

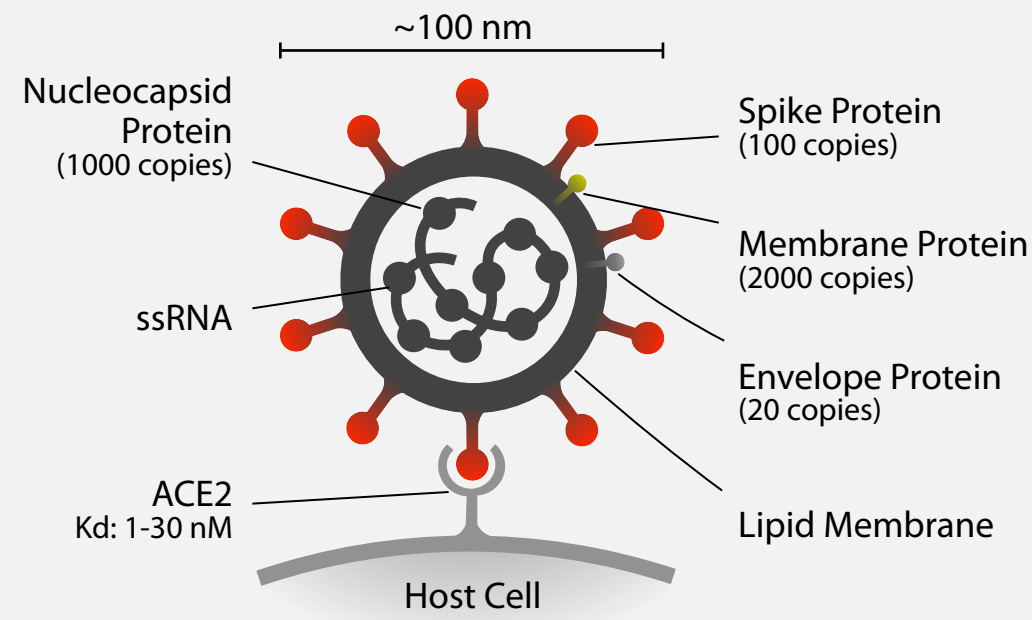
COVID-19 Diagnostics In Context

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For updated version see [here](#)
Version v1.44 (08/31/2020)



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 ($\delta > \text{♀}$)
- Age (Old > Young)
- Cardiovascular diseases, cancer, respiratory diseases, diabetes, others

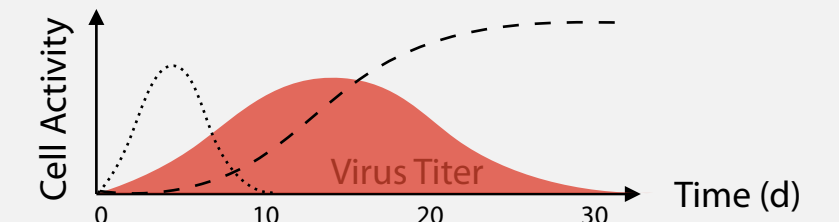
Impact

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

Immune responses & outcomes

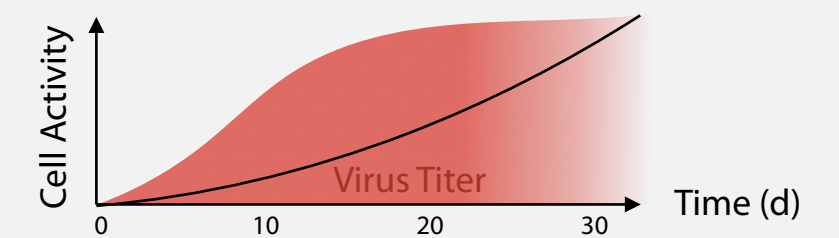
Good outcome ***

- 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

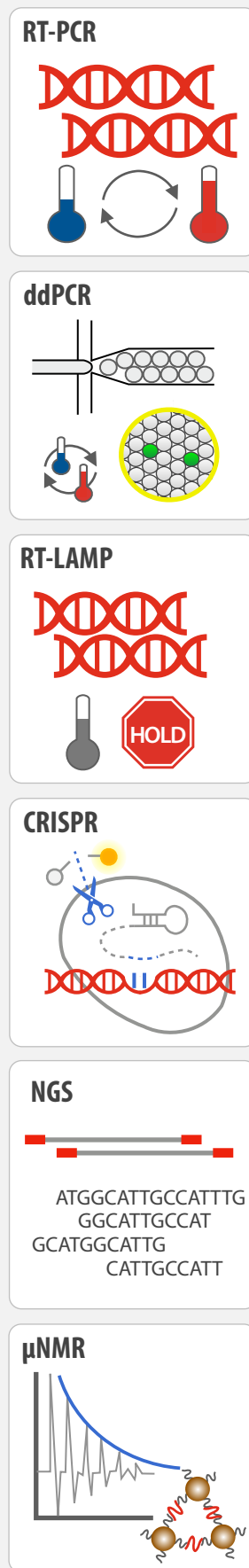
- Different methods (CAS12a or CAS13a) currently in development for POC use
- Simple readout (lateral flow detection). Rapid (<1 hr) and highly specific
- Developers: Mammoth Biosciences (DNA endonuclease-targeted CRISPR trans reporter; DETECTR), SHERLOCK Biosciences (COVID-19 detection protocol)

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 (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)

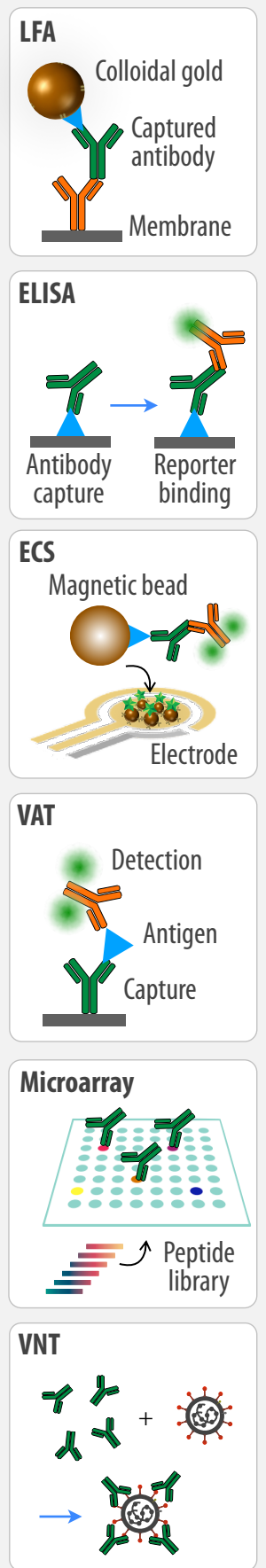
- Detects viral nucleocapsid N or S proteins using capture antibodies via LFA or ELISA
- Can be used for respiratory tract samples
- Developers: Quidel, Sona Nanotech, RayBiotech, SD Biosensors, Bioeasy

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	201	FDA-EUA NAT	143	LDT-EUA NAT	17	FDA-EUA Prot	46
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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	131	#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
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	1	Mammoth Biosciences (CAS12a), #UCSF
NGS	Viral RNA	SARS-CoV-2	Days		3	#IDbyDNA, Vision, #Illumina, #Helix
μ NMR	Viral RNA	SARS-CoV-2	2 h	Cartridge	0	T2 Biosystems
LFA	IgG, IgM	SARS-CoV-2	15 min	Cartridge	15	#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	6	#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	14	#Abbott, #DiaSorin, #Ortho-Clinical (2), #Vibrant America, #Siemens (4), #Babson Diagnostics, #Diazyme, #Beckman, #Diazyme,
EIA	IgG, IgM	SARS-CoV-2	2 h	Plate	2	#BioRAD, #BioMerieux
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	0	Accure Health
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	0	RayBiotech, PEPperPRINT
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
- Volatile organic compounds (breath)

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		
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
Accula SARS -CoV2 test	Mesa	RNA		PCR-POC	<1					100/rx					H/M/W	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
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
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%	150/ml	100%	100%			H/M	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
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
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
SARS-CoV-2 RNA DETECTR Assay	UCSF Health Clinical Lab	RNA		CRISPR						20000/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						560GE/ml					H	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	
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	
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	
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	
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	
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	
	In-house	IgG, IgM		ELISA							81.8%	99.1%				
Novel Coronavirus Ab test**	Innovita	IgG, IgM		LFA							66.7%	100%				
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	
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	
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	
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	
COVID-19 Rapid Test**	Sure	IgG, IgM		LFA							90.9%	100%				
Coronavirus IgG/IgM Antibody Test**	UCP	IgG, IgM		LFA							81.8%	98.1%				
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	

Abbreviations

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

* 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.