COVID-19 Diagnostics In Context

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For updated version see here
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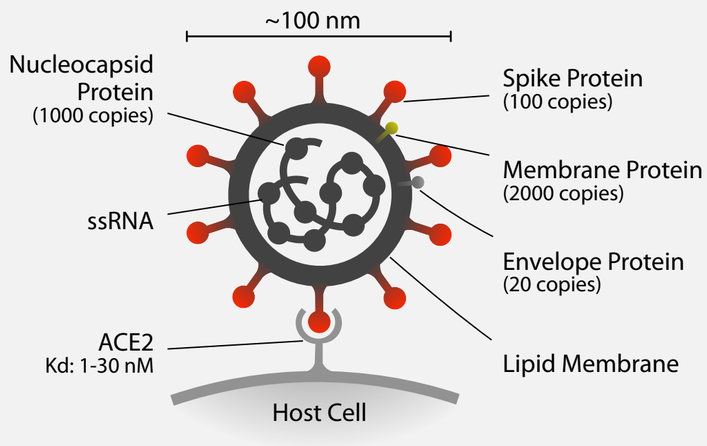
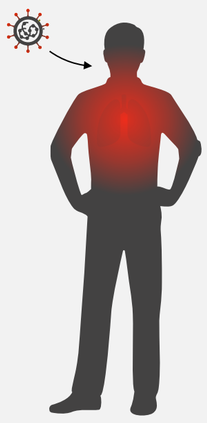
csb.mgh.harvard.edu

Viral composition



Clinical factors



Timing
- Incubation: ~5d after exposure (range 2-14d)
- Symptoms: ~12d after exposure (range 8-16d, or never)
- Infectiousness: before onset of symptoms
- Seroconversion: ~5-10d after symptom onset
- Diagnosis of infection: typically after onset of symptoms

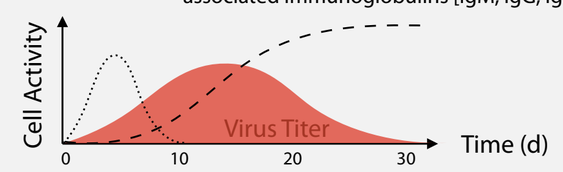
Viral Concentrations *,*,*
- Nasal (10^{6-9} RNA/swab)
- Throat (10^{4-8} RNA/swab)
- Sputum (10^{6-11} RNA/mL)
- Stool (10^{4-8} RNA/g)
- Blood (low levels)
- Urine (not detectable?)

Variables Affecting Disease Severity *,*
- Sex (♂ > ♀)
- Age (Old > Young)
- Cardiovascular diseases, cancer, respiratory diseases, diabetes, others

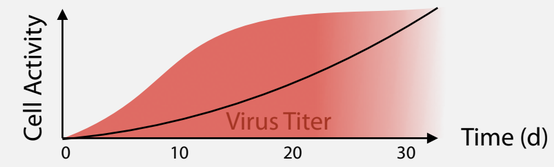
Impact
- Confirmed cases, outcomes, simulators, others: JHU Covid Center; MGH Simulator; Our World In Data; DIVOC

Immune responses & outcomes

Good outcome *,*,*
- Innate immune cells, type I interferon, others
- Adaptive immune cells (T cells, B cells and associated immunoglobulins [IgM, IgG, IgA])



Bad outcome *,*,*
- Inflammatory cells (monocytes, neutrophils) and cytokine storm (IL-1, IL-6, TNF-α, others)



Nucleic acid tests (NATs, for viral RNA)

Most common targets: Viral genome sequence #MN908947 *,*
- CDC approved targets: N1, N2 genes (single or multiple)
- Other emerging targets: E gene, S gene, Orf1ab gene, RdRP gene

Key reagents: CDC approved kits include 2019-nCoV CDC Probe and Primer Kit for SAR2-CoV-2 (Biosearch Technologies) and 2019-nCoV Kit (IDT), rRT-PCR Enzyme Mastermix from Quantabio, Promega, and Thermo Fisher

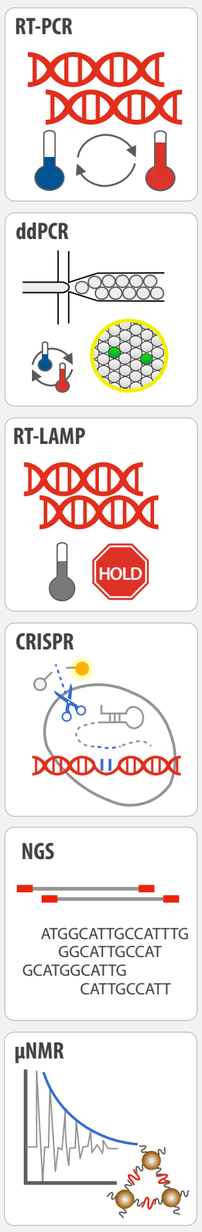
1. Real time RT-PCR
- Widely available, highly specific method. Uses thermal cycling based amplification of nucleic acids from SARS-CoV-2. Main types:
  - Quantitative PCR (qPCR): highly sensitive, widely available and current standard
  - Droplet digital PCR (ddPCR): absolute quantification, 5-plex, reference not needed
- Developers: Roche, LabCorp, PerkinElmer (RUO), Mesa Biotech, Cepheid, Qiagen, Thermo Fisher, BioRAD (Research Use Only, RUO)

2. Isothermal amplification
- Ultra-fast method that does not require thermal cycling. Potential for point-of-care (POC) use. Main types:
  - Loop mediated isothermal amplification (RT-LAMP): one-step amplification at 60-65 °C; more sensitive than conventional RT-PCR
  - Sequence specific LAMP: more robust and specific compared to regular LAMP
  - Rolling circle amplification (RCA): uses a circular template, simple and efficient
  - Nicking endonuclease amplification reaction (NEAR): ultra-fast (<10 min) amplification at 37-42 °C, as sensitive as qPCR
- Developers: Atila Biosystems, Abbott

3. CRISPR
- Different methods (CAS12a or CAS13a) currently in development for POC use
- Simple readout (lateral flow detection). Rapid (<1 hr) and highly specific
- Developers: Mammoth Biosciences (DNA endonuclease-targeted CRISPR trans reporter; DETECTR), SHERLOCK Biosciences (COVID-19 detection protocol)

4. Next generation sequencing (NGS)
- Primarily used to track transmission routes globally, population management, viral mutation and discovery of targets for therapy.
- Developers: Illumina (Shotgun metagenomic sequencing), Thermo Fisher (Ion AmpliSeq SARS-CoV-2)

5. Micro NMR (μNMR)
- Uses magnetic assays to detect PCR products
- Does not require lengthy sample purification. Developers: T2 Biosystems



Protein tests (immunoglobulins, viral antigens)

Most common targets: human IgG, human IgM; IL-6 and other interleukins; Viral antigens: nucleocapsid (N) protein and spike (S) protein *,*

Key reagents: antiviral IgG, IgM; recombinant N and S proteins

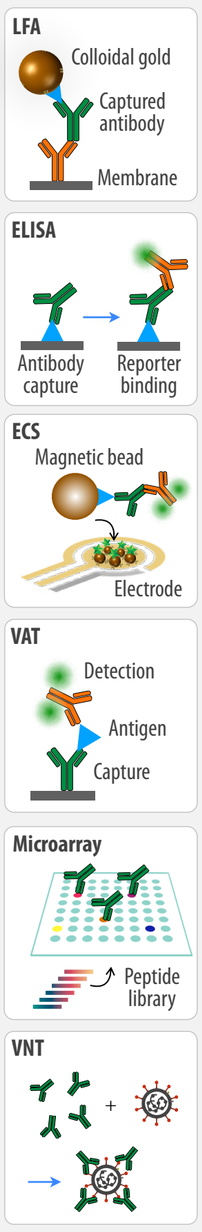
1. Serological rapid diagnostic test (RDT)
- Detects SARS-CoV-2 IgG/IgM in blood using lateral flow assay (LFA)
- Rapid (<20 min), qualitative, equipment-free
- Colorimetric read out (gold nanoparticles)
- Developers: Cellex, BioMedomics, Sugentech, SD Biosensor, RayBiotech, 20/20 GeneSystems, Surescreen Diagnostics

2. Serological ELISA
- Detects SARS-CoV-2 IgG/IgM on a plate coated with capture agents
- High throughput, quantitative, multiple formats (ECLIA, EIA, FIA, ECS)
- Signal amplification allows low detection limit (~pM)
- Uses blood samples
- Developers: Eagle Bioscience, RayBiotech, Creative Diagnostics, Epitope Diagnostics, Accure Health

3. Viral antigen tests (VAT)
- Detects viral nucleocapsid N or S proteins using capture antibodies via LFA or ELISA
- Can be used for respiratory tract samples
- Developers: Quidel, Sona Nanotech, RayBiotech, SD Biosensors, Bioeasy

4. Microarrays
- Discovery of IgG/IgM targets at the epitope level
- Peptide-coated chips are used to capture IgG/IgM
- Applications in diagnostics, vaccine research
- Developers: PEPperPRINT (PEPperCHIP®, 4883 peptides), State Key Laboratory of Proteomics (China)

5. Other methods
- Virus neutralization test (VNT): detects presence of active antibodies
- Western blots (WB): detects viral proteins
- Immunofluorescence microscopy (IFM): antibody interaction with virus proteins



Performance comparison of different test types

For chance of infection at different pretest probabilities see here

FDA cleared tests:

Total **253** | FDA-EUA NAT **173** | LDT-EUA NAT **17** | FDA-EUA Prot **63**

Type	Target	Virus	Assay time	Process type	FDA-EUA	Examples (# FDA-EUA cleared; see next page for details)
PCR	Viral RNA	SARS-CoV-2	2-8 h; >12h	Plate	152	#Roche, #LabCorp, #BioMerieux, #Qiagen, #Perkin-Elmer, #Becton Dickinson, #Luminex, #Thermo Fisher, others
PCR-POC	Viral RNA	SARS-CoV-2	<1 h	Cartridge	2	#Cepheid, #Mesa, Credo
ddPCR	Viral RNA	SARS-CoV-2	2-4 h	Manual	1	#BioRAD
NEAR	Viral RNA	SARS-CoV-2	15 min	Cartridge	1	#Abbott
LAMP	Viral RNA	SARS-CoV-2			1	#SEASUN
OMEGA	Viral RNA	SARS-CoV-2	1 h	Plate	1	#Atila BioSystems
RCA	Viral RNA	SARS-CoV	2 h		0	
SHERLOCK	Viral RNA	SARS-CoV-2	1.5 h	Kit	1	#Sherlock Biosciences (CAS13a)
DETECTR	Viral RNA	SARS-CoV-2	1 h	Kit	2	#Mammoth Biosciences (CAS12a), #UCSF
NGS	Viral RNA	SARS-CoV-2	Days		5	#IDbyDNA, Vision, #Illumina, #Helix, #Clear Labs, #UCLA
μNMR	Viral RNA	SARS-CoV-2	2 h	Cartridge	1	#T2 Biosystems
LFA	IgG, IgM	SARS-CoV-2	15 min	Cartridge	18	#Cellex, #Autobio, #ChemBio, #Healgen, Innovita, #Hangzhou Biotest Biotech, #Biohit, #Hangzhou Laihe Biotech, #BD, #Assure, others
ELISA	IgG, IgM	SARS-CoV-2	2-4 h	Plate	10	#Mount Sinai, #EUROIMMUN US Inc., #InBios, #Emory Medical, BioRAD, Snibe, Zhejiang Orient, Creative Dx, #InBios, #Beijing Wantai
CLIA	IgG, IgM	SARS-CoV-2	30 min	Cartridge	18	#Abbott, #DiaSorin, #Ortho-Clinical (2), #Vibrant America, #Siemens (4), #Babson Diagnostics, #Diazyme, #Beckman (2), #Diazyme,
EIA	IgG, IgM	SARS-CoV-2	2 h	Plate	2	#BioRAD, #BioMérieux
MIA	IgG, IgM	SARS-CoV-2		Plate	4	#Wadsworth Center, #Siemens (2), #Luminex
ECLIA	IgG, IgM	SARS-CoV-2	20 min	Plate	2	#Roche (2)
ECS	IgG, cytokine	SARS-CoV-2	1 h	Cartridge	1	Accure Health, Genmark
VAT	Viral antigen	SARS-CoV-2	20 min	Cartridge	1	#Quidel, Sona NT, RayBiotech, SD Biosensors, Bioeasy
Microarrays	Ig epitopes	SARS-CoV-2	1.5 h	Plate	2	RayBiotech, PEPperPRINT, #Quotient Suisse SA, #Alimetrix
IFM	Viral protein	SARS-CoV	3 h	Manual	1	#LumiraDx
WB	IgG, IgM; viral protein	SARS-CoV	4 h	Manual	0	

Aggregator websites: Find, Artis, FDA, WHO, Covid testing; #: FDA-EUA cleared tests commercially available

Applications

Family/Home

- Simple
- Inexpensive
- Low throughput

Health Care Facility

- Fast
- High throughput
- High sensitivity

Population

- Fast
- High throughput
- Inexpensive

Other useful diagnostics

Family/Home
- Symptom apps (Apple, CDC)
- Distancing apps
- Contact tracing apps
- Wearable sensors (pO2)
- Physiological monitoring (temp, HR, RR)
- Thermography

Hospital
- Blood gas analyzers: Manage hypoxia and ventilation parameters
- Coagulation: Thromboprophylaxis
- Electrolyte analyzers:
- Enzymes: determine and manage multi-organ failure
- CXR, CT: manage pulmonary manifestations

FDA cleared NATs

For chance of infection at different pretest probabilities see here

Test	Company	Source	Target	Type	Time (h)	Manufacturer data					Trial data (published)*				Use	Clearance
						Sens	Spec	PPV	NPV	LOD	Sens	Spec	PPV	NPV		
1copy COVID-19 qPCR Multi Kit	1drop Inc.	RNA		PCR		100%	100%	NA	NA	200/ml					H	FDA-EUA
TRUPCR SARS-CoV-2 Kit	3B Blackbio Biotech India	RNA		PCR						10000/ml					H	FDA-EUA
ID NOW COVID-19 test	Abbott	RNA		NEAR	5-15 min			100%	100%	125/ml	87.7%	100%	94%	82%	H/M/W	FDA-EUA
m2000 RealTime SARS-CoV-2	Abbott	RNA		PCR	4-6	100%	100%	NA	NA	100/ml					H	FDA-EUA
Alinity m SARS-CoV-2 assay	Abbott	RNA		PCR		100%	100%	NA	NA	100/ml			s		H/M	FDA-EUA
CareStart COVID-19 MDx RT-PCR	Access Bio, Inc.	RNA		PCR		100%	100%								H	FDA-EUA
OraRisk COVID-19 RT-PCR	Access Genetics, LLC	RNA		PCR		100%	100%			15000/ml					H	FDA-EUA
Acupath COVID-19 RT-PCR Assay	Acupath Laboratories	RNA		PCR		100%	100%			25000/ml					H	FDA-EUA
Aeon Global Health SARS-CoV-2 Assay	Aeon Global Health	RNA		PCR		100%	97.1%			250/ml					H	FDA-EUA
MassARRAY SARS-CoV-2 Panel	Agena Bioscience, Inc.	RNA		PCR, MALDI-TOF						310/ml					H	FDA-EUA
Akron Children's Hospital SARS-CoV-2	Akron Children's Hospital	RNA		PCR											H	FDA-EUA
Alimetrix SARS-CoV-2 RT-PCR Assay	Alimetrix	RNA		PCR, Microarray											H	FDA-EUA
Alpha Genomix TaqPath SARS-CoV-2	Alpha Genomix	RNA		PCR		96.7%	100%			4000/ml					H	FDA-EUA
RealStar SARS-CoV02 RT-PCR Kits U.S.	Altona Diagnostics	RNA	E, S	PCR	4-6			NA	NA	0.1PFU/ml	100%	100%			H	FDA-EUA
BioCode SARS-CoV-2 Assay	Applied BioCode	RNA		PCR											H	FDA-EUA
Linea COVID-19 Assay Kit	Applied DNA Sciences	RNA		PCR						1250/ml					H	FDA-EUA
Assurance SARS-CoV-2 Panel	Assurance Scientific	RNA		PCR						37/rx					H	FDA-EUA
iAMP Covid-19 detection kit	Atila BioSystems	RNA	ORF1ab, N	LAMP (OMEGA)	1	100%	NA	NA	NA	4000/ml	100%	99%			H	FDA-EUA
Avellino CoV2 kit	Avellino Labs	RNA		PCR	24-48	100%	100%	NA	NA	55000/ml					H	FDA-EUA
BayCare SARS-CoV-2 RT PCR Assay	BayCare Laboratories	RNA		PCR		88%	100%								H	FDA-EUA
BD SARS-CoV-2 Reagents	BD	RNA		PCR	2-3					40/ml					H/M	FDA-EUA
BioGX SARS-CoV-2 Reagents	BD	RNA		PCR						40/ml					H/M	FDA-EUA
Wantai SARS-CoV-2 RT-PCR Kit	Beijing Wantai Biological	RNA		PCR		100%	100%			50/ml					H	FDA-EUA
Real Time Fluorescent RT-PCR kit	BGI	RNA		PCR	2	88.1%	99.6%	NA	NA	100/ml	100%	99%			H	FDA-EUA
qSanger-COVID-19 Assay	BillionToOne, Inc.	RNA		PCR		90%	100%			3200/ml					H	FDA-EUA
BioCore 2019-nCoV Real Time PCR	BioCore	RNA		PCR		100%	100%	NA	NA	500/ml					H	FDA-EUA
Bio-Speedy Direct RT-qPCR SARS-CoV-2	Bioeksen R&D	RNA		PCR											H	FDA-EUA
Real-Q 2019-nCoV Detection Kit	BioSewoom	RNA		PCR		100%	100%			6250/ml					H	FDA-EUA
Bio-RAD SARS-CoV-2 ddPCR Test	Bio-RAD	RNA		ddPCR		94.9%	94.9%	NA	NA	625/ml					H	FDA-EUA
BioFire COVID-19 Test	BioFire Defense, LLC	RNA		PCR		90%	100%	NA	NA	330/ml					H/M	FDA-EUA
BioFire Respiratory Panel 2.1	BioFire Diagnostics	RNA		PCR		98%	100%	NA	NA	300/ml					H/M	FDA-EUA
Biomeme SARS-CoV-2 Real-Time RT-	Biomeme	RNA		PCR		96.9%	98.3%			1800GE/ml					H	FDA-EUA
BIOFIRE COVID-19 test	BioMérieux	RNA		PCR	<1	100%	100%	NA	NA	380/ml	100%	100%			H	FDA-EUA
Boston Heart COVID-19 RT-PCR Test	Boston Heart Diagnostics	RNA		PCR						125/ml					H	FDA-EUA
BMC-CReM COVID-19 Test	Boston Medical Center	RNA		PCR						1000/ml					H	FDA-EUA
Influenza SARS-CoV-2 Multiplex assay	CDC	RNA		PCR											H	FDA-EUA
2019-nCoV Real-Time RT-PCR Dx Panel	CDC	RNA		PCR	24-48					1000/ml					H	FDA-EUA
CentoFast-SARS-CoV-2 RT-PCR assay	Centogene US	RNA		PCR		100%	100%			5000/ml					H	FDA-EUA
Xpert Xpress SARS-CoV-2	Cepheid	RNA		PCR-POC	45 min			100%	100%	250/ml	100%	100%			H/M/W	FDA-EUA
HDPCR SARS-CoV-2 Assay	ChromaCode	RNA		PCR						1000/ml					H	FDA-EUA
Clear Dx SARS-CoV-2 Test	Clear Labs	RNA		PCR, NGS											H	FDA-EUA
Cleveland Clinic SARS-CoV-2 Assay	Cleveland Clinic	RNA		PCR						10000/ml					H	FDA-EUA
CRL Rapid Response	Clinical Reference Lab					100%	100%			250/ml					H	FDA-EUA
Logix Smart Coronavirus Disease kit	Co-Diagnostics	RNA		PCR	1-2					4290/ml					H	FDA-EUA
Compass Laboratory Services SARS-	Compass Laboratory	RNA		PCR		100%	96%			5000/ml					H	FDA-EUA
CRSP SARS-CoV-2 RT-PCR assay	CRSP, Broad of MIT and	RNA		PCR						4000/ml					H	FDA-EUA
Cue COVID-19 Test	Cue Health	RNA		PCR						20					H/M/W	FDA-EUA
Cuur Diagnostics SARS-CoV-2	Cuur Diagnostics	RNA		PCR						25000/ml					H	FDA-EUA
Hymon SARS-CoV-2 Test Kit	dba SpectronRx	RNA		PCR		100%	100%	NA	NA	1200/ml					H	FDA-EUA
MobileDetect Bio BCC19 Test Kit	Detectachem	RNA		PCR						75000/ml					H	FDA-EUA
QuantiVirus SARS-CoV-2 test	DiaCarta	RNA		PCR	2					100/ml					H	FDA-EUA
QuantiVirus SARS-CoV-2 Multiplex Test	DiaCarta	RNA		PCR		97.6%	100%			50/ml					H	FDA-EUA
DSL COVID-19 Assay	Diagnostic Solutions Lab	RNA		PCR		100%	97%			10/swab					H	FDA-EUA
Simplexa COVID-19 direct assay	DiaSorin Molecular	RNA		PCR	1	100%	100%	NA	NA	242/ml	100%	100%			H/M	FDA-EUA
DxTerity SARS-CoV-2 RT-PCR Test	DxTerity Diagnostics, Inc.	RNA		PCR						50/ml					H	FDA-EUA
Lilly SARS-CoV-2 Assay	Eli Lilly and Company	RNA		PCR						1000/ml					H	FDA-EUA
AMPIPROBE SARS-CoV-2 Test system	Enzo Life Sciences	RNA		PCR						280/ml					H	FDA-EUA
Ethos Laboratories SARS-CoV-2 MALDI-	Ethos Laboratories	RNA		PCR / Mass											H	FDA-EUA
EUORealTime SARS-CoV-2	Euroimmun US	RNA		PCR						150/ml					H	FDA-EUA
Everlywell COVID-19 Test Home	Everlywell, Inc.	RNA		PCR					s						NA	FDA-EUA
SARS-CoV-2 Test	Exact Sciences	RNA		PCR		100%	100%			1200/ml					H	FDA-EUA
FTD SARS-CoV-2	Fast Track Diagnostics	RNA		PCR						0.0023					H	FDA-EUA
Advanta Dx SARS-CoV-2 RT-PCR Assay	Fluidigm Corporation	RNA		PCR		100%	100%			6250GE/ml					H	FDA-EUA
Fosun COVID-19 RT-PCR Detection Kit	Fosun Pharma USA	RNA		PCR	2	99.5%	96%	NA	NA	300/ml					H	FDA-EUA
Fulgent COVID-19 by RT-PCR test	Fulgent Therapeutics	RNA		PCR						5000/ml					H	FDA-EUA
GenePro SARS-CoV-2 Test	Genccurix, Inc.	RNA		PCR						5550GE/ml					H	FDA-EUA
ePlex SARS-CoV-2 test	GenMark Diagnostics	RNA		PCR, ECS	2					10/ml	91.4%	100%			H/M	FDA-EUA
Gene By Gene SAR-CoV-2 Detection	Gene By Gene	RNA		PCR						6250/ml					H	FDA-EUA
NeoPlex COVID-19 Detection Kit	GeneMatrix, Inc.	RNA		PCR		100%	100%	NA	NA	50/rx					H	FDA-EUA
Genetrack SARS-CoV-2 Molecular Assay	Genetrack Biolabs	RNA		PCR						1000/ml					H	FDA-EUA
Genetron SARS-CoV-2 RNA Test	Genetron Health	RNA		PCR		100%	97.1%			1000/ml					H	FDA-EUA
ePlex Respiratory Pathogen Panel 2	GenMark Diagnostics	RNA		PCR		100%	100%			250/ml					H/M	FDA-EUA
GS COVID-19 RT-PCR KIT	GenoSensor	RNA		PCR	4-6	100%	100%	NA	NA	1000/ml					H	FDA-EUA
GWU SARS-CoV-2 RT-PCR Kit	George Washington	RNA		PCR		95%	100%			12500/ml					H	FDA-EUA
GK ACCU-RIGHT SARS-CoV-2 RT-PCR	GK Pharmaceuticals	RNA		PCR											H	FDA-EUA
COVID-19-RT-qPCR Detection Kit	Gnomegen	RNA		PCR		100%	100%	NA	NA	500/ml					H	FDA-EUA
COVID-19 RT-Digital	Gnomegen	RNA		PCR	4-6	100%	100%	NA	NA	200/ml					H	FDA-EUA
Gravity Diagnostics COVID-19 Assay	Gravity Diagnostics	RNA		PCR		100%	100%			4800/ml					H	FDA-EUA
Guarant-19	Guardant Health	RNA		PCR		95.5%	98.3%			125/ml					H	FDA-EUA
HealthQuest Esoterics TaqPath Assay	HealthQuest Esoterics	RNA		PCR		100%	100%			20000/ml					H	FDA-EUA
Helix COVID-19 Test	Helix OpCo LLC	RNA		PCR						1000/ml					H	FDA-EUA
Helix COVID-19 NGS Test	Helix OpCo LLC	RNA		NGS						125GCE/ml					H	FDA-EUA
Panther Fusion SARS CoV-2	Hologic	RNA		PCR	3	100%	100%	NA	NA	0.01	94.1%	100%			H	FDA-EUA
Aptima SARS-CoV-2 assay	Hologic	RNA		PCR		100%	98.2%	NA	NA	0.01					H	FDA-EUA
Illumina COVIDSeq Test	Illumina	RNA		NGS						1000/ml					H	FDA-EUA
Smart Detect SARS	InBios Intl	RNA		PCR	4-6	97%	100%	NA	NA	1100/ml					H	FDA-EUA
Inform Diagnostics SARS-CoV-2 RT-PCR	Inform Diagnostics, Inc.	RNA		PCR		93.9%	100%			20000/ml					H	FDA-EUA
COV-19 IDx	Ipsum Dx	RNA		PCR	24					8500/ml					H	FDA-EUA
Genus SARS-CoV-2 Assay	ISPM Labs	RNA		PCR		100%	100%			40000/ml					H	FDA-EUA
COVID-19 Real Time PCR Kit	Jiangsu Bioperfectus	RNA		PCR						350/ml					H	FDA-EUA
SARS-CoV-2 Fast Nucleic Acid	Jiangsu CoWin Biotech	RNA		PCR		100%	100%			300/ml					H	FDA-EUA
KPMAS COVID-19 Test	Kaiser Permanente	RNA		PCR											H	FDA-EUA
KimForest SARS-CoV-2 Detection Kit	KimForest Enterprise	RNA		PCR											H	FDA-EUA
PowerChek 2019-nCoV Real-time PCR	KogeneBiotech	RNA		PCR		100%	100%			4000/ml					H	FDA-EUA
Curative-Korva SARS-Cov-2 Assay	KorvaLabs	RNA		PCR	4-6	97%	100%	NA	NA						H	FDA-EUA
COV-19 RT-PCR	Labcorp	RNA		PCR	24					6250/ml					H	FDA-EUA
LabGun COVID-19 RT-PCR Kit	LabGenomics Co.	RNA		PCR						20000/ml					H	FDA-EUA
Laboratorio Clinico Toledo SARS-CoV-2	Laboratorio Clinico Toledo	RNA		PCR		100%	100%			21000/ml					H	FDA-EUA
LifeHope 2019-nCoV RT-PCR Panel	LifeHope Labs	RNA		PCR		100%	100%			2500/ml					H	FDA-EUA
Aries SARS-CoV2 assay	Luminex	RNA		PCR	2	100%	100%	NA	NA	1000/ml					H/M	FDA-EUA

* Mostly unreported at time of writing; will be added as information emerges. Data from publications (click sensitivity value for hyperlink), FIND or TestingCovid

FDA cleared NATs

For chance of infection at different pretest probabilities see here

Test	Company	Source	Target	Type	Time (h)	Manufacturer data					Trial data (published)*				Use	Clearance
						Sens	Spec	PPV	NPV	LOD	Sens	Spec	PPV	NPV		
Aries SARS-CoV2 assay	Luminex	RNA		PCR	2	100%	100%	NA	NA	1000/ml					H/M	FDA-EUA
NxTAG CoV Extended Panel Assay	Luminex	RNA		PCR	4	100%	100%	NA	NA	5000/ml					H	FDA-EUA
LumiraDx SARS-CoV-2 RNA STAR	LumiraDx UK	RNA		PCR						500/ml					H	FDA-EUA
SARS-CoV-2 Fluorescent PCR Kit	Maccura Biotech	RNA		PCR	2	100%	97%	NA	NA	1000/ml					H	FDA-EUA
SARS-CoV-2 DETECTR Reagent Kit	Mammoth Biosciences	RNA		CRISPR						20000/ml					H	FDA-EUA
Accula SARS -CoV2 test	Mesa	RNA		PCR-POC	<1					100/rx					H/M/W	FDA-EUA
MiraDx SARS-CoV-2 RT-PCR assay	MiraDx	RNA		PCR		96.9%	100%			4000/ml					H	FDA-EUA
SARS-CoV-2 MassArray Test	National Jewish Health	RNA		PCR, mass spec		100%	99.5%			690/ml					H	FDA-EUA
NeuMo Dx SARS-CoV2	NeuMoDx	RNA		PCR	1-2					150/ml					H/M	FDA-EUA
OPTI SARS-CoV-2 RT PCR Test	OPTI Medical Systems	RNA		PCR						900/ml	100%	100%			H	FDA-EUA
GeneFinder COVID-19 Plus RealAmp Kit	OsangHealthcare	RNA		PCR	4-6										H	FDA-EUA
OSUWMC COVID-19 RT-PCR Test	Ohio State University	RNA		PCR						2000/ml					H	FDA-EUA
Omni COVID-19 Assay	Omnipathology Solutions	RNA		PCR						1230/ml					H	FDA-EUA
Kaira 2019-nCoV Detection Kit	OPTOLANE Technologies	RNA		PCR		100%	100%			2500/ml					H	FDA-EUA
P23 Labs TaqPath SARS-CoV-2 Assay	P23 Labs	RNA		PCR											H	FDA-EUA
New Coronavirus	Perkin Elmer	RNA		PCR	4-6					9-30/ml					H	FDA-EUA
Phosphorus COVID-19 RT-qPCR test	Phosphorus Diagnostics	RNA		PCR											H	FDA-EUA
IntelliPlex SARS-CoV-2 Detection kit	PlexBio Co., Ltd	RNA		PCR						140/ml					H	FDA-EUA
FastPlex Triplex SARS-CoV-2 detection	PreciGenome LLC	RNA		PCR		96.3%	96.7%			571.4/ml					H	FDA-EUA
COVID19 genesis realtime PCR test	Primerdesign	RNA		PCR	2	95%	100%	NA	NA	330/ml	100%	100%			H	FDA-EUA
LetsGetChecked COVID-19 Test	PrivaPath Diagnostics	RNA		PCR											H	FDA-EUA
Pro-AmpRT SARS-CoV-2 Test	Pro-Lab Diagnostics	RNA		PCR		96.6%	100%			125GE/swab					H	FDA-EUA
Psoma COVID-19 RT Test	Psomagen	RNA		PCR		100%	100%			1000/ml					H	FDA-EUA
QDX SARS-CoV-2 Assay	QDx Pathology Services	RNA		PCR											H	FDA-EUA
Qiastat-Dx Respiratory	Qiagen	RNA		PCR	96-120	100%	100%	NA	NA	500/ml					H/M	FDA-EUA
Clarifi COVID-19 Test Kit	Quadrant Biosciences	RNA		PCR											H	FDA-EUA
Quest SARS-CoV2 rRT-PCR	Quest	RNA		PCR	1					136/ml					H	FDA-EUA
Quest Diagnostics PF SARS-CoV-2	Quest	RNA		PCR											H	FDA-EUA
Quest Diagnostics HA SARS-CoV-2	Quest	RNA		PCR											H	FDA-EUA
Quest Diagnostics RC SARS-CoV-2	Quest	RNA		PCR											H	FDA-EUA
Lyra SARS-CoV2 assay	Quidel	RNA		PCR	4-6					800/ml					H	FDA-EUA
Rheonix COVID-19 MDx Assay	Rheonix	RNA		PCR						625/ml					H	FDA-EUA
Cobas SARS-CoV2	Roche	RNA		PCR	3.5	100%	100%	100%	100%	12/ml	100%	100%			H/M/W	FDA-EUA
Diagnovital SARS-CoV-2 Real-Time PCR	RTA Laboratories	RNA		PCR		100%	100%			38/ml					H	FDA-EUA
SARS CoV2 assay	Rutgers Clinical Genomics	RNA		PCR	4-6										H	FDA-EUA
SNL-NM 2019 nCoV Real-Time RT-PCR	Sandia National Lab	RNA		PCR						3125-6250/					H	FDA-EUA
2019-nCoV Nucleic Acid Diagnostic Kit	Sansure BioTech	RNA		PCR		94%	99%	NA	NA	200/ml					H	FDA-EUA
SARS-CoV RT-PCR kit	ScienCell Research Labs	RNA		PCR	4-6					3162/ml					H	FDA-EUA
STANDARD M nCoV Real-Time	SD Biosensor	RNA		PCR	6					125-500/ml	100%	99%			H	FDA-EUA
AQ-TOP COVID-19 Detection Kit	SEASUN BIOMATERIALS	RNA		PCR						7000/ml					H	FDA-EUA
AQ-TOP COVID-19 Detection Kit PLUS	SEASUN BIOMATERIALS	RNA		RT-LAMP		100%	100%			1000/ml					H	FDA-EUA
U-TOP COVID-19 Detection Kit	SEASUN BIOMATERIALS	RNA		PCR						1000/ml					H	FDA-EUA
Allplex 2019-nCoV	Seegene	RNA		PCR	4	100%	97%	NA	NA	1250/ml	98.5%	100%			H	FDA-EUA
CRISPR SARS-CoV-2	SHERLOCK Biosciences	RNA		CRISPR	1					900/ml					H	FDA-EUA
Solaris Multiplex SARS-CoV-2 Assay	Solaris Diagnostics	RNA		PCR		100%	100%			10000/ml					H	FDA-EUA
DiaPlexQ 2019-nCoV Detection Kit	Solgent	RNA		PCR						200/ml					H	FDA-EUA
ExProbe SARS-CoV-2 Testing Kit	TBG Biotechnology	RNA		PCR		100%	99.5%			10000/ml					H	FDA-EUA
iC SARS-CoV2 Test	Tempus Labs	RNA		PCR		100%	100%			250/ml					H	FDA-EUA
Texas Department of State Health	Texas Department of State	RNA		PCR						20/ml					H	FDA-EUA
Kroger Health COVID-19 Test Home	The Kroger Co.	RNA														FDA-EUA
TagPath Covid-19 Combo kit	Thermo Fisher	RNA	ORF1ab, S, N	PCR	4					10/ml					H	FDA-EUA
DTPM COVID-19 RT-PCR Test	Tide Laboratories	RNA		PCR						22000/ml					H	FDA-EUA
COVID-19 RT-PCR PNA kit	TNS Co., Ltd	RNA		PCR						2524/ml					H	FDA-EUA
PhoenixDx SARS-CoV-2 Multiplex	Trax Management	RNA		PCR		100%	100%			0.05/ml					H	FDA-EUA
PhoenixDx 2019-CoV	Trax Management	RNA		PCR	4-6					100/ml					H	FDA-EUA
T2SARS-CoV-2 Panel	T2 Biosystems	RNA		µNMR		95%	100%			2000/ml					H	FDA-EUA
UCLA SwabSeq COVID-19 Diagnostic	UCLA	RNA		NGS						250/ml					H	FDA-EUA
SARS-CoV-2 RNA DETECTR Assay	UCSF Health Clinical Lab	RNA		CRISPR						20000/ml					H	FDA-EUA
UMass Molecular Virology Laboratory	UMass Memorial Medical	RNA		PCR		100%	100%			4000/ml					H	FDA-EUA
FRL SARS CoV-2 Test	Univ. of Alabama	RNA		PCR						125/ml					H	FDA-EUA
UCSD RC SARS-CoV-2 Assay	Univ. of California San	RNA		PCR		100%	98.3%								H	FDA-EUA
MD Anderson High-throughput SARS-	Univ. of Texas MD	RNA		PCR		100%	100%			5000/ml					H	FDA-EUA
ViroKey SARS-CoV-2 RT-PCR Test	Vela Operations	RNA		PCR											H	FDA-EUA
Verily COVID-19 RT-PCR Test	Verily Life Sciences	RNA		PCR		100%	100%			60GCE/ml					H	FDA-EUA
Visby Medical COVID-19	Visby Medical	RNA		PCR		100%	100%			1112/ml					H/M	FDA-EUA
NY SARS-CoV	Wadsworth Center	RNA		PCR	24-72					25/ml					H	FDA-EUA
Wren Laboratories COVID-19 PCR Test	Wren Laboratories	RNA		PCR		100%	95%			10000/ml					H	FDA-EUA
SARS-CoV-2 Test Kit (Real-time PCR)	Xiamen Zeesan Biotech	RNA		PCR		100%	100%			200/ml					H	FDA-EUA
SalivaDirect	Yale School of Public	RNA		PCR		94.1%	90.9%			6000/ml					H	FDA-EUA
COVID-19 Nucleic Acid RT-PCR Test Kit	ZhuHai Sinochips	RNA		PCR		96.5%	100%			2000/ml					H	FDA-EUA
Quick SARS-CoV-2rRT-PCR Kit	Zymo Research Corp.	RNA		PCR		100%	100%	NA	NA	83/ml					H	FDA-EUA
COVID-19 RT-PCR Test	Baptist Hospital Miami	RNA		PCR	4-6											LDT-EUA
Childrens-Altona-SARS-CoV-2 Assay	Boston Children's Hospital	RNA		PCR	4-6											LDT-EUA
SARS CoV2 RT-PCR	CHOP	RNA		PCR	4-6											LDT-EUA
CirrusDx SARS-CoV-2 Assay	CirrusDx Laboratories	RNA		PCR	4-6											LDT-EUA
SARS-CoV-2 PCR Test	Diatherix Eurofins	RNA		PCR	4-6											LDT-EUA
CDI Enhanced COVID-19 Test	Hackensack University	RNA		PCR	3-5											LDT-EUA
Explify Respiratory	IDbyDNA	RNA		NGS	4-6											LDT-EUA
SARS-CoV-2 Assay	Integrity Laboratories	RNA		PCR	4-6											LDT-EUA
MGH COVID19	Massachusetts General	RNA		PCR	4-6											LDT-EUA
SARS-CoV-2 Molecular Detection Assay	Mayo Clinic	RNA		PCR	4-6											LDT-EUA
SARS CoV2 assay	Northwestern Medicine	RNA		PCR	4-6											LDT-EUA
Orig3n 2019 nCoR (COVID-19) Test	Orig3n	RNA		PCR	4-6											LDT-EUA
SDI SARS-CoV-2 Assay	SDI Labs	RNA		PCR	4-6											LDT-EUA
SARS CoV2 assay	Stanford	RNA		PCR	4-6											LDT-EUA
SARS-CoV-2 real-time RT-PCR test	UNC Medical Center	RNA		PCR	4-6											LDT-EUA
SARS CoV2 assay	Viracor	RNA		PCR	4-6											LDT-EUA
SARS CoV2 PCR	Yale	RNA		PCR	4-6											LDT-EUA

* Mostly unreported at time of writing; will be added as information emerges. Data from publications (click sensitivity value for hyperlink), FIND or TestingCovid

FDA cleared protein tests

For chance of infection at different pretest probabilities see here

Test	Company	Source	Target	Type	Time (h)	Manufacturer data					Trial data (published)*				Use	Clearance
						Sens	Spec	PPV5%	NPV5%	LOD	Sens	Spec	PPV	NPV		
Alinity i SARS-CoV-2 IgG	Abbott	Ig	NC	CLIA	30 min	100%	99%	84%	100%						H/M	FDA-EUA
AdviseDx SARS-CoV-2 IgM	Abbott	IgM		CLIA											H/M	FDA-EUA
Architect SARS-CoV-2 IgG	Abbott	Ig	NC	CLIA		100%	99.6%	92.9%	100%						H/M	FDA-EUA
BinaxNOW COVID-19 Ag Card	Abbott	Antigen		LFA											H/M/W	FDA-EUA
CareStart COVID-19 Antigen Test	Access Bio	Antigen		ELISA											H/M	FDA-EUA
Assure COVID-19 IgG/IgM	Assure Tech.	Ig		LFA	15 min										H/M	FDA-EUA
Anti-SARS-CoV-2 Rapid Test	Autobio Diagnostics	Ig	Spike	LFA	15-20 min	99%	99%	84.4%	99.9%		93.3%	100%			H/M	FDA-EUA
Babson Diagnostics aC19G1	Babson Diagnostics	IgG		CLIA		100%	100%								H	FDA-EUA
Access SARS-CoV-2 IgG	Beckman Coulter	IgG		CLIA											H/M	FDA-EUA
Access SARS-CoV-2 IgM	Beckman Coulter	IgM		CLIA			99.9%								H/M	FDA-EUA
Access IL-6	Beckman Coulter	IL-6		CLIA		85.4%	64.7%	74.5%	78.6%						H/M	FDA-EUA
BD Veritor System	BD	Antigen		LFA		95%									H/M/W	FDA-EUA
WANTAI SARS-CoV-2 Ab Rapid Test	Beijing Wantai	Ig		LFA		100%	98.8%	80.8%	100%						H/M	FDA-EUA
WANTAI SARS-CoV-2 Ab ELISA	Beijing Wantai	Ig		ELISA		96.7%	97.5%	67.1%	99.8%						H	FDA-EUA
Tell Me Fast Novel Coronavirus IgG/IgM	Biocan Diagnostics	IgG, IgM		LFA		100%	99.4%	89.8%	100%						H/M	FDA-EUA
BioCheck SARS-CoV-2 IgG and IgM	BioCheck, Inc.	IgG, IgM		CLIA											H/M	FDA-EUA
Biohit SARS-CoV-2 IgM/IgG Test Kit	Biohit Healthcare	Ig		LFA		96.7%	95%	50.4%	99.8%						H/M	FDA-EUA
COVID-19 IgM/IgG Rapid Test**	Biomedomics	IgG, IgM		LFA							81.8%	96.3%				
VIDA SARS-CoV-2 IgG	BioMérieux SA	IgG		EIA / FIA											H/M	FDA-EUA
VIDAS SARS-CoV-2 IgM	BioMérieux SA	IgM		EIA / FIA											H/M	FDA-EUA
PerfectPOC IgM/IgG Rapid Test Kit**	Bioperfectus	IgG, IgM		LFA							90%	98.1%				
Platelia SARS-CoV-2 Total Ab test	BioRAD	Ig	NC	EIA	2	92.2%	99.6%	91.7%	99.6%						H	FDA-EUA
qSARS-CoV-2 IgG/IgM Rapid Test Kit	Cellex	Ig	Spike + NC	LFA	<1	93.8%	96%	55.2%	99.7%						H/M	FDA-EUA
Sampinute COVID-19 Antigen MIA	Celltrion USA, Inc.	Antigen		MESIA		94.4%	100%	100%	94.7%						H/M	FDA-EUA
DPP COVID-19 IgM/IgG System	ChemBioDx Systems	Ig	NC	LFA	<1	93.5%	94.4%	46.8%	99.6%						H/M	FDA-EUA
SARS-CoV-2 IgM/IgG Combo Rapid Test**	DecomBio	IgG, IgM		LFA							90.9%	91.6%				
COVID-19 Antibody Test IgG/IgM**	DeepBlue	IgG, IgM		LFA							81.8%	99.1%				
LIAISON SARS-CoV-2 S1/S2 IgG	DiaSorin Inc.	Ig	Spike	CLIA		97.6%	99.3%	88%	99.9%		NA	100%			H/M	FDA-EUA
Diazyme DZ-Lite SARS-CoV-2 IgG	Diazyme Laboratories	IgG		CLIA		100%	100%								H/M	FDA-EUA
Diazyme Dz-Lite SARS-CoV-2 IgM CLIA	Diazyme Laboratories	IgM		CLIA			98.3%								H/M	FDA-EUA
EDI Novel COVID-19 ELISA Kit**	Epitope	IgG, IgM		ELISA							90.9%	90.7%				
SARS-CoV-2 RBD IgG Test	Emory Medical	IgG		ELISA		100%	97.7%								H	FDA-EUA
Anti-SARS-CoV-2 ELISA (IgG)	EUROIMMUN US Inc.	IgG, IgA	Spike (S1	ELISA				100%	99%		61.7%	98.6%			H	FDA-EUA
Maverick SARS-CoV-2 Multi-Antigen	Genalyte	Antigen		PRI			97.7%								H/M	FDA-EUA
LYHER 2019-nCOV IgM/IgG test	Hangzhou Laihe	Ig	Spike	LFA											H/M	FDA-EUA
RightSign COVID-19 IgG/IgM Rapid Test	Hangzhou Biotest	Ig	Spike	LFA	20 min	100%	100%	100%	100%		35.5%	84.2%			H	FDA-EUA
COVID-19 IgG/IgM Rapid Test Cassette	Healgen Scientific	Ig	Spike	LFA		97.8%	99%	67.8%	100%						H/M	FDA-EUA
SCoV-2 Detect IgG ELISA	InBios International	Ig		ELISA		97.8%	99%								H	FDA-EUA
SCoV-2 Detect IgM ELISA	InBios International	Ig		ELISA											H	FDA-EUA
Novel Coronavirus Ab test**	Innovita	IgG, IgM		LFA							66.7%	100%				
Orawell IgM/IgG Rapid Test	Jiangsu Well Biotech	IgG, IgM		LFA											H	FDA-EUA
xMAP SARS-CoV-2 Multi-Antigen IgG	Luminex	IgG		MIA		100%	99.2%								H	FDA-EUA
LumiraDx SARS-CoV-2 Ag Test	LumiraDx UK Ltd.	Antigen		IFM		97.6%	96.6%	93.1%	98.8%						H/M/W	FDA-EUA
Rapid COVID-19 IgM/IgG Combo Test Kit	Megna Health, Inc.	Ig		LFA											H/M	FDA-EUA
COVID-19 ELISA IgG Antibody Test	Mount Sinai	Ig	Spike	ELISA	<1	92.5%	100%	100%	99.6%						H	FDA-EUA
FREND COVID-19 total Ab	NanoEntek America	Ig		FIA		96.7%	98.8%	80.3%	99.8%						H/M	FDA-EUA
Nirmidas COVID-19 IgM/IgG Antibody	Nirmidas Biotech	IgG, IgM		FIA				71.1%	99.8%						H/M	FDA-EUA
VITROS Immunodiagnostic Total	Ortho Clinical	Ig	Spike	CLIA	<1	100%	100%	100%	100%						H/M	FDA-EUA
VITROS Immunodiagnostic IgG	Ortho Clinical	Ig	Spike	CLIA	<1	90%	100%	100%	99.5%		77.4%	99.6%			H/M	FDA-EUA
COVID-19 IgG and IgM Rapid Test**	Premier	IgG, IgM		LFA							81.8%	100%				
Sofia 2 SARS Antigen FIA	Quidel	Antigen		FIA	15 min	80%	100%								H/M/W	FDA-EUA
Sofia 2 Flu + SARS Antigen FIA	Quidel	Antigen		FIA											H/M/W	FDA-EUA
MosaiQ COVID-19 Antibody Magazine	Quotient Suisse SA	Ig		Microarray			99.8%								H	FDA-EUA
Elecsys Anti-SARS-CoV-2 Cobas	Roche	Ig	NC	ECLIA	20 min	100%	99.8%	96.5%	100%		83.9%	NA			H/M	FDA-EUA
Elecsys IL-6	Roche	IL-6		ECLIA		84%	63%			1.5 pg/ml					H/M	FDA-EUA
Sienna-Clarity COVIBLOCK COVID-19	Salofa Oy	Ig		LFA											H/M	FDA-EUA
MAGLUMI 2019-nCoV IgM/IgG	Shenzhen New	Ig		CLIA											H/M	FDA-EUA
Atellica IM SARS-CoV-2 Total	Siemens Healthcare	Ig	Spike	MIA		100%	99.8%	96.7%	100%						H/M	FDA-EUA
ADVIA Centaur SARS-CoV-2 Total	Siemens Healthcare	Ig	Spike	MIA		100%	99.8%	96.5%	100%						H/M	FDA-EUA
Atellica IM SARS-CoV-2 IgG	Siemens Healthcare	IgG		CLIA		100%	99.95%								H/M	FDA-EUA
ADVIA Centaur SARS-CoV-2 IgG	Siemens Healthcare	IgG		CLIA		100%	99.9%								H/M	FDA-EUA
Dimension Vista (COV2T)	Siemens Healthcare	Ig		CLIA											H/M	FDA-EUA
Dimension EXL (CV2T)	Siemens Healthcare	Ig		CLIA											H/M	FDA-EUA
SGTi-flex COVID-19 IgG	Sugentech	IgG		LFA		96.7%	100%	100%	99.8%						H/M	FDA-EUA
COVID-19 Rapid Test**	Sure	IgG, IgM		LFA							90.9%	100%				
TBG SARS-CoV-2 IgG/IgM Rapid Test Kit	TBG Biotechnology	IgG, IgM		LFA		93.3%	95%	49.6%	99.6%						H/M	FDA-EUA
OmniPATH COVID-19 Total Antibody	Thermo Fisher	Ig		ELISA		96.7%	97.5%	67.1%	99.8%						H/M	FDA-EUA
Coronavirus IgG/IgM Antibody Test**	UCP	IgG, IgM		LFA							81.8%	98.1%				
COVID-19 ELISA pan-Ig Antibody Test	U of Arizona Genetics	Ig		ELISA		97.5%	99%								H	FDA-EUA
Vibrant COVID-19 Ab Assay	Vibrant America	Ig		CLIA		98.1%	98.6%								H	FDA-EUA
VivaDiag COVID-19 IgM/IgG Rapid Test**	VivaChek	IgG, IgM		LFA							90%	96%				
NY SARS-CoV Microsphere Immunoassay	Wadsworth Center	Ig	NC	MIA		88%	98.8%	79.4%	99.4%						H	FDA-EUA
Wondfo SARS-CoV-2 Antibody Test**	Wondfo	IgG, IgM		LFA							81.8%	99.1%				
BIOTIME SARS-CoV-2 IgG/IgM Rapid	Xiamen Biotime Biotech	Ig		LFA		100%	96.2%	58.4%	100%						H/M	FDA-EUA
ZEUS ELISA SARS-CoV-2 IgG Test System	ZEUS Scientific	IgG		ELISA		93.3%	100%	100%	99.7%						H/M	FDA-EUA

Abbreviations

ACE2	Angiotensin converting enzyme 2
CDC	Center for Disease control
CE Mark	European community certification
CLIA	Chemiluminescence Immunoassay
ddPCR	Digital droplet PCR
DETECTR	DNA endonuclease-targeted CRISPR transreporter
ECLIA	Electrochemiluminescence immunoassay
ECS	Electrochemical sensing
EIA	Enzyme Immunoassay
ELISA	Enzyme linked immunoabsorbent assay
EUA	Emergency Use Authorization
FDA	Federal Drug agency
FIA	Fluorescence immunoassay
H	H - Laboratory CLIA certified
HC FL	Hybrid Capture Fluorescence Immunoassay
HR	Heart rate
IFM	Immunofluorescence microscopy
Ig	Immunoglobulin
LAMP	Loop Mediated Isothermal Amplification
LDT	Laboratory diagnostic test
LFA	Lateral flow assay
LOD	Limit of detection
M	M - Laboratory CLIA certified
MESIA	Magnetic force-assisted electrochemical immunoassay
MIA	Microsphere Immunoassay
NEAR	Nicking endonuclease amplification reaction
NA	Not available
NC	Nucleocapsid
NGS	Next generation sequencing
NPV	Negative predictive value
PCR	Polymerase chain reaction
PCR-POC	PCR point of care
pO2	Oxygen tension
PRI	Photonic ring immunoassay
POC	Point of care
PPV	Positive predictive value
RCA	Rolling circle amplification
RPA	Recombinase Polymerase Amplification
RR	Respiratory rate
RUO	Research use only
Sens	Sensitivity
Spec	Specificty
SHERLOCK	Specific high-sensitivity enzymatic reporter unlocking CRISPR
VAT	Viral antigen test
VNT	Virus neutralization assay
W	CLIA waiver
WB	Western blot
µNMR	Micro nuclear magnetic resonance

* Mostly unreported at time of writing; will be added as information emerges. Data from publications (click sensitivity value for hyperlink), FIND or TestingCovid

** Sensitivity at >20 days after patient-reported symptom onset and specificity of an IgG test are reported.