexes formed in positive wells. The ELISA was used to characterize confirmed SARS patient sera and to survey healthcare workers.

Patent US20070092938 reports that a Western blot assay was performed using purified recombinant protein fragments separated by an SDS gradient (12-15%) PAGE gel and

transferred to a nitrocellulose membrane. The membranes were cut into 3-cm strips before incubating them with SARS positive and negative serum at 1:100 dilution at room temperature for 1 hour. The membrane strips were probed with human anti-IgG or IgM conjugated with horseradish peroxidase (HRP) and specific reaction bands were visualized by DAB (3,3'-diaminobenzidine tetrahydrochloride).

Table S3. Selected patents with SARS-CoV-related sequences for potential applications in diagnostics

Patent Number	Title	Patent Assignee	Nucleic Acids	Proteins
CN1727486	cDNA library of differential expression genes in lymphocytes from patients recovered from SARS	General hospital of PLA, China	95	
US7220852	Isolation of human coronavirus (SARS-CoV), the causative agent of severe acute respiratory syndrome	US Department of Health and Human Services, USA	40	11
US7361747	Isolation and characterization of the SARS-associated coronavirus-like virus precursor of human SARS virus	The University of Hong Kong, China	7	2451
WO2013083847	Multiplex immuno screening assay (SARS)	Institut Pasteur, France	80	12

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