

COVID-19 Diagnostics In Context

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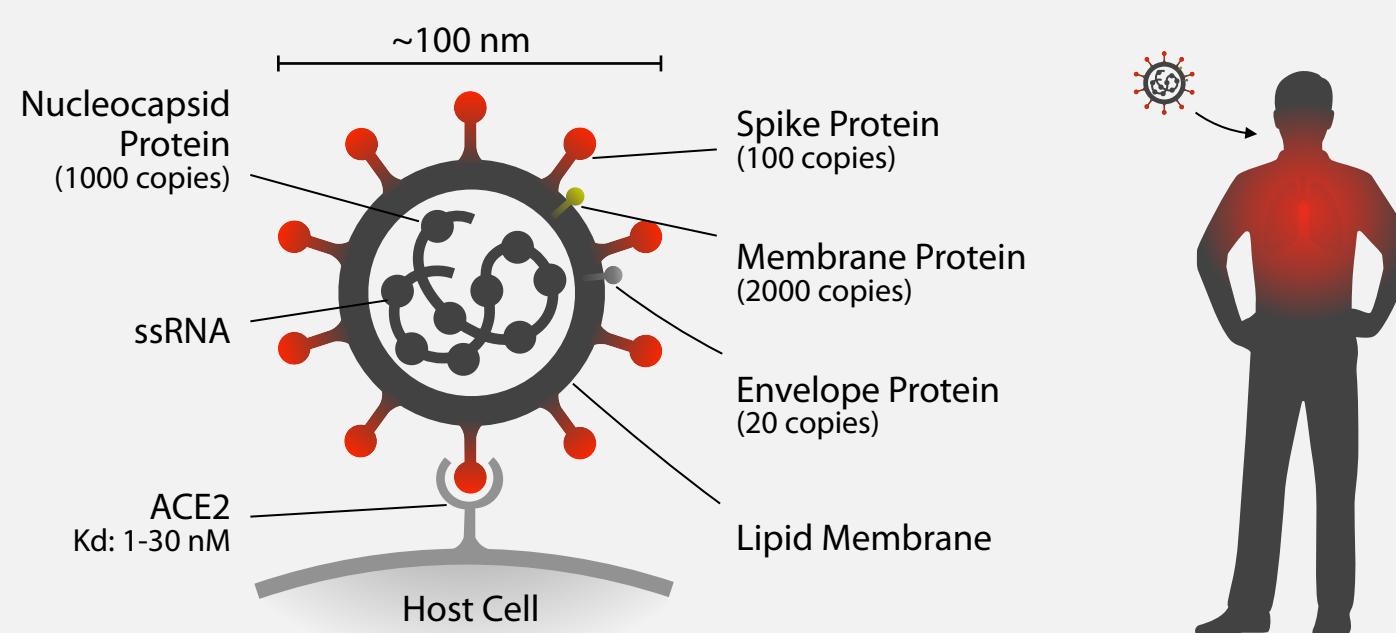
For updated version see [here](#)
Version v1.52 (09/09/2021)



Science Transl Med. 2020; 12:eabc1931

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

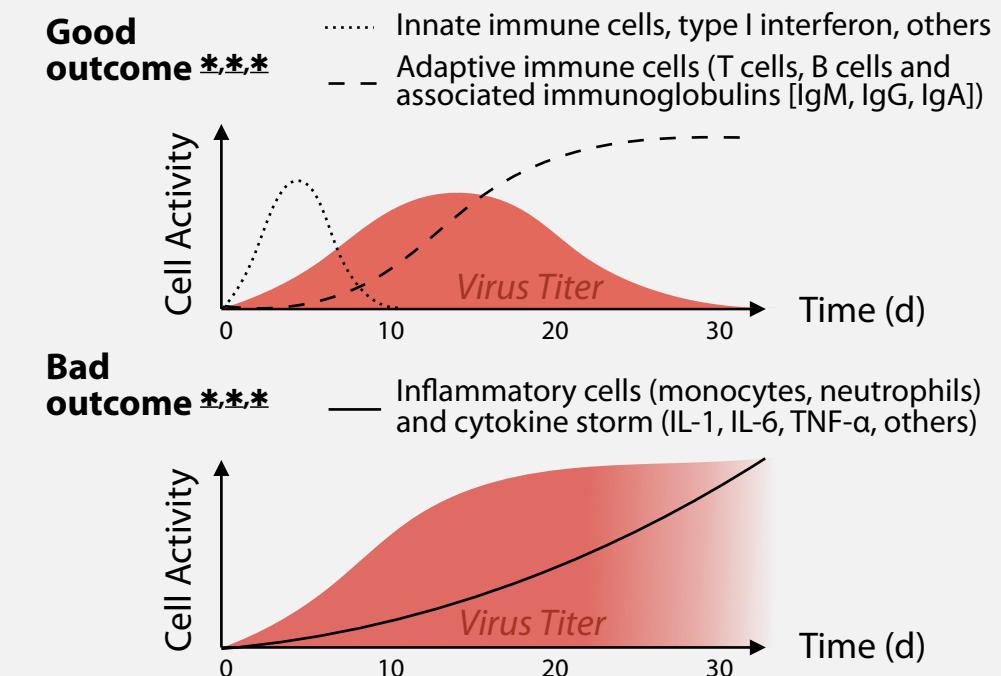
Viral Concentrations **

- 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?)

Impact

- Confirmed cases, outcomes, simulators, others: [JHU Covid Center](#); [MGH Simulator](#); [Our World In Data](#); [DIVOC](#)

Immune responses & outcomes



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

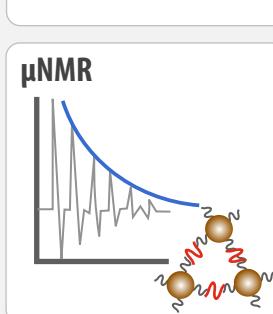
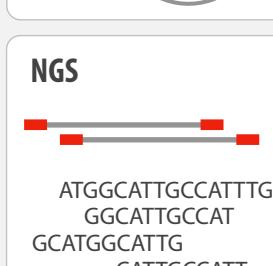
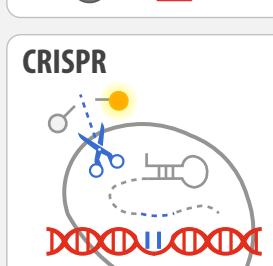
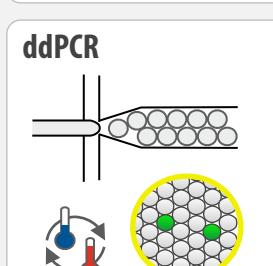
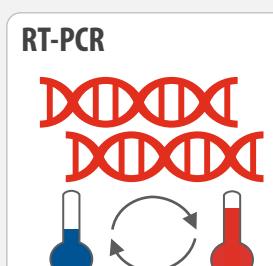
- Different methods (CAS12a or CAS13a) currently in development for POC use
- Simple readout (lateral flow detection). Rapid (<1 hr) and highly specific
- Developers: Mammoth Biosciences (DNA endonuclease-targeted CRISPR trans reporter; DETECTR), SHERLOCK Biosciences (COVID-19 detection protocol)

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 (μ NMR)

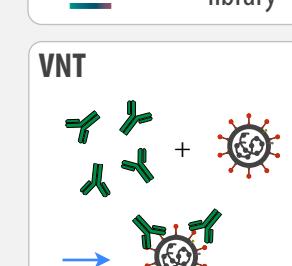
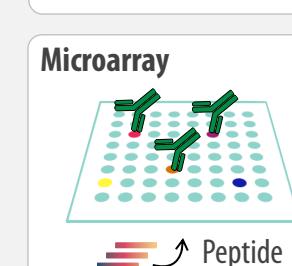
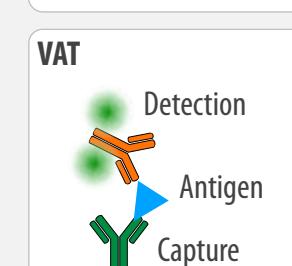
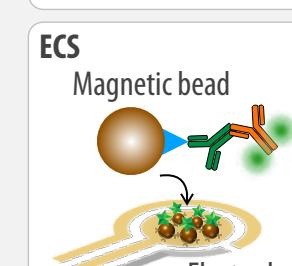
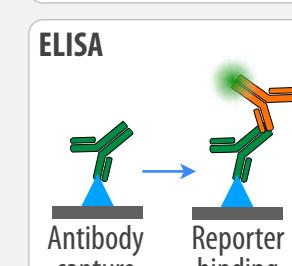
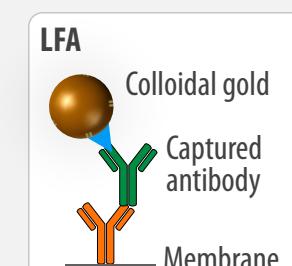
- Uses magnetic assays to detect PCR products
- Does not require lengthy sample purification. Developers: T2 Biosystems



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 **261**

FDA-EUA NAT **175**

LDT-EUA NAT **17**

FDA-EUA Prot **69**

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	154	#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
μ NMR	Viral RNA	SARS-CoV-2	2 h	Cartridge	1	#T2 Biosystems
LFA	IgG, IgM	SARS-CoV-2	15 min	Cartridge	22	#Cellex, #Autobio, #ChemBio, #Healgen, Innovita, #Hangzhou Biostest Biotech, #Biohit, #Hangzhou Laihe Biotech, #BD, #Assure, others
ELISA	IgG, IgM	SARS-CoV-2	2-4 h	Plate	12	#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, #Alimatrix
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					H/M	FDA-EUA
CareStart COVID-19 MDx RT-PCR	Access Bio, Inc.	RNA	PCR			100%	100%			15000/ml					H	FDA-EUA
OraRisk COVID-19 RT-PCR	Access Genetics, LLC	RNA	PCR			100%	100%								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	Aqena 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
Alimatrix SARS-CoV-2 RT-PCR Assay	Alimatrix	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%			40/ml					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												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
Xpert Omni SARS-CoV-2	Cepheid	RNA	PCR			100%	100%			400/ml					H/M	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	Diaognostic 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
DxTeryt SARS-CoV-2 RT-PCR Test	DxTeryt 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
EURORealTime 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-																

FDA cleared NATs

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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
MatMaCrop COVID-19 2SF Test	MatMaCrop, Inc.	RNA	PCR		88.5%	100%			2000/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																

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	PPV	NPV	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						22.5 TCID ₅₀ /ml					H/M/W	FDA-EUA
CareStart COVID-19 Antigen Test	Access Bio	Antigen		ELISA											H/M	FDA-EUA
ACON SARS-CoV-2 IgG/IgM Rapid Test	ACON Laboratories	IgG, IgM		LFA		100%	96.2%	58.4%	100%						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%						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
Ellume COVID-19 Home Test	Ellume Limited	Antigen		LFA						6310 TCID ₅₀ /						
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
cPass SARS-CoV-2 Neutralization Ab kit	GenScript USA Inc.	Ig		ELISA											H	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		100%	97.5%	67.8%	100%					66.7% 100%	H/M	FDA-EUA
Orwell IgM/IgG Rapid Test	Jianqsu Well Biotech	IgG, IgM		LFA											H	FDA-EUA
COVID-SeroKlir Kantaro SARS-CoV-2 IgG	Kantaro Biosciences	IgG		ELISA											H	FDA-EUA
xMAP SARS-CoV-2 Multi-Antigen IgG	Luminex	IgG		MIA		100%	99.2%								H	FDA-EUA
Clip COVID Rapid Antigen Test	Luminostics, Inc.	Antigen		LFA						880 TCID ₅₀ /ml					H/M/W	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	Meqna 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
FRENDR 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	97%	100%			113 TCID ₅₀ /ml					H/M/W	FDA-EUA
Sofia 2 Flu + SARS Antigen FIA	Quidel	Antigen		FIA											H/M/W	FDA-EUA
QuickVue SARS Antigen Test	Quidel	Antigen		LFA		96.6%	99.3%			7570 TCID ₅₀ /					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	M												

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	Specificity
SHERLOCK	Specific high-sensitivity enzymatic reporter unlocking CRISPR
VAT	Viral antigen test
VNT	Virus neutralization assay
W	CLIA waiver
WB	Western blot
μ NMR	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.