In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases. There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests** - Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody Tests** - Tests that detect antibodies (e.g., IgM, IgG) to the SARS-CoV-2 virus. Serology/antibody tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients** - Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

- Molecular Diagnostic Template for Manufacturers (/web/20200617161219/https://www.fda.gov/media/135900/download) (updated June 16, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20200617161219/https://www.fda.gov/media/135658/download) (updated June 16, 2020)
- Serology Template for Manufacturers (/web/20200617161219/https://www.fda.gov/media/137698/download)(May 4, 2020)
- Serology Template for Laboratories (/web/20200617161219/https://www.fda.gov/media/137697/download) (May 4, 2020)
- Antigen Template for Manufacturers (/web/20200617161219/https://www.fda.gov/media/137907/download) (May 11, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20200617161219/https://www.fda.gov/media/138412/download) (May 29, 2020)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20200617161219/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200617161219/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200617161219mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200617161219/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200617161219mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20200617161219/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) -*

Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20200617161219/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200617161219/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200617161219mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Tables of IVD EUAs:

- Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
- Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests
- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Individual EUAs for Serology Tests for SARS-CoV-2
- Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2
- Individual EUAs for IVDs for Management of COVID-19 Patients

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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search:

Show 100 entries

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/15/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/139046/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/13/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test (/web/20200617161219/https://www.fda.gov/media/139066/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd
+ 06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit (/web/20200617161219/https://www.fda.gov/media/138929/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test (/web/20200617161219/https://www.fda.gov/media/138815/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 06/10/2020	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit (/web/20200617161219/https://www.fda.gov/media/138819/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/10/2020	Cue Health Inc.	Cue COVID-19 Test (/web/20200617161219/https://www.fda.gov/media/138823/download)	Molecular	H, M, W	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/09/2020	Illumina, Inc.	Illumina COVIDSeq Test (/web/20200617161219/https://www.fda.gov/media/138778/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/09/2020	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138787/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/08/2020	Euroimmun US, Inc.	EURORealTime SARS-Cov-2 (/web/20200617161219/https://www.fda.gov/media/138758/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/05/2020	Genetron Health (Beijing) Co., Ltd.	Genetron SARS-CoV-2 RNA Test (/web/20200617161219/https://www.fda.gov/media/138682/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 06/04/2020	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test (/web/20200617161219/https://www.fda.gov/media/138652/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd (Clinic) (/web/20200617161219/https://www.fd
+ 06/01/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay (/web/20200617161219/https://www.fda.gov/media/138532/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 05/28/2020	PrivaPath Diagnostics, Inc.	LetsGetChecked Coronavirus (COVID-19) Test (/web/20200617161219/https://www.fda.gov/media/138405/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd
+ 05/22/2020	dba SpectronRX	Hymon SARS-CoV-2 Test Kit (/web/20200617161219/https://www.fda.gov/media/138343/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/21/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138295/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit (/web/20200617161219/https://www.fda.gov/media/138300/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/21/2020	SolGent Co., Ltd	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit (/web/20200617161219/https://www.fda.gov/media/138306/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit (/web/20200617161219/https://www.fda.gov/media/138292/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/18/2020	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138179/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test (/web/20200617161219/https://www.fda.gov/media/138147/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary, (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd
+ 05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (/web/20200617161219/https://www.fda.gov/media/138144/download)	Home Collection Kit	N/A	IFU (/web/20200617161219/https://ww EUA Summary (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/web/20200617161219/https://www.fda.gov/media/138151/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay (/web/20200617161219/https://www.fda.gov/media/138097/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/14/2020	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (/web/20200617161219/https://www.fda.gov/media/138101/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit (/web/20200617161219/https://www.fda.gov/media/138060/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/web/20200617161219/https://www.fda.gov/media/137934/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/11/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay (/web/20200617161219/https://www.fda.gov/media/137980/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit (/web/20200617161219/https://www.fda.gov/media/137892/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/07/2020	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay (/web/20200617161219/https://www.fda.gov/media/137773/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd IFU-Home Collect (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd Summary (/web/20200617161219/https://www.fd
+ 05/07/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit (/web/20200617161219/https://www.fda.gov/media/137781/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 05/06/2020	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test (/web/20200617161219/https://www.fda.gov/media/137737/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/06/2020	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit (/web/20200617161219/https://www.fda.gov/media/137747/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/06/2020	BioMérieux SA	SARS-COV-2 R-GENE (/web/20200617161219/https://www.fda.gov/media/137743/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/05/2020	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2 (/web/20200617161219/https://www.fda.gov/media/137687/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (/web/20200617161219/https://www.fda.gov/media/137652/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/01/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test (/web/20200617161219/https://www.fda.gov/media/137576/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 05/01/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1 (RP2.1) (/web/20200617161219/https://www.fda.gov/media/137580/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/29/2020	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit (/web/20200617161219/https://www.fda.gov/media/137484/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/29/2020	Rheonix, Inc.	Rheonix COVID-19 MDx Assay (/web/20200617161219/https://www.fda.gov/media/137490/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/27/2020	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit (/web/20200617161219/https://www.fda.gov/media/137420/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/23/2020	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit (/web/20200617161219/https://www.fda.gov/media/137303/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/22/2020	altona Diagnostics GmbH	RealStar SARS-CoV02 RT-PCR Kits U.S. (/web/20200617161219/https://www.fda.gov/media/137257/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/21/2020	Seegene, Inc.	Allplex 2019-nCoV Assay (/web/20200617161219/https://www.fda.gov/media/137179/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/20/2020	Trax Management Services Inc.	PhoenixDx 2019-CoV (/web/20200617161219/https://www.fda.gov/media/137150/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/18/2020	OSANG Healthcare	GeneFinder COVID-19 Plus RealAmp Kit (/web/20200617161219/https://www.fda.gov/media/137113/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/17/2020	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit (/web/20200617161219/https://www.fda.gov/media/137117/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/16/2020	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay (/web/20200617161219/https://www.fda.gov/media/137088/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 04/16/2020	GenoSensor, LLC	GS"ç COVID-19 RT-PCR KIT (/web/20200617161219/https://www.fda.gov/media/137090/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/15/2020	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit (/web/20200617161219/https://www.fda.gov/media/137023/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/10/2020	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit (/web/20200617161219/https://www.fda.gov/media/136872/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/08/2020	DiaCarta, Inc	QuantiVirus SARS-CoV-2 Test kit (/web/20200617161219/https://www.fda.gov/media/136806/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/08/2020	Becton, Dickinson & Company	BD SARS-CoV-2Reagents for BD MAX System (/web/20200617161219/https://www.fda.gov/media/136813/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/07/2020	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit (/web/20200617161219/https://www.fda.gov/media/136787/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/06/2020	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit (/web/20200617161219/https://www.fda.gov/media/136735/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/03/2020	Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (/web/20200617161219/https://www.fda.gov/media/136684/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/03/2020	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (/web/20200617161219/https://www.fda.gov/media/136688/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/03/2020	Luminex Corporation	ARIES SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136694/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 04/02/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System (/web/20200617161219/https://www.fda.gov/media/136650/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https:/ (/web/20200617161219/https://www.fd
+ 04/01/2020	Ipsum Diagnostics, LLC	COV-19 IDx assay (/web/20200617161219/https://www.fda.gov/media/136618/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 03/30/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel (/web/20200617161219/https://www.fda.gov/media/136569/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/30/2020	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136566/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay (/web/20200617161219/https://www.fda.gov/media/136497/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 (/web/20200617161219/https://www.fda.gov/media/136522/download)	Molecular	H, M, W	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/26/2020	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 (/web/20200617161219/https://www.fda.gov/media/136473/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test (/web/20200617161219/https://www.fda.gov/media/136450/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 03/24/2020	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit (/web/20200617161219/https://www.fda.gov/media/136407/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/23/2020	Mesa Biotech Inc.	Accula SARS-Cov-2 Test (/web/20200617161219/https://www.fda.gov/media/136345/download)	Molecular	H, M, W	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/23/2020	BioFire Defense, LLC	BioFire COVID-19 Test (/web/20200617161219/https://www.fda.gov/media/136356/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/20/2020	Cepheid	Xpert Xpress SARS-CoV-2 test (/web/20200617161219/https://www.fda.gov/media/136316/download)	Molecular	H, M, W	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd for Labs (/web/20200617161219/https://www.fd IFU for Point-of-Care (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/20/2020	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (/web/20200617161219/https://www.fda.gov/media/136306/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/19/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test (/web/20200617161219/https://www.fda.gov/media/136283/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/19/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay (/web/20200617161219/https://www.fda.gov/media/136288/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/18/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay (/web/20200617161219/https://www.fda.gov/media/136255/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/17/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR (/web/20200617161219/https://www.fda.gov/media/136228/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd (Home Collect) (/web/20200617161219/https://www.fd
+ 03/17/2020	Quidel Corporation	Lyra SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136224/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/16/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test (/web/20200617161219/https://www.fda.gov/media/136148/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd IFU-Home Collect (/web/20200617161219/https://www.fd
+ 03/16/2020	Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136153/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 03/13/2020	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit (/web/20200617161219/https://www.fda.gov/media/136113/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/12/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/web/20200617161219/https://www.fda.gov/media/136046/download)	Molecular	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 02/29/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (/web/20200617161219/https://www.fda.gov/media/135661/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd
+ 02/04/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) (/web/20200617161219/https://www.fda.gov/media/134919/download)	Molecular	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd (/web/20200617161219/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. A manufacturer may request the addition of an eligible molecular-based LDT to Appendix A by submitting a request to CDRH-EUA-Templates@FDA.HHS.GOV (https://web.archive.org/web/20200617161219/mailto:CDRH-EUA-Templates@FDA.HHS.GOV) (https://web.archive.org/web/20200617161219mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/web/20200617161219/https://www.fda.gov/media/136598/download)
- Fact Sheet for Healthcare Providers (/web/20200617161219/https://www.fda.gov/media/136599/download)
- Fact Sheet for Patients (/web/20200617161219/https://www.fda.gov/media/136600/download)
- See Appendix A table below for a current list of included laboratories and their LTDs

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this Umbrella EUA (/web/20200617161219/https://www.fda.gov/media/136598/download) during the COVID-19 public health emergency.

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

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Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 06/12/2020	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138933/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138934/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138791/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138790/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/web/20200617161219/https://www.fda.gov/media/138624/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138625/download)
+ 06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV rRT Assay (/web/20200617161219/https://www.fda.gov/media/138527/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138526/download)
+ 06/01/2020	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/web/20200617161219/https://www.fda.gov/media/138529/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138528/download)
+ 05/22/2020	Exact Sciences Laboratories	Exact Sciences SARS-CoV-2 (N gene detection) Test (/web/20200617161219/https://www.fda.gov/media/138327/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138328/download)
+ 05/22/2020	Express Gene LLC (dba Molecular Diagnostics Laboratory)	Express Gene 2019-nCoV RT-PCR Diagnostic Panel (/web/20200617161219/https://www.fda.gov/media/138329/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138330/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/138331/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138332/download)
+ 05/18/2020	Color Genomics, Inc.	Color SARS Cov-2 Diagnostic Assay (/web/20200617161219/https://www.fda.gov/media/138248/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138249/download)
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/web/20200617161219/https://www.fda.gov/media/138062/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138063/download)
+ 05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/web/20200617161219/https://www.fda.gov/media/138064/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/138065/download)
+ 05/12/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/web/20200617161219/https://www.fda.gov/media/137982/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137983/download)
+ 05/07/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/web/20200617161219/https://www.fda.gov/media/137896/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137897/download)
+ 05/03/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/web/20200617161219/https://www.fda.gov/media/137654/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137656/download)
+ 04/30/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/web/20200617161219/https://www.fda.gov/media/137545/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137546/download)
+ 04/28/2020	Biocerna	SARS-CoV-2 Test (/web/20200617161219/https://www.fda.gov/media/137451/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137450/download)
+ 04/27/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/137424/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137423/download)
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/web/20200617161219/https://www.fda.gov/media/137371/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137372/download)

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 04/24/2020	AIT Laboratories	SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/137373/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137374/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/web/20200617161219/https://www.fda.gov/media/137369/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137370/download)
+ 04/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/web/20200617161219/https://www.fda.gov/media/137256/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137255/download)
+ 04/20/2020	Mayo Clinic Laboratories, Rochester, MN	SARS-CoV-2 Molecular Detection Assay (/web/20200617161219/https://www.fda.gov/media/137162/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137163/download)
+ 04/15/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/web/20200617161219/https://www.fda.gov/media/137037/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137036/download)
+ 04/15/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/137035/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137034/download)
+ 04/14/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136972/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136971/download)
+ 04/14/2020	Exact Sciences Laboratories	SARS-CoV-2 Test (/web/20200617161219/https://www.fda.gov/media/137094/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/137095/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136941/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136942/download)
+ 04/13/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test (/web/20200617161219/https://www.fda.gov/media/136943/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136944/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/web/20200617161219/https://www.fda.gov/media/136874/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/web/20200617161219/https://www.fda.gov/media/136878/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136877/download)
+ 04/10/2020	University of North Carolina Medical Center	UNC Health SARS-CoV-2 real-time RT-PCR test (/web/20200617161219/https://www.fda.gov/media/136879/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136880/download)
+ 04/08/2020	Stanford Health Care Clinical Virology Laboratory	Stanford SARS-CoV-2 assay (/web/20200617161219/https://www.fda.gov/media/136817/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136818/download)
+ 04/06/2020	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay (/web/20200617161219/https://www.fda.gov/media/136739/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136740/download)
+ 04/03/2020	Massachusetts General Hospital	MGH COVID-19 qPCR assay (/web/20200617161219/https://www.fda.gov/media/136700/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136699/download)

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/web/20200617161219/https://www.fda.gov/media/136658/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/web/20200617161219/https://www.fda.gov/media/136657/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136656/download)
+ 03/31/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/web/20200617161219/https://www.fda.gov/media/136601/download)	EUA Summary (/web/20200617161219/https://www.fda.gov/media/136602/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 antigen diagnostic tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 05/08/2020	Quidel Corporation	Sofia SARS Antigen FIA (/web/20200617161219/https://www.fda.gov/media/137886/download)	Antigen	H, M, W	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Individual EUAs for Serology Tests for SARS-CoV-2

On June 16, 2020 (/web/20200617161219/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test), based on FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.'s DPP COVID-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20200617161219/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3265-a001.pdf), FDA determined that the statutory criteria for issuing an EUA in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20200617161219/https://www.fda.gov/media/139109/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

This table includes information about authorized SARS-CoV-2 serology/antibody assays that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

For additional performance information about EUA authorized serology/antibody tests, please see the EUA Authorized Serology Test Performance (/web/20200617161219/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance) webpage.

Search:

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/15/2020	Emory Medical Laboratories	SARS-CoV-2 RBD IgG test (/web/20200617161219/https://www.fda.gov/media/139050/download)	Serology IgG	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 06/10/2020	InBios International, Inc.	SCoV-2 Detect IgG ELISA (/web/20200617161219/https://www.fda.gov/media/138807/download)	Serology IgG	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 06/08/2020	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (/web/20200617161219/https://www.fda.gov/media/138750/download)	Total Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 06/08/2020	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (/web/20200617161219/https://www.fda.gov/media/138754/download)	Total Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 06/04/2020	Vibrant America Clinical Labs	Vibrant COVID-19 Ab Assay (/web/20200617161219/https://www.fda.gov/media/138626/download)	Serology IgM and IgG	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/04/2020	Hangzhou Biotest Biotech Co., Ltd.	RightSign COVID-19 IgG/IgM Rapid Test Cassette (/web/20200617161219/https://www.fda.gov/media/138657/download)	Serology IgM and IgG	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (/web/20200617161219/https://www.fda.gov/media/138435/download)	Serology IgM and IgG	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T) (/web/20200617161219/https://www.fda.gov/media/138439/download)	Total Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T) (/web/20200617161219/https://www.fda.gov/media/138443/download)	Total Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 05/04/2020	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG) (/web/20200617161219/https://www.fda.gov/media/137606/download)	Serology IgG	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 05/02/2020	Roche Diagnostics	Elecsys Anti-SARS-CoV-2 (/web/20200617161219/https://www.fda.gov/media/137602/download)	Serology Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection (/web/20200617161219/https://www.fda.gov/media/137540/download)	Serology Total Antibody	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 04/29/2020	Bio-Rad Laboratories, Inc.	Platelia SARS-CoV-2 Total Ab assay (/web/20200617161219/https://www.fda.gov/media/137494/download)	Serology Total Antibody	H	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/26/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay (/web/20200617161219/https://www.fda.gov/media/137384/download)	Serology IgG only	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU-ARCHITECT (/web/20200617161219/https://www.fd IFU-Alinityi (/web/20200617161219/https://www.fd
+ 04/24/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG (/web/20200617161219/https://www.fda.gov/media/137356/download)	Serology IgG only	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 04/24/2020	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack (/web/20200617161219/https://www.fda.gov/media/137360/download)	Serology IgG only	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 04/24/2020	Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test (/web/20200617161219/https://www.fda.gov/media/137364/download)	Serology IgM and IgG	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test (/web/20200617161219/https://www.fda.gov/media/137032/download)	Serology IgG	H	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd EUA Summary (/web/20200617161219/https://www.fd
+ 04/14/2020	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (/web/20200617161219/https://www.fda.gov/media/136966/download)	Serology Total Antibody	H, M	HCP (/web/20200617161219/https://www.fd Recipients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd
+ 04/01/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test (/web/20200617161219/https://www.fda.gov/media/136622/download)	Serology IgM and IgG	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.

- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2

On April 28, 2020, FDA issued an umbrella EUA for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by the FDA, and are confirmed by the FDA to meet the criteria set forth in the Scope of Authorization of the EUA. Under this EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum.

Emergency use of these tests is limited to use at laboratories certified by CLIA to perform moderate or high complexity tests. Authorized devices will be added to Appendix A (below) as described in the EUA.

- Letter of Authorization - Serology IVD Umbrella (/web/20200617161219/https://www.fda.gov/media/137470/download)
- Fact Sheet for Healthcare Providers (/web/20200617161219/https://www.fda.gov/media/137468/download)
- Fact Sheet for Recipients (/web/20200617161219/https://www.fda.gov/media/137469/download)
- Appendix A Table (/web/20200617161219/https://www.fda.gov/media/137471/download)

This table includes information about the authorized serological antibody tests authorized by this Umbrella EUA for use during the COVID-19 public health emergency.

For additional performance information about EUA authorized serology/antibody tests, please see the EUA Authorized Serology Test Performance (/web/20200617161219/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance) webpage.

Lateral Flow Tests

None currently.

ELISA Tests

None currently.

Individual EUAs For IVDs for Management of COVID-19 Patients

This table includes information about authorized in vitro diagnostic tests that may be used in the management of patients with COVID-19 that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search:

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/02/2020	Roche Diagnostics	Elecsys IL-6 (/web/20200617161219/https://www.fda.gov/media/138596/download)	Immunoassay-IL-6	H, M	HCP (/web/20200617161219/https://www.fd Patients (/web/20200617161219/https://www.fd IFU (/web/20200617161219/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20200617161219/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20200617161219/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20200617161219/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases. There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests** - Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody Tests** - Tests that detect antibodies (e.g., IgM, IgG) to the SARS-CoV-2 virus. Serology/antibody tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients** - Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

- Molecular Diagnostic Template for Commercial Manufacturers (/web/20200816201843/https://www.fda.gov/media/135900/download) (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20200816201843/https://www.fda.gov/media/135658/download) (updated July 28, 2020)
- Serology Template for Commercial Manufacturers (/web/20200816201843/https://www.fda.gov/media/137698/download)(updated June 26, 2020)
- Serology Template for Laboratories (/web/20200816201843/https://www.fda.gov/media/137697/download) (updated June 26, 2020)
- Antigen Template for Manufacturers (/web/20200816201843/https://www.fda.gov/media/137907/download) (May 11, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20200816201843/https://www.fda.gov/media/138412/download) (May 29, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20200816201843/https://www.fda.gov/media/140615/download) (July 29, 2020)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20200816201843/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200816201843/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200816201843mp_/https://web.archive.org/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200816201843/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200816201843mp_/https://web.archive.org/about-fda/website-policies/website-disclaimer), or they can

submit comments regarding the templates to the public docket (https://web.archive.org/web/20200816201843/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20200816201843/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20200816201843/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20200816201843mp_/https://web.archive.org/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) webpage.

Tables of IVD EUAs:

- Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
- Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests
- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Individual EUAs for Serology Tests for SARS-CoV-2
- Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2
- Individual EUAs for IVDs for Management of COVID-19 Patients

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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/15/2020	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect (/web/20200816201843/https://www.fda.gov/media/141194/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/13/2020	Pro-Lab Diagnostics	Pro-AmpRT SARS-CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/141146/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patient (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/11/2020	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/141049/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patient (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/11/2020	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR (/web/20200816201843/https://www.fda.gov/media/141054/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patient (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 08/10/2020	Solaris Diagnostics	Solaris Multiplex SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/141013/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/10/2020	Alpha Genomix Laboratories	Alpha Genomix TaqPath SARS-CoV-2 Combo Assay (/web/20200816201843/https://www.fda.gov/media/141017/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/07/2020	George Washington University Public Health Laboratory	GWU SARS-CoV-2 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/140977/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/06/2020	Helix OpCo LLC (dba Helix)	Helix COVID-19 NGS Test (/web/20200816201843/https://www.fda.gov/media/140914/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/05/2020	Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/140919/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 08/03/2020	Wren Laboratories LLC	Wren Laboratories COVID-19 PCR Test (/web/20200816201843/https://www.fda.gov/media/140773/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/03/2020	Ethos Laboratories	Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay (/web/20200816201843/https://www.fda.gov/media/140777/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/03/2020	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	Cleveland Clinic SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140785/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/03/2020	Poplar Healthcare	Poplar SARS-CoV-2 TMA Pooling assay (/web/20200816201843/https://www.fda.gov/media/140789/download)	Molecular, Sample Pooling	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 08/03/2020	ISPM Labs, LLC dba Capstone Healthcare	Genus SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140815/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/31/2020	Xiamen Zeesan Biotech Co., Ltd.	SARS-CoV-2 Test Kit (Real-time PCR) (/web/20200816201843/https://www.fda.gov/media/140718/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/31/2020	University of California San Diego Health	UCSD RC SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140714/download)	Molecular, Pooling	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/30/2020	Clinical Reference Laboratory, Inc.	CRL Rapid Response (/web/20200816201843/https://www.fda.gov/media/140664/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 07/27/2020	Eli Lilly and Company	Lilly SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140540/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/27/2020	Sandia National Laboratories	SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay (/web/20200816201843/https://www.fda.gov/media/140544/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 07/24/2020	Jiangsu CoWin Biotech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing) (/web/20200816201843/https://www.fda.gov/media/140426/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/23/2020	Helix OpCo LLC (dba Helix)	Helix COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/140422/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/21/2020	DiaCarta, Inc.	QuantiVirus SARS-CoV-2 Multiplex Test Kit (/web/20200816201843/https://www.fda.gov/media/140355/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/17/2020	Access Genetics, LLC	OraRisk COVID-19 RT-PCR (/web/20200816201843/https://www.fda.gov/media/140290/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/16/2020	Boston Heart Diagnostics	Boston Heart COVID-19 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/140261/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/15/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics PF SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140226/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 07/15/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140231/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 07/15/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics HA SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/140236/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd

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+ 07/13/2020	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit (/web/20200816201843/https://www.fda.gov/media/140066/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/13/2020	Trax Management Services Inc.	PhoenixDx SARS-CoV-2 Multiplex (/web/20200816201843/https://www.fda.gov/media/140070/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/13/2020	Compass Laboratory Services, LLC	Compass Laboratory Services SARS-CoV2 Assay (/web/20200816201843/https://www.fda.gov/media/140074/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/10/2020	Boston Medical Center	BMC-CReM COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/140024/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/09/2020	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	SARS-CoV-2 RNA DETECTR Assay (/web/20200816201843/https://www.fda.gov/media/139934/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/09/2020	BioSewoom, Inc.	Real-Q 2019-nCoV Detection Kit (/web/20200816201843/https://www.fda.gov/media/139938/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/08/2020	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (/web/20200816201843/https://www.fda.gov/media/139860/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/07/2020	Enzo Life Sciences, Inc.	AMPIPROBE SARS-CoV-2 Test System (/web/20200816201843/https://www.fda.gov/media/139829/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/07/2020	Access Bio, Inc.	CareStart COVID-19 MDx RT-PCR (/web/20200816201843/https://www.fda.gov/media/139833/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

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+ 07/07/2020	Gene By Gene	Gene By Gene SARS-CoV-2 Detection Test (/web/20200816201843/https://www.fda.gov/media/139838/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/06/2020	Laboratorio Clinico Toledo	Laboratorio Clinico Toledo SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/139785/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 07/02/2020	Centers for Disease Control and Prevention (CDC)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (/web/20200816201843/https://www.fda.gov/media/139744/download)	Molecular, Multi-analyte	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 07/01/2020	CENTOGENE US, LLC	CentoFast-SARS-CoV-2 RT-PCR Assay (/web/20200816201843/https://www.fda.gov/media/139722/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/30/2020	Psomagen, Inc.	Psoma COVID-19 RT Test (/web/20200816201843/https://www.fda.gov/media/139673/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/30/2020	TNS Co., Ltd (Bio TNS)	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit (/web/20200816201843/https://www.fda.gov/media/139677/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/30/2020	The Kroger Co.	Kroger Health COVID-19 Test Home Collection Kit (/web/20200816201843/https://www.fda.gov/media/139681/download)	Home Collection Kit		IFU (/web/20200816201843/https://www EUA Summary (/web/20200816201843/https://www.fd
+ 06/29/2020	LifeHope Labs	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel (/web/20200816201843/https://www.fda.gov/media/139620/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/29/2020	Acupath Laboratories, Inc.	Acupath COVID-19 Real-Time (RT-PCR) Assay (/web/20200816201843/https://www.fda.gov/media/139669/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd

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+ 06/26/2020	Inform Diagnostics, Inc.	Inform Diagnostics SARS-CoV-2 RT-PCR Assay (/web/20200816201843/https://www.fda.gov/media/139569/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/25/2020	Diagnostic Solutions Laboratory, LLC	DSL COVID-19 Assay (/web/20200816201843/https://www.fda.gov/media/139513/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/25/2020	PreciGenome LLC	FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR) (/web/20200816201843/https://www.fda.gov/media/139524/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/25/2020	PlexBio Co., Ltd.	IntelliPlex SARS-CoV-2 Detection Kit (/web/20200816201843/https://www.fda.gov/media/139528/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/24/2020	University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory	MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay (/web/20200816201843/https://www.fda.gov/media/139509/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/23/2020	HealthQuest Esoterics	HealthQuest Esoterics TaqPath SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/139449/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/23/2020	University of Alabama at Birmingham Fungal Reference Lab	FRL SARS CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/139439/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/23/2020	Gencurix, Inc.	GenePro SARS-CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/139443/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/18/2020	Jiangsu Bioperfectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit (/web/20200816201843/https://www.fda.gov/media/139284/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

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+ 06/18/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	TRUPCR SARS-CoV-2 Kit (/web/20200816201843/https://www.fda.gov/media/139293/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/17/2020	The Ohio State University Wexner Medical Center	OSUWMC COVID-19 RT-PCR test (/web/20200816201843/https://www.fda.gov/media/139285/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/17/2020	Omnipathology Solutions Medical Corporation	Omni COVID-19 Assay by RT-PCR (/web/20200816201843/https://www.fda.gov/media/139289/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/15/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/139046/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/13/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/139066/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit (/web/20200816201843/https://www.fda.gov/media/138929/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/138815/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 06/10/2020	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit (/web/20200816201843/https://www.fda.gov/media/138819/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/10/2020	Cue Health Inc.	Cue COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/138823/download)	Molecular	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

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+ 06/09/2020	Illumina, Inc.	Illumina COVIDSeq Test (/web/20200816201843/https://www.fda.gov/media/138778/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/09/2020	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138787/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/08/2020	Euroimmun US, Inc.	EURORealTime SARS-Cov-2 (/web/20200816201843/https://www.fda.gov/media/138758/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/05/2020	Genetron Health (Beijing) Co., Ltd.	Genetron SARS-CoV-2 RNA Test (/web/20200816201843/https://www.fda.gov/media/138682/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 06/04/2020	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test (/web/20200816201843/https://www.fda.gov/media/138652/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd (Clinic) (/web/20200816201843/https://www.fd
+ 06/01/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay (/web/20200816201843/https://www.fda.gov/media/138532/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 05/28/2020	PrivaPath Diagnostics, Inc.	LetsGetChecked Coronavirus (COVID-19) Test (/web/20200816201843/https://www.fda.gov/media/138405/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 05/22/2020	dba SpectronRX	Hymon SARS-CoV-2 Test Kit (/web/20200816201843/https://www.fda.gov/media/138343/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

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+ 05/22/2020	Exact Sciences Laboratories	SARS-CoV-2 (N gene detection) Test (/web/20200816201843/https://www.fda.gov/media/138327/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 05/21/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138295/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd IFU1 (Home Collect) (/web/20200816201843/https://www.fd IFU2 (Home Collect) (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit (/web/20200816201843/https://www.fda.gov/media/138300/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/21/2020	SolGent Co., Ltd	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit (/web/20200816201843/https://www.fda.gov/media/138306/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit (/web/20200816201843/https://www.fda.gov/media/138292/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/18/2020	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138179/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/18/2020	Color Genomics, Inc.	Color SARS Cov-2 Diagnostic Assay (/web/20200816201843/https://www.fda.gov/media/138248/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd (On-site Collect) (/web/20200816201843/https://www.fd
+ 05/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/138147/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary, (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd

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+ 05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (/web/20200816201843/https://www.fda.gov/media/138144/download)	Home Collection Kit	N/A	IFU (/web/20200816201843/https://ww EUA Summary (/web/20200816201843/https://www.fd
+ 05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/web/20200816201843/https://www.fda.gov/media/138151/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay (/web/20200816201843/https://www.fda.gov/media/138097/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/14/2020	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (/web/20200816201843/https://www.fda.gov/media/138101/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit (/web/20200816201843/https://www.fda.gov/media/138060/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/web/20200816201843/https://www.fda.gov/media/137934/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/11/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay (/web/20200816201843/https://www.fda.gov/media/137980/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit (/web/20200816201843/https://www.fda.gov/media/137892/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/07/2020	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay (/web/20200816201843/https://www.fda.gov/media/137773/download)	Molecular, Home Collection	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd

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+ 05/07/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit (/web/20200816201843/https://www.fda.gov/media/137781/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/06/2020	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test (/web/20200816201843/https://www.fda.gov/media/137737/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/06/2020	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit (/web/20200816201843/https://www.fda.gov/media/137747/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/06/2020	BioMérieux SA	SARS-COV-2 R-GENE (/web/20200816201843/https://www.fda.gov/media/137743/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/05/2020	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/media/137687/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (/web/20200816201843/https://www.fda.gov/media/137652/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/01/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test (/web/20200816201843/https://www.fda.gov/media/137576/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 05/01/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1 (RP2.1) (/web/20200816201843/https://www.fda.gov/media/137580/download)	Molecular, Multi-analyte	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/29/2020	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit (/web/20200816201843/https://www.fda.gov/media/137484/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/29/2020	Rheonix, Inc.	Rheonix COVID-19 MDx Assay (/web/20200816201843/https://www.fda.gov/media/137490/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/27/2020	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit (/web/20200816201843/https://www.fda.gov/media/137420/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/23/2020	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit (/web/20200816201843/https://www.fda.gov/media/137303/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/22/2020	altona Diagnostics GmbH	RealStar SARS-CoV02 RT-PCR Kits U.S. (/web/20200816201843/https://www.fda.gov/media/137257/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/21/2020	Seegene, Inc.	Allplex 2019-nCoV Assay (/web/20200816201843/https://www.fda.gov/media/137179/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/20/2020	Trax Management Services Inc.	PhoenixDx 2019-CoV (/web/20200816201843/https://www.fda.gov/media/137150/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/18/2020	OSANG Healthcare	GeneFinder COVID-19 Plus RealAmp Kit (/web/20200816201843/https://www.fda.gov/media/137113/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/17/2020	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit (/web/20200816201843/https://www.fda.gov/media/137117/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/16/2020	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay (/web/20200816201843/https://www.fda.gov/media/137088/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 04/16/2020	GenoSensor, LLC	GS"ç COVID-19 RT-PCR KIT (/web/20200816201843/https://www.fda.gov/media/137090/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/15/2020	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit (/web/20200816201843/https://www.fda.gov/media/137023/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/10/2020	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit (/web/20200816201843/https://www.fda.gov/media/136872/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/08/2020	DiaCarta, Inc	QuantiVirus SARS-CoV-2 Test kit (/web/20200816201843/https://www.fda.gov/media/136806/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/08/2020	Becton, Dickinson & Company	BD SARS-CoV-2Reagents for BD MAX System (/web/20200816201843/https://www.fda.gov/media/136813/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/07/2020	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit (/web/20200816201843/https://www.fda.gov/media/136787/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/06/2020	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit (/web/20200816201843/https://www.fda.gov/media/136735/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/03/2020	Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (/web/20200816201843/https://www.fda.gov/media/136684/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/03/2020	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (/web/20200816201843/https://www.fda.gov/media/136688/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/03/2020	Luminex Corporation	ARIES SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136694/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 04/02/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System (/web/20200816201843/https://www.fda.gov/media/136650/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https:/ (/web/20200816201843/https://www.fd
+ 04/01/2020	Ipsum Diagnostics, LLC	COV-19 IDx assay (/web/20200816201843/https://www.fda.gov/media/136618/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/30/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel (/web/20200816201843/https://www.fda.gov/media/136569/download)	Molecular, Multi-analyte	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/30/2020	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136566/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay (/web/20200816201843/https://www.fda.gov/media/136497/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 (/web/20200816201843/https://www.fda.gov/media/136522/download)	Molecular	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/26/2020	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/media/136473/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test (/web/20200816201843/https://www.fda.gov/media/136450/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd
+ 03/24/2020	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit (/web/20200816201843/https://www.fda.gov/media/136407/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/23/2020	Mesa Biotech Inc.	Accula SARS-Cov-2 Test (/web/20200816201843/https://www.fda.gov/media/136345/download)	Molecular	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/23/2020	BioFire Defense, LLC	BioFire COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/136356/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/20/2020	Cepheid	Xpert Xpress SARS-CoV-2 test (/web/20200816201843/https://www.fda.gov/media/136316/download)	Molecular	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd for Labs (/web/20200816201843/https://www.fd IFU for Point-of-Care (/web/20200816201843/https://www.fd
+ 03/20/2020	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (/web/20200816201843/https://www.fda.gov/media/136306/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/19/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/136283/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/19/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay (/web/20200816201843/https://www.fda.gov/media/136288/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/18/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay (/web/20200816201843/https://www.fda.gov/media/136255/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/17/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR (/web/20200816201843/https://www.fda.gov/media/136228/download)	Molecular, Home Collection, Sample Pooling	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd (Home Collect) (/web/20200816201843/https://www.fd
+ 03/17/2020	Quidel Corporation	Lyra SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136224/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/16/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/136148/download)	Molecular, Home Collection, Pooling, Screening	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd Summary (/web/20200816201843/https://www.fd (Pixel Home Collect) (/web/20200816201843/https://www.fd LabCorp Home Collect (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/16/2020	Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136153/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/13/2020	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit (/web/20200816201843/https://www.fda.gov/media/136113/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 03/12/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/media/136046/download)	Molecular	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 02/29/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (/web/20200816201843/https://www.fda.gov/media/135661/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd
+ 02/04/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) (/web/20200816201843/https://www.fda.gov/media/134919/download)	Molecular	H	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd (/web/20200816201843/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. A manufacturer may request the addition of an eligible molecular-based LDT to Appendix A by submitting a request to CDRH-EUA-Templates@FDA.HHS.GOV (https://web.archive.org/web/20200816201843/mailto:CDRH-EUA-Templates@FDA.HHS.GOV) (https://web.archive.org/web/20200816201843mp_/https://web.archive.org/about-fda/website-policies/website-disclaimer).

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/web/20200816201843/https://www.fda.gov/media/136598/download)
- Fact Sheet for Healthcare Providers (/web/20200816201843/https://www.fda.gov/media/136599/download)
- Fact Sheet for Patients (/web/20200816201843/https://www.fda.gov/media/136600/download)
- See Appendix A table below for a current list of included laboratories and their LTDs

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this Umbrella EUA (/web/20200816201843/https://www.fda.gov/media/136598/download) during the COVID-19 public health emergency.

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

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Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 06/12/2020	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138933/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138934/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138791/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138790/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/web/20200816201843/https://www.fda.gov/media/138624/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138625/download)
+ 06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV rRT Assay (/web/20200816201843/https://www.fda.gov/media/138527/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138526/download)
+ 06/01/2020	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/web/20200816201843/https://www.fda.gov/media/138529/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138528/download)
+ 05/22/2020	Express Gene LLC (dba Molecular Diagnostics Laboratory)	Express Gene 2019-nCoV RT-PCR Diagnostic Panel (/web/20200816201843/https://www.fda.gov/media/138329/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138330/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/138331/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138332/download)
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/web/20200816201843/https://www.fda.gov/media/138062/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138063/download)
+ 05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/web/20200816201843/https://www.fda.gov/media/138064/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/138065/download)
+ 05/12/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/web/20200816201843/https://www.fda.gov/media/137982/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137983/download)
+ 05/07/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/web/20200816201843/https://www.fda.gov/media/137896/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137897/download)
+ 05/03/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/web/20200816201843/https://www.fda.gov/media/137654/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137656/download)
+ 04/30/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/web/20200816201843/https://www.fda.gov/media/137545/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137546/download)

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 04/28/2020	Biocerna	SARS-CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/137451/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137450/download)
+ 04/27/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/137424/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137423/download)
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/web/20200816201843/https://www.fda.gov/media/137371/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137372/download)
+ 04/24/2020	AIT Laboratories	SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/137373/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137374/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/web/20200816201843/https://www.fda.gov/media/137369/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137370/download)
+ 04/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/web/20200816201843/https://www.fda.gov/media/137256/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137255/download)
+ 04/20/2020	Mayo Clinic Laboratories, Rochester, MN	SARS-CoV-2 Molecular Detection Assay (/web/20200816201843/https://www.fda.gov/media/137162/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137163/download)
+ 04/15/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/web/20200816201843/https://www.fda.gov/media/137037/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137036/download)
+ 04/15/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/137035/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137034/download)
+ 04/14/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136972/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136971/download)
+ 04/14/2020	Exact Sciences Laboratories	SARS-CoV-2 Test (/web/20200816201843/https://www.fda.gov/media/137094/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/137095/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136941/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136942/download)
+ 04/13/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test (/web/20200816201843/https://www.fda.gov/media/136943/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136944/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/web/20200816201843/https://www.fda.gov/media/136874/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/web/20200816201843/https://www.fda.gov/media/136878/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136877/download)
+ 04/10/2020	University of North Carolina Medical Center	UNC Health SARS-CoV-2 real-time RT-PCR test (/web/20200816201843/https://www.fda.gov/media/136879/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136880/download)
+ 04/08/2020	Stanford Health Care Clinical Virology Laboratory	Stanford SARS-CoV-2 assay (/web/20200816201843/https://www.fda.gov/media/136817/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136818/download)

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary
+ 04/06/2020	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay (/web/20200816201843/https://www.fda.gov/media/136739/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136740/download)
+ 04/03/2020	Massachusetts General Hospital	MGH COVID-19 qPCR assay (/web/20200816201843/https://www.fda.gov/media/136700/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136699/download)
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/web/20200816201843/https://www.fda.gov/media/136658/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/web/20200816201843/https://www.fda.gov/media/136657/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136656/download)
+ 03/31/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/web/20200816201843/https://www.fda.gov/media/136601/download)	EUA Summary (/web/20200816201843/https://www.fda.gov/media/136602/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 antigen diagnostic tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 07/02/2020	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/media/139752/download)	Antigen	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 05/08/2020	Quidel Corporation	Sofia SARS Antigen FIA (/web/20200816201843/https://www.fda.gov/media/137886/download)	Antigen	H, M, W	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Individual EUAs for Serology Tests for SARS-CoV-2

On August 6, 2020, based on FDA's continued review of the scientific evidence available for Autobio Diagnostics Co. Ltd.'s Anti-SARS-CoV-2 Rapid Test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated blood (Heparin/ EDTA/ sodium citrate) or serum 2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20200816201843/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3306-a001.pdf), FDA determined that the statutory criteria for the authorization in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, FDA determined that it is not reasonable to believe the product may be effective in detecting IgM antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20200816201843/https://www.fda.gov/media/140908/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

On June 16, 2020 (/web/20200816201843/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test), based on FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.'s DPP COVID-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20200816201843/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3265-a001.pdf), FDA determined that the statutory criteria for issuing an EUA in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20200816201843/https://www.fda.gov/media/139109/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

This table includes information about authorized SARS-CoV-2 serology/antibody assays that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

For additional performance information about EUA authorized serology/antibody tests, please see the EUA Authorized Serology Test Performance (/web/20200816201843/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance) webpage.

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/06/2020	bioMérieux SA	VIDAS SARS-CoV-2 IgM (/web/20200816201843/https://www.fda.gov/media/140930/download)	IgM, ELFA	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 08/06/2020	bioMérieux SA	VIDAS SARS-CoV-2 IgG (/web/20200816201843/https://www.fda.gov/media/140934/download)	IgG, ELFA	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 08/05/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA (/web/20200816201843/https://www.fda.gov/media/140926/download)	Total Antibody, ELISA	H	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 IgG (COV2G) (/web/20200816201843/https://www.fda.gov/media/140700/download)	IgG, Semi-quantitative	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 IgG (COV2G) (/web/20200816201843/https://www.fda.gov/media/140703/download)	IgG, Semi-quantitative	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 07/24/2020	Xiamen Biotime Biotechnology Co., Ltd.	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test (/web/20200816201843/https://www.fda.gov/media/140440/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 07/24/2020	Access Bio, Inc.	CareStart COVID-19 IgM/IgG (/web/20200816201843/https://www.fda.gov/media/140444/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd
+ 07/17/2020	Megna Health, Inc.	Rapid COVID-19 IgM/IgG Combo Test Kit (/web/20200816201843/https://www.fda.gov/media/140294/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fd Recipients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 07/16/2020	Luminex Corporation	xMAP SARS-CoV-2 Multi-Antigen IgG Assay (/web/20200816201843/https://www.fda.gov/media/140257/download)	IgG, FMIA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 07/13/2020	Salofa Oy	Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette (/web/20200816201843/https://www.fda.gov/media/140079/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 07/10/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test (/web/20200816201843/https://www.fda.gov/media/140035/download)	Total Antibody, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 07/08/2020	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit (/web/20200816201843/https://www.fda.gov/media/139866/download)	IgG, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 07/06/2020	Assure Tech. (Hangzhou Co., Ltd)	Assure COVID-19 IgG/IgM Rapid Test Device (/web/20200816201843/https://www.fda.gov/media/139789/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/30/2020	InBios International, Inc.	SCoV-2 Detect IgM ELISA (/web/20200816201843/https://www.fda.gov/media/139726/download)	IgM, ELISA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/26/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgG (/web/20200816201843/https://www.fda.gov/media/139624/download)	IgG, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/23/2020	Babson Diagnostics, Inc.	Babson Diagnostics aC19G1 (/web/20200816201843/https://www.fda.gov/media/139450/download)	IgG, CLIA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc EUA Summary (/web/20200816201843/https://www.fc
+ 06/19/2020	Hangzhou Laihe Biotech Co., Ltd.	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) (/web/20200816201843/https://www.fda.gov/media/139407/download)	IgM and IgG Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/18/2020	Biohit Healthcare (Hefei) Co. Ltd.	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (/web/20200816201843/https://www.fda.gov/media/139280/download)	IgM and IgG Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/15/2020	Emory Medical Laboratories	SARS-CoV-2 RBD IgG test (/web/20200816201843/https://www.fda.gov/media/139050/download)	IgG, ELISA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc EUA Summary (/web/20200816201843/https://www.fc
+ 06/10/2020	InBios International, Inc.	SCoV-2 Detect IgG ELISA (/web/20200816201843/https://www.fda.gov/media/138807/download)	IgG, ELISA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/08/2020	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (/web/20200816201843/https://www.fda.gov/media/138750/download)	Total Antibody, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/08/2020	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (/web/20200816201843/https://www.fda.gov/media/138754/download)	Total Antibody, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 06/04/2020	Vibrant America Clinical Labs	Vibrant COVID-19 Ab Assay (/web/20200816201843/https://www.fda.gov/media/138626/download)	IgM and IgG, CLIA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc EUA Summary (/web/20200816201843/https://www.fc
+ 06/04/2020	Hangzhou Biotest Biotech Co., Ltd.	RightSign COVID-19 IgG/IgM Rapid Test Cassette (/web/20200816201843/https://www.fda.gov/media/138657/download)	IgM and IgG Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (/web/20200816201843/https://www.fda.gov/media/138435/download)	IgM and IgG Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T) (/web/20200816201843/https://www.fda.gov/media/138439/download)	Total Antibody, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T) (/web/20200816201843/https://www.fda.gov/media/138443/download)	Total Antibody, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 05/04/2020	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG) (/web/20200816201843/https://www.fda.gov/media/137606/download)	IgG, ELISA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 05/02/2020	Roche Diagnostics	Elecsys Anti-SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/media/137602/download)	Total Antibody, ECLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection (/web/20200816201843/https://www.fda.gov/media/137540/download)	Total Antibody, FMIA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc EUA Summary (/web/20200816201843/https://www.fc
+ 04/29/2020	Bio-Rad Laboratories, Inc.	Platelia SARS-CoV-2 Total Ab assay (/web/20200816201843/https://www.fda.gov/media/137494/download)	Total Antibody, ELISA	H	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 04/26/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay (/web/20200816201843/https://www.fda.gov/media/137384/download)	IgG, CMIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU-ARCHITECT (/web/20200816201843/https://www.fc IFU-Alinityi (/web/20200816201843/https://www.fc
+ 04/24/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG (/web/20200816201843/https://www.fda.gov/media/137356/download)	IgG, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 04/24/2020	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack (/web/20200816201843/https://www.fda.gov/media/137360/download)	IgG, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test (/web/20200816201843/https://www.fda.gov/media/137032/download)	IgG, ELISA	H	HCP (/web/20200816201843/https://www.fc Patients (/web/20200816201843/https://www.fc EUA Summary (/web/20200816201843/https://www.fc
+ 04/14/2020	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (/web/20200816201843/https://www.fda.gov/media/136966/download)	Total Antibody, CLIA	H, M	HCP (/web/20200816201843/https://www.fc Recipients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc
+ 04/01/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test (/web/20200816201843/https://www.fda.gov/media/136622/download)	IgM and IgG, Lateral Flow	H, M	HCP (/web/20200816201843/https://www.fc Patients (/web/20200816201843/https://www.fc IFU (/web/20200816201843/https://www.fc

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay, CMIA = chemiluminescent microparticle immunoassay; ELFA = enzyme-linked fluorescence assay

Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2

On April 28, 2020, FDA issued an umbrella EUA for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by the FDA, and are confirmed by the FDA to meet the criteria set forth in the Scope of Authorization of the EUA. To date, however, no device has been added to the list of authorized devices in Appendix A of the letter of authorization.

On July 21, 2020, FDA determined, based on information and experience since issuing this EUA, that circumstances support revocation of this umbrella EUA so that FDA may issue individual EUAs. Individual EUAs will allow for broader indications and scopes of authorization, individualized conditions of authorization to address any issue unique to a specific test, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA.

Accordingly, the EUA was revoked (/web/20200816201843/https://www.fda.gov/media/140351/download) under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Individual EUAs For IVDs for Management of COVID-19 Patients

This table includes information about authorized in vitro diagnostic tests that may be used in the management of patients with COVID-19 that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search:

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/02/2020	Roche Diagnostics	Elecsys IL-6 (/web/20200816201843/https://www.fda.gov/media/138596/download)	Immunoassay-IL-6	H, M	HCP (/web/20200816201843/https://www.fd Patients (/web/20200816201843/https://www.fd IFU (/web/20200816201843/https://www.fd

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20200816201843/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20200816201843/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20200816201843/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- EUA Authorized Serology Test Performance (/web/20200816201843/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance)

The Wayback Machine - https://web.archive.org/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitr…

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic Template for Commercial Manufacturers (/web/20210319141203/https://www.fda.gov/media/135900/download) (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20210319141203/https://www.fda.gov/media/135658/download) (updated July 28, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20210319141203/https://www.fda.gov/media/138412/download) (May 29, 2020)
- Antigen Template for Test Developers (/web/20210319141203/https://www.fda.gov/media/137907/download) (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20210319141203/https://www.fda.gov/media/140615/download) (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20210319141203/https://www.fda.gov/media/146695/download) (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (/web/20210319141203/https://www.fda.gov/media/137698/download)(March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20210319141203/https://www.fda.gov/media/146746/download) (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (/web/20210319141203/https://www.fda.gov/media/143941/download) (November 24, 2020)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210319141203/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210319141203/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210319141203mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210319141203/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210319141203mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20210319141203/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210319141203/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210319141203/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210319141203mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

- Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
- Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests
- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2
- Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2
- Individual EUAs for IVDs for Management of COVID-19 Patients

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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests).

Molecular SARS-CoV-2 Diagnostic Tests for COVID-19 that have been granted a De Novo, 510(k) clearance or PMA

- BioFire Respiratory Panel 2.1 (RP2.1) - On March 17, 2021, FDA granted the first marketing authorization using the De Novo review pathway for the BioFire Respiratory Panel 2.1 (RP2.1) (https://web.archive.org/web/20210319141203/https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf) (PDF - 630 KB). The BioFire RP2.1 is for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. Also see the FDA news release: FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process (/web/20210319141203/https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process). With granting of the De Novo for the BioFire RP2.1, the FDA revoked the EUA for this device (/web/20210319141203/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations), which was initially authorized for emergency use in May 2020.

  The BioFire Respiratory Panel 2.1 (RP2.1) was reviewed under the De Novo premarket review pathway (/web/20210319141203/https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing criteria, called special controls, that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Search:

Show entries

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/11/2021	Infinity BiologiX LLC	Infinity BiologiX TaqPath SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/137773/download) 04/10/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 03/10/2021	Becton, Dickinson & Company	BD SARS-CoV-2 Reagents for BD MAX System (/web/20210319141203/https://www.fda.gov/media/136813/download) 04/08/2020	Real-time RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/09/2021	Quidel Corporation	Solana SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/144756/download) 12/23/2020	Isothermal Reverse Transcriptase – Helicase-Dependent Amplification (RT-HDA)	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/09/2021	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits (/web/20210319141203/https://www.fda.gov/media/145977/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 03/09/2021	GetMyDNA	GetMyDNA COVID-19 Test Home Collection Kit (/web/20210319141203/https://www.fda.gov/media/146541/download) 03/09/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/05/2021	Cue Health Inc.	Cue COVID-19 Test for Home and Over The Counter (OTC) Use (/web/20210319141203/https://www.fda.gov/media/146467/download) 03/05/2021	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Home Test) (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/05/2021	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) (/web/20210319141203/https://www.fda.gov/media/146496/download) 03/05/2021	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 03/04/2021	Abbott Molecular Inc.	Alinity m Resp-4-Plex (/web/20210319141203/https://www.fda.gov/media/146488/download) 03/04/2021	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/03/2021	Ambry Genetics Laboratory	Ambry COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/145406/download) 01/22/2021	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 03/03/2021	Luminex Molecular Diagnostics, Inc.	NxTAG Respiratory Pathogen Panel + SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/146492/download) 03/03/2021	RT-PCR, Multi-analyte	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/02/2021	binx health, Inc.	binx health At-Home Nasal Swab COVID-19 Sample Collection Kit (/web/20210319141203/https://www.fda.gov/media/143183/download) 10/20/2020	Home Collection Kit	N/A	EUA Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 03/01/2021	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test (/web/20210319141203/https://www.fda.gov/media/138652/download) 06/04/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda (Clinic) (/web/20210319141203/https://www.fda
+ 02/26/2021	Fluidigm Corporation	Advanta Dx SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/141538/download) 08/25/2020	Real-time RT-PCR, Saliva, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/26/2021	Clinical Enterprise, Inc.	EmpowerDX COVID-19 Home Collection Kit DTC (/web/20210319141203/https://www.fda.gov/media/143063/download) 10/15/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/26/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay (/web/20210319141203/https://www.fda.gov/media/143070/download) 04/06/2020	Real-Time RT-PCR, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 02/26/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay DTC (/web/20210319141203/https://www.fda.gov/media/146322/download) 02/26/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 02/24/2021	Hologic, Inc.	Aptima SARS-CoV-2/Flu assay (/web/20210319141203/https://www.fda.gov/media/144587/download) 12/16/2020	Real-time TMA, chemiluminescent, Multi-analyte	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/24/2021	University of Illinois Office of the Vice President for Economic Development and Innovation	covidSHIELD (/web/20210319141203/https://www.fda.gov/media/146314/download) 02/24/2021	Real-time RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 02/23/2021	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit (/web/20210319141203/https://www.fda.gov/media/136113/download) 03/13/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/23/2021	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit (/web/20210319141203/https://www.fda.gov/media/138300/download) 05/21/2020	RT-LAMP	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/22/2021	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT PCR CE Test (/web/20210319141203/https://www.fda.gov/media/141666/download) 08/28/2020	RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/19/2021	LetsGetChecked, Inc.	LetsGetChecked Coronavirus (COVID-19) Test (/web/20210319141203/https://www.fda.gov/media/138405/download) 05/28/2020	TMA, chemiluminescent, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/18/2021	Color Health, Inc.	Color COVID-19 Self-Swab Collection Kit (/web/20210319141203/https://www.fda.gov/media/141796/download) 08/31/2020	Home Collection Kit	N/A	EUA Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/13/2021	The Kroger Co.	Kroger Health COVID-19 Test Home Collection Kit (/web/20210319141203/https://www.fda.gov/media/139681/download) 06/30/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	Individuals (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 02/13/2021	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel DTC (/web/20210319141203/https://www.fda.gov/media/145981/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/13/2021	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit DTC (/web/20210319141203/https://www.fda.gov/media/145986/download) 02/13/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	Individuals (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/12/2021	RCA Laboratory Services LLC dba GENETWORx	GENETWORx Covid-19 Nasal Swab Test (/web/20210319141203/https://www.fda.gov/media/144550/download) 12/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/11/2021	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit (/web/20210319141203/https://www.fda.gov/media/145920/download) 02/11/2021	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/10/2021	Becton, Dickinson and Company (BD)	BD SARS-CoV-2/Flu for BD MAX System (/web/20210319141203/https://www.fda.gov/media/145924/download) 02/10/2021	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/10/2021	Thermo Fisher Scientific	TaqPath COVID-19, FluA, FluB Combo Kit (/web/20210319141203/https://www.fda.gov/media/145928/download) 02/10/2021	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/10/2021	Grifols Diagnostic Solutions Inc.	Procleix SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/145934/download) 02/10/2021	TMA	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/09/2021	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit (/web/20210319141203/https://www.fda.gov/media/137420/download) 04/27/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/09/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR Complete (/web/20210319141203/https://www.fda.gov/media/143059/download) 10/14/2020	RT, qSTAR amplification	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/08/2021	QDx Pathology Services	QDX SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/141542/download) 08/25/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 02/08/2021	Visby Medical, Inc.	Visby Medical COVID-19 Point of Care Test (/web/20210319141203/https://www.fda.gov/media/145914/download) 02/08/2021	RT-PCR	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Collect) (/web/20210319141203/https://www.fda
+ 02/05/2021	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit (/web/20210319141203/https://www.fda.gov/media/136407/download) 03/24/2020	Real-time RT-PCR, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/05/2021	Access Bio, Inc.	CareStart COVID-19 MDx RT-PCR (/web/20210319141203/https://www.fda.gov/media/139833/download) 07/07/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/05/2021	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect (/web/20210319141203/https://www.fda.gov/media/141194/download) 08/15/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 02/04/2021	Quidel Corporation	Lyra SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136224/download) 03/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/04/2021	Clinomics USA Inc.	Clinomics TrioDx RT-PCR COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/145686/download) 02/04/2021	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/03/2021	Mesa Biotech Inc.	Accula SARS-Cov-2 Test (/web/20210319141203/https://www.fda.gov/media/136345/download) 03/23/2020	RT and amplification	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/03/2021	DiaCarta, Inc	QuantiVirus SARS-CoV-2 Test kit (/web/20210319141203/https://www.fda.gov/media/136806/download) 04/08/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/03/2021	PlexBio Co., Ltd.	IntelliPlex SARS-CoV-2 Detection Kit (/web/20210319141203/https://www.fda.gov/media/139528/download) 06/25/2020	RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 02/01/2021	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/136473/download) 03/26/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/29/2021	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test (/web/20210319141203/https://www.fda.gov/media/137737/download) 05/06/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/29/2021	Diagnostic Solutions Laboratory, LLC	DSL COVID-19 Assay (/web/20210319141203/https://www.fda.gov/media/139513/download) 06/25/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 01/29/2021	Sandia National Laboratories	SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay (/web/20210319141203/https://www.fda.gov/media/140544/download) 07/27/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 01/28/2021	Alpha Genomix Laboratories	Alpha Genomix TaqPath SARS-CoV-2 Combo Assay (/web/20210319141203/https://www.fda.gov/media/141017/download) 08/10/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 01/28/2021	BayCare Laboratories, LLC	BayCare SARS-CoV-2 RT PCR Assay (/web/20210319141203/https://www.fda.gov/media/141766/download) 08/31/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 01/27/2021	Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV (/web/20210319141203/https://www.fda.gov/media/142434/download) 09/24/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda for Labs (/web/20210319141203/https://www.fda for Point-of-Care (/web/20210319141203/https://www.fda
+ 01/27/2021	Agena Bioscience, Inc.	MassARRAY SARS-CoV-2 Panel (/web/20210319141203/https://www.fda.gov/media/143331/download) 10/26/2020	RT-PCR, chip array and MALDI-TOF Mass Spec.	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/26/2021	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/137687/download) 05/05/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/26/2021	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (/web/20210319141203/https://www.fda.gov/media/138101/download) 05/14/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/26/2021	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138179/download) 05/18/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/22/2021	Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136153/download) 03/16/2020	Real-time RT-PCR, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/22/2021	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136566/download) 03/30/2020	RT-PCR, Collection Kit, Saliva	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Collect) (/web/20210319141203/https://www.fda
+ 01/22/2021	Hologic, Inc.	Aptima SARS-CoV-2 assay (/web/20210319141203/https://www.fda.gov/media/138097/download) 05/14/2020	TMA, chemiluminescent, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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+ 01/22/2021	Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory	Express Gene 2019-nCoV RT-PCR Diagnostic Panel (/web/20210319141203/https://www.fda.gov/media/143881/download) 05/22/2020	Real-time RT-PCR, Collection Kit, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/19/2021	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	Cleveland Clinic SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140785/download) 08/03/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 01/19/2021	Hospital of the University of Pennsylvania	BD MAX COVID-19 ASSAY (Authorized by HHS/OASH) (/web/20210319141203/https://www.fda.gov/media/145675/download) 01/19/2021	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 01/19/2021	INNO Diagnostics Reference Laboratory, Ponce Medical School	PMSF-INNO SARS-CoV-2 RT-PCR Test (Authorized by HHS/OASH) (/web/20210319141203/https://www.fda.gov/media/145679/download) 01/19/2021	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 01/15/2021	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit (/web/20210319141203/https://www.fda.gov/media/145267/download) 01/15/2021	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/14/2021	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit (/web/20210319141203/https://www.fda.gov/media/137747/download) 05/06/2020	RT-LAMP, CRISPR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/13/2021	SML GENETREE Co., Ltd.	Ezplex SARS-CoV-2 G Kit (/web/20210319141203/https://www.fda.gov/media/145131/download) 01/14/2021	Real-time RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/08/2021	Centers for Disease Control and Prevention (CDC)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (/web/20210319141203/https://www.fda.gov/media/139744/download) 07/02/2020	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 01/07/2021	Cepheid	Xpert Xpress SARS-CoV-2 test (/web/20210319141203/https://www.fda.gov/media/136316/download) 03/20/2020	Real-time RT-PCR	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda for Labs (/web/20210319141203/https://www.fda IFU for Point-of-Care (/web/20210319141203/https://www.fda
+ 01/06/2021	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit (/web/20210319141203/https://www.fda.gov/media/138819/download) 06/10/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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+ 01/05/2021	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (/web/20210319141203/https://www.fda.gov/media/136306/download) 03/20/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/30/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit (/web/20210319141203/https://www.fda.gov/media/137781/download) 05/07/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/30/2020	Jiangsu Bioperfectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit (/web/20210319141203/https://www.fda.gov/media/139284/download) 06/18/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/30/2020	Enzo Life Sciences, Inc.	AMPIPROBE SARS-CoV-2 Test System (/web/20210319141203/https://www.fda.gov/media/139829/download) 07/07/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/30/2020	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/141049/download) 08/11/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patient (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit (/web/20210319141203/https://www.fda.gov/media/136787/download) 04/07/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit (/web/20210319141203/https://www.fda.gov/media/136872/download) 04/10/2020	RT, Isothermal amplification	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit (/web/20210319141203/https://www.fda.gov/media/137023/download) 04/15/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit (/web/20210319141203/https://www.fda.gov/media/137117/download) 04/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	SolGent Co., Ltd	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit (/web/20210319141203/https://www.fda.gov/media/138306/download) 05/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Omnipathology Solutions Medical Corporation	Omni COVID-19 Assay by RT-PCR (/web/20210319141203/https://www.fda.gov/media/139289/download) 06/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 12/28/2020	Gencurix, Inc.	GenePro SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/139443/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Laboratorio Clinico Toledo	Laboratorio Clinico Toledo SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/139785/download) 07/06/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	Gene By Gene	Gene By Gene SARS-CoV-2 Detection Test (/web/20210319141203/https://www.fda.gov/media/139838/download) 07/07/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	BioSewoom, Inc.	Real-Q 2019-nCoV Detection Kit (/web/20210319141203/https://www.fda.gov/media/139938/download) 07/09/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	DiaCarta, Inc.	QuantiVirus SARS-CoV-2 Multiplex Test Kit (/web/20210319141203/https://www.fda.gov/media/140355/download) 07/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Solaris Diagnostics	Solaris Multiplex SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/141013/download) 08/10/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR (/web/20210319141203/https://www.fda.gov/media/141054/download) 08/11/2020	RT, non-isothermal nucleic acid amplification qSTAR	H	HCP (/web/20210319141203/https://www.fda Patient (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Guardant Health, Inc.	Guardant-19 (/web/20210319141203/https://www.fda.gov/media/141484/download) 08/21/2020	Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	Texas Department of State Health Services, Laboratory Services Section	Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/141493/download) 08/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	T2 Biosystems, Inc.	T2SARS-CoV-2 Panel (/web/20210319141203/https://www.fda.gov/media/141752/download) 08/31/2020	RT, amplification, T2 Magnetic resonance	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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+ 12/28/2020	OPTOLANE Technologies, Inc.	Kaira 2019-nCoV Detection Kit (/web/20210319141203/https://www.fda.gov/media/141792/download) 09/01/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Visby Medical, Inc.	Visby Medical COVID-19 (/web/20210319141203/https://www.fda.gov/media/142225/download) 09/16/2020	RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	Clear Labs, Inc.	Clear Dx SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/142419/download) 09/23/2020	RT-PCR and Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/28/2020	UMass Memorial Medical Center	UMass Molecular Virology Laboratory 2019-nCoV rRT-PCR Dx Panel (/web/20210319141203/https://www.fda.gov/media/142689/download) 10/01/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/28/2020	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/143932/download) 11/23/2020	Real-time RT-PCR, Home Collection, Screening, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/23/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay (/web/20210319141203/https://www.fda.gov/media/137980/download) 05/11/2020	Real-time RT-PCR, Pooling, Screening	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/23/2020	Cepheid	Xpert Omni SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/144029/download) 11/27/2020	Real-time RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/23/2020	Cepheid	Xpert Xpress SARS-CoV-2 DoD (/web/20210319141203/https://www.fda.gov/media/144790/download) 12/23/2020	Real-time RT-PCR, Pooling	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/22/2020	Verily Life Sciences	Verily COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/141948/download) 09/08/2020	Real-time RT-PCR, Pooling, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 12/22/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) (/web/20210319141203/https://www.fda.gov/media/142693/download) 10/02/2020	RT, Nested multiplex PCR, Multi-analyte	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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+ 12/18/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit (/web/20210319141203/https://www.fda.gov/media/138292/download) 05/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/18/2020	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (/web/20210319141203/https://www.fda.gov/media/139860/download) 07/08/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 12/17/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	TRUPCR SARS-CoV-2 Kit (/web/20210319141203/https://www.fda.gov/media/139293/download) 06/18/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/17/2020	Materials and Machines Corporation of America (DBA MatmaCorp, Inc.)	MatMaCorp COVID-19 2SF Test (/web/20210319141203/https://www.fda.gov/media/144656/download) 12/17/2020	RT-PCR and isothermal nucleic acid amplification	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/15/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B (/web/20210319141203/https://www.fda.gov/media/141884/download) 09/03/2020	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/11/2020	ResearchDx, Inc., DBA Pacific Diagnostics	PacificDx Covid-19 (/web/20210319141203/https://www.fda.gov/media/144555/download) 12/11/2020	TMA, chemiluminescent, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 12/10/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System (/web/20210319141203/https://www.fda.gov/media/142190/download) 09/14/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/09/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/136148/download) 03/16/2020	Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda LabCorp Home Collect (/web/20210319141203/https://www.fda
+ 12/09/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test (/web/20210319141203/https://www.fda.gov/media/137576/download) 05/01/2020	RT-droplet PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/09/2020	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/141488/download) 08/21/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 12/09/2020	Bioeksen R&D Technologies Ltd.	Bio-Speedy Direct RT-qPCR SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/141824/download) 09/02/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/09/2020	Laboratory Corporation of America (LabCorp)	Pixel by LabCorp COVID-19 Test Home Collection Kit (/web/20210319141203/https://www.fda.gov/media/144333/download) 12/09/2020	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP (/web/20210319141203/https://www.fda Individuals (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 12/07/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/139046/download) 06/15/2020	RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/04/2020	BioFire Defense, LLC	BioFire COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/136356/download) 03/23/2020	RT, Nested multiplex PCR, Pooling	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/04/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC COVID-19+Flu RT-PCR (/web/20210319141203/https://www.fda.gov/media/144180/download) 12/04/2020	Real-time RT-PCR, Multi-analyte, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda EUA Summary (/web/20210319141203/https://www.fda (Home Collection) (/web/20210319141203/https://www.fda
+ 12/03/2020	Rheonix, Inc.	Rheonix COVID-19 MDx Assay (/web/20210319141203/https://www.fda.gov/media/137490/download) 04/29/2020	RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 12/01/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) (/web/20210319141203/https://www.fda.gov/media/134919/download) 02/04/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/27/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140231/download) 07/15/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 11/24/2020	Stanford Health Care Clinical Virology Laboratory	SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/136817/download) 04/08/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collection) (/web/20210319141203/https://www.fda

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+ 11/23/2020	RapidRona, Inc.	RapidRona Self-Collection Kit (/web/20210319141203/https://www.fda.gov/media/143927/download) 11/23/2020	Home Collection Kit	N/A	EUA Summary (/web/20210319141203/https://www.fda (Collection) (/web/20210319141203/https://www.fda
+ 11/21/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit (/web/20210319141203/https://www.fda.gov/media/138060/download) 05/13/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/20/2020	Trax Management Services Inc.	PhoenixDx SARS-CoV-2 Multiplex (/web/20210319141203/https://www.fda.gov/media/140070/download) 07/13/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/18/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/136046/download) 03/12/2020	Real-time RT-PCR, Pooling	H, M, H-Pooling	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/18/2020	Lucira Health, Inc.	Lucira COVID-19 All-In-One Test Kit (/web/20210319141203/https://www.fda.gov/media/143810/download) 11/17/2020	Prescription Home Testing	Home, H, M, W	HCP (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Home Test) (/web/20210319141203/https://www.fda
+ 11/13/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR (/web/20210319141203/https://www.fda.gov/media/136228/download) 03/17/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 11/10/2020	Xiamen Zeesan Biotech Co., Ltd.	SARS-CoV-2 Test Kit (Real-time PCR) (/web/20210319141203/https://www.fda.gov/media/140718/download) 07/31/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/06/2020	BioMérieux SA	SARS-COV-2 R-GENE (/web/20210319141203/https://www.fda.gov/media/137743/download) 05/06/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/04/2020	Euroimmun US, Inc.	EURORealTime SARS-Cov-2 (/web/20210319141203/https://www.fda.gov/media/138758/download) 06/08/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/02/2020	Seegene, Inc.	Allplex 2019-nCoV Assay (/web/20210319141203/https://www.fda.gov/media/137179/download) 04/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 11/02/2020	Color Genomics, Inc.	Color SARS-CoV-2 RT-LAMP Diagnostic Assay (/web/20210319141203/https://www.fda.gov/media/138248/download) 05/18/2020	RT, LAMP, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 10/31/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 RT-PCR Kit (/web/20210319141203/https://www.fda.gov/media/141994/download) 09/09/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/28/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay (/web/20210319141203/https://www.fda.gov/media/136497/download) 03/27/2020	RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/28/2020	Luminex Corporation	ARIES SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136694/download) 04/03/2020	RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/28/2020	Illumina, Inc.	Illumina COVIDSeq Test (/web/20210319141203/https://www.fda.gov/media/138778/download) 06/09/2020	Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/28/2020	DNA Genotek Inc.	ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 saliva collection devices (/web/20210319141203/https://www.fda.gov/media/143415/download) 10/28/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/28/2020	DNA Genotek Inc.	OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) saliva collection devices (/web/20210319141203/https://www.fda.gov/media/143418/download) 10/14/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/22/2020	Helix OpCo LLC	Helix COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/140422/download) 07/23/2020	Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 10/20/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138295/download) 05/21/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda IFU1 (Home Collect) (/web/20210319141203/https://www.fda IFU2 (Home Collect) (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 10/20/2020	Wren Laboratories LLC	Wren Laboratories COVID-19 PCR Test (/web/20210319141203/https://www.fda.gov/media/140773/download) 08/03/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda

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+ 10/17/2020	Genetrack Biolabs, Inc.	Genetrack SARS-CoV-2 Molecular Assay (/web/20210319141203/https://www.fda.gov/media/142479/download) 09/25/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary, (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 10/16/2020	Spectrum Solutions LLC	SDNA-1000 Saliva Collection Device (/web/20210319141203/https://www.fda.gov/media/142906/download) 10/08/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/08/2020	University of California, Los Angeles (UCLA)	UCLA SwabSeq COVID-19 Diagnostic Platform (/web/20210319141203/https://www.fda.gov/media/142802/download) 10/06/2020	RT-PCR and Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 10/07/2020	GenMark Diagnostics, Inc.	ePlex Respiratory Pathogen Panel 2 (/web/20210319141203/https://www.fda.gov/media/142902/download) 10/07/2020	RT-PCR and electrochemical detection, Multi-analyte	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/06/2020	Detectachem Inc.	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit (/web/20210319141203/https://www.fda.gov/media/141788/download) 09/01/2020	RT-LAMP	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/05/2020	SEASUN BIOMATERIALS, Inc.	AQ-TOP COVID-19 Rapid Detection Kit PLUS (/web/20210319141203/https://www.fda.gov/media/142797/download) 10/05/2020	RT-LAMP	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 10/02/2020	Cuur Diagnostics	Cuur Diagnostics SARS-CoV-2 Molecular Assay (/web/20210319141203/https://www.fda.gov/media/141624/download) 08/26/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 10/01/2020	Tempus Labs, Inc.	iC SARS-CoV2 Test (/web/20210319141203/https://www.fda.gov/media/142593/download) 10/01/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/30/2020	Aeon Global Health	Aeon Global Health SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/142532/download) 09/30/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/30/2020	Alimetrix, Inc.	Alimetrix SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/142589/download) 09/30/2020	RT-PCR, Microarray Hybridization	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 09/29/2020	CENTOGENE US, LLC	CentoSure SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/142536/download) 09/29/2020	Real-time RT-PCR, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/29/2020	Akron Children's Hospital	Akron Children's Hospital SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/142540/download) 09/29/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/29/2020	National Jewish Health	SARS-CoV-2 MassArray Test (/web/20210319141203/https://www.fda.gov/media/142545/download) 09/29/2020	RT-PCR and MALDI-TOF Mass Spec.	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test (/web/20210319141203/https://www.fda.gov/media/136450/download) 03/25/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/25/2020	Access Genetics, LLC	OraRisk COVID-19 RT-PCR (/web/20210319141203/https://www.fda.gov/media/140290/download) 07/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/24/2020	Acupath Laboratories, Inc.	Acupath COVID-19 Real-Time (RT-PCR) Assay (/web/20210319141203/https://www.fda.gov/media/139669/download) 06/29/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/22/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System (/web/20210319141203/https://www.fda.gov/media/136650/download) 04/02/2020	Real-time RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https:/ (/web/20210319141203/https://www.fda
+ 09/22/2020	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (/web/20210319141203/https://www.fda.gov/media/136688/download) 04/03/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/22/2020	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit (/web/20210319141203/https://www.fda.gov/media/137484/download) 04/29/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/22/2020	Quadrant Biosciences Inc.	Clarifi COVID-19 Test Kit (/web/20210319141203/https://www.fda.gov/media/142376/download) 09/22/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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+ 09/22/2020	Vela Operations Singapore Pte. Ltd.	ViroKey SARS-CoV-2 RT-PCR Test v2.0 (/web/20210319141203/https://www.fda.gov/media/142380/download) 09/22/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/21/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel (/web/20210319141203/https://www.fda.gov/media/136569/download) 03/30/2020	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/21/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/web/20210319141203/https://www.fda.gov/media/138151/download) 05/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 09/21/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay (/web/20210319141203/https://www.fda.gov/media/138532/download) 06/01/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/21/2020	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138787/download) 06/09/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/21/2020	HealthQuest Esoterics	HealthQuest Esoterics TaqPath SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/139449/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/21/2020	Psomagen, Inc.	Psoma COVID-19 RT Test (/web/20210319141203/https://www.fda.gov/media/139673/download) 06/30/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/21/2020	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit (/web/20210319141203/https://www.fda.gov/media/140066/download) 07/13/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/21/2020	Boston Heart Diagnostics	Boston Heart COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/140261/download) 07/16/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/21/2020	Eli Lilly and Company	Lilly SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140540/download) 07/27/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 09/21/2020	Ethos Laboratories	Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay (/web/20210319141203/https://www.fda.gov/media/140777/download) 08/03/2020	RT-PCR and MALDI-TOF Mass Spec., Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 09/21/2020	Exact Sciences Laboratories	SARS-CoV-2 (N gene detection) Test (/web/20210319141203/https://www.fda.gov/media/138327/download) 05/22/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect (/web/20210319141203/https://www.fda
+ 09/21/2020	Patients Choice Laboratories, LLC	PCL SARS-CoV-2 Real-Time RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/141662/download) 08/28/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 09/21/2020	KimForest Enterprise Co., Ltd.	KimForest SARS-CoV-2 Detection Kit v1 (/web/20210319141203/https://www.fda.gov/media/142360/download) 09/21/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/18/2020	GK Pharmaceuticals Contract Manufacturing Operations	GK ACCU-RIGHT SARS-CoV-2 RT-PCR KIT (/web/20210319141203/https://www.fda.gov/media/142307/download) 09/18/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/17/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 (/web/20210319141203/https://www.fda.gov/media/136522/download) 03/27/2020	RT, Isothermal amplification	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 09/09/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/139066/download) 06/13/2020	Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 09/04/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (/web/20210319141203/https://www.fda.gov/media/138144/download) 05/15/2020	Home Collection Kit	N/A	IFU (/web/20210319141203/https://www EUA Summary (/web/20210319141203/https://www.fda
+ 09/04/2020	BillionToOne, Inc.	qSanger-COVID-19 Assay (/web/20210319141203/https://www.fda.gov/media/141932/download) 09/04/2020	Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/31/2020	MiraDx	MiraDx SARS-CoV-2 RT-PCR assay (/web/20210319141203/https://www.fda.gov/media/141756/download) 08/31/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/31/2020	Mammoth Biosciences, Inc.	SARS-CoV-2 DETECTR Reagent Kit (/web/20210319141203/https://www.fda.gov/media/141762/download) 08/31/2020	RT-LAMP, CRISPR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/21/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics PF SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140226/download) 07/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 08/21/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics HA SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140236/download) 07/15/2020	TMA, chemiluminescent, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 08/20/2020	Cue Health Inc.	Cue COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/138823/download) 06/10/2020	RT, Isothermal amplification	H, M, W	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/18/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/136283/download) 03/19/2020	RT-PCR and electrochemical detection	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/17/2020	ZhuHai Sinochips Bioscience Co., Ltd.	COVID-19 Nucleic Acid RT-PCR Test Kit (/web/20210319141203/https://www.fda.gov/media/141243/download) 08/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/13/2020	Pro-Lab Diagnostics	Pro-AmpRT SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/141146/download) 08/13/2020	RT, Isothermal amplification	H	HCP (/web/20210319141203/https://www.fda Patient (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 08/11/2020	dba SpectronRX	Hymon SARS-CoV-2 Test Kit (/web/20210319141203/https://www.fda.gov/media/138343/download) 05/22/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/08/2020	Trax Management Services Inc.	PhoenixDx 2019-CoV (/web/20210319141203/https://www.fda.gov/media/137150/download) 04/20/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/07/2020	George Washington University Public Health Laboratory	GWU SARS-CoV-2 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/140977/download) 08/07/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/06/2020	Helix OpCo LLC (dba Helix)	Helix COVID-19 NGS Test (/web/20210319141203/https://www.fda.gov/media/140914/download) 08/06/2020	Sequencing	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 08/05/2020	Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/140919/download) 08/05/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 08/03/2020	Poplar Healthcare	Poplar SARS-CoV-2 TMA Pooling assay (/web/20210319141203/https://www.fda.gov/media/140789/download) 08/03/2020	TMA, chemiluminescent, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 08/03/2020	ISPM Labs, LLC dba Capstone Healthcare	Genus SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140815/download) 08/03/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 07/31/2020	University of California San Diego Health	UCSD RC SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/140714/download) 07/31/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 07/30/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay (/web/20210319141203/https://www.fda.gov/media/136255/download) 03/18/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 07/30/2020	Clinical Reference Laboratory, Inc.	CRL Rapid Response (/web/20210319141203/https://www.fda.gov/media/140664/download) 07/30/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 07/24/2020	Jiangsu CoWin Biotech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing) (/web/20210319141203/https://www.fda.gov/media/140426/download) 07/24/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 07/13/2020	Compass Laboratory Services, LLC	Compass Laboratory Services SARS-CoV2 Assay (/web/20210319141203/https://www.fda.gov/media/140074/download) 07/13/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 07/10/2020	Boston Medical Center	BMC-CReM COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/140024/download) 07/10/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 07/09/2020	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	SARS-CoV-2 RNA DETECTR Assay (/web/20210319141203/https://www.fda.gov/media/139934/download) 07/09/2020	RT-LAMP	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 07/01/2020	CENTOGENE US, LLC	CentoFast-SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/139722/download) 07/01/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/30/2020	TNS Co., Ltd (Bio TNS)	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit (/web/20210319141203/https://www.fda.gov/media/139677/download) 06/30/2020	RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 06/29/2020	LifeHope Labs	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel (/web/20210319141203/https://www.fda.gov/media/139620/download) 06/29/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/26/2020	Inform Diagnostics, Inc.	Inform Diagnostics SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/139569/download) 06/26/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/25/2020	PreciGenome LLC	FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR) (/web/20210319141203/https://www.fda.gov/media/139524/download) 06/25/2020	RT-digital droplet PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 06/24/2020	University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory	MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/139509/download) 06/24/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/23/2020	University of Alabama at Birmingham Fungal Reference Lab	FRL SARS CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/139439/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/17/2020	The Ohio State University Wexner Medical Center	OSUWMC COVID-19 RT-PCR test (/web/20210319141203/https://www.fda.gov/media/139285/download) 06/17/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda

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+ 06/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/138147/download) 05/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary, (/web/20210319141203/https://www.fda (Home Collect) (/web/20210319141203/https://www.fda
+ 06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit (/web/20210319141203/https://www.fda.gov/media/138929/download) 06/12/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 06/11/2020	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay (/web/20210319141203/https://www.fda.gov/media/137088/download) 04/16/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/138815/download) 06/10/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 06/05/2020	Genetron Health (Beijing) Co., Ltd.	Genetron SARS-CoV-2 RNA Test (/web/20210319141203/https://www.fda.gov/media/138682/download) 06/05/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 06/04/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay (/web/20210319141203/https://www.fda.gov/media/136288/download) 03/19/2020	Real-time RT-PCR	H, M	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/web/20210319141203/https://www.fda.gov/media/137934/download) 05/11/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit (/web/20210319141203/https://www.fda.gov/media/137892/download) 05/08/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (/web/20210319141203/https://www.fda.gov/media/137652/download) 05/04/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/28/2020	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit (/web/20210319141203/https://www.fda.gov/media/136735/download) 04/06/2020	Real-time RT-digital PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/23/2020	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit (/web/20210319141203/https://www.fda.gov/media/137303/download) 04/23/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/22/2020	altona Diagnostics GmbH	RealStar SARS-CoV02 RT-PCR Kits U.S. (/web/20210319141203/https://www.fda.gov/media/137257/download) 04/22/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/18/2020	OSANG Healthcare	GeneFinder COVID-19 Plus RealAmp Kit (/web/20210319141203/https://www.fda.gov/media/137113/download) 04/18/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/16/2020	GenoSensor, LLC	GS"ç COVID-19 RT-PCR KIT (/web/20210319141203/https://www.fda.gov/media/137090/download) 04/16/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/03/2020	Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (/web/20210319141203/https://www.fda.gov/media/136684/download) 04/03/2020	RT-PCR, CoPrimer technology	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda
+ 04/01/2020	Ipsum Diagnostics, LLC	COV-19 IDx assay (/web/20210319141203/https://www.fda.gov/media/136618/download) 04/01/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda Summary (/web/20210319141203/https://www.fda
+ 03/15/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (/web/20210319141203/https://www.fda.gov/media/135661/download) 02/29/2020	Real-time RT-PCR	H	HCP (/web/20210319141203/https://www.fda Patients (/web/20210319141203/https://www.fda (/web/20210319141203/https://www.fda

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations:

- RT-PCR = reverse transcriptase polymerase chain reaction;
- RT = reverse transcriptase;
- LAMP = loop-mediated isothermal amplification;
- MALDI-TOF = Matrix Assisted Laser Desorption/Ionization - Time of Flight;

- TMA = Transcription Mediated Amplification;
- qSTAR = Selective Temperature Amplification Reaction;
- CRISPR = clustered regularly interspaced short palindromic repeats;

Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. A manufacturer may request the addition of an eligible molecular-based LDT to Appendix A by submitting a request to CDRH-EUA-Templates@FDA.HHS.GOV (https://web.archive.org/web/20210319141203/mailto:CDRH-EUA-Templates@FDA.HHS.GOV) (https://web.archive.org/web/20210319141203mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/web/20210319141203/https://www.fda.gov/media/136598/download)
- Fact Sheet for Healthcare Providers (/web/20210319141203/https://www.fda.gov/media/136599/download)
- Fact Sheet for Patients (/web/20210319141203/https://www.fda.gov/media/136600/download)
- See Appendix A table below for a current list of included laboratories and their LTDs

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this Umbrella EUA (/web/20210319141203/https://www.fda.gov/media/136598/download) during the COVID-19 public health emergency.

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

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Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 02/03/2021	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138933/download) 06/12/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138934/download)
+ 01/29/2021	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/web/20210319141203/https://www.fda.gov/media/138529/download) 06/01/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138528/download)
+ 01/28/2021	AIT Laboratories	SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/137373/download) 04/24/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137374/download)
+ 12/28/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/137424/download) 04/27/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137423/download)
+ 12/28/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/137654/download) 05/03/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137656/download)
+ 12/28/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/web/20210319141203/https://www.fda.gov/media/137896/download) 05/07/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137897/download)
+ 09/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/web/20210319141203/https://www.fda.gov/media/137256/download) 04/22/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137255/download)
+ 09/21/2020	University of North Carolina Medical Center	UNC Health SARS-CoV-2 real-time RT-PCR test (/web/20210319141203/https://www.fda.gov/media/136879/download) 04/10/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136880/download)

Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 09/21/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test (/web/20210319141203/https://www.fda.gov/media/136943/download) 04/13/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136944/download)
+ 09/21/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136972/download) 04/14/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136971/download)
+ 09/21/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/137037/download) 04/15/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137036/download)
+ 09/21/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/137035/download) 04/15/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137034/download)
+ 09/14/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/web/20210319141203/https://www.fda.gov/media/137982/download) 05/12/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137983/download)
+ 07/29/2020	Mayo Clinic Laboratories, Rochester, MN	SARS-CoV-2 Molecular Detection Assay (/web/20210319141203/https://www.fda.gov/media/137162/download) 04/20/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137163/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138791/download) 06/10/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138790/download)
+ 06/04/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/web/20210319141203/https://www.fda.gov/media/137545/download) 04/30/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137546/download)
+ 06/04/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/web/20210319141203/https://www.fda.gov/media/136601/download) 03/31/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136602/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/web/20210319141203/https://www.fda.gov/media/138624/download) 06/04/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138625/download)
+ 06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV rRT Assay (/web/20210319141203/https://www.fda.gov/media/138527/download) 06/01/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138526/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/138331/download) 05/22/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138332/download)
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/web/20210319141203/https://www.fda.gov/media/138062/download) 05/13/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138063/download)
+ 05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/web/20210319141203/https://www.fda.gov/media/138064/download) 05/13/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/138065/download)
+ 04/28/2020	Biocerna	SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/137451/download) 04/28/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137450/download)

Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/web/20210319141203/https://www.fda.gov/media/137371/download) 04/24/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137372/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/web/20210319141203/https://www.fda.gov/media/137369/download) 04/23/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137370/download)
+ 04/14/2020	Exact Sciences Laboratories	SARS-CoV-2 Test (/web/20210319141203/https://www.fda.gov/media/137094/download) 04/14/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/137095/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136941/download) 04/13/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136942/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/web/20210319141203/https://www.fda.gov/media/136874/download) 04/10/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/web/20210319141203/https://www.fda.gov/media/136878/download) 04/10/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136877/download)
+ 04/03/2020	Massachusetts General Hospital	MGH COVID-19 qPCR assay (/web/20210319141203/https://www.fda.gov/media/136700/download) 04/03/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136699/download)
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/web/20210319141203/https://www.fda.gov/media/136658/download) 04/02/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/web/20210319141203/https://www.fda.gov/media/136657/download) 04/02/2020	EUA Summary (/web/20210319141203/https://www.fda.gov/media/136656/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 antigen diagnostic tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests).

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/01/2021	Quidel Corporation	QuickVue At-Home COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/146309/download) 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g IFU (Home Test) (/web/20210319141203/https://www.fda.g
+ 02/22/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 02/11/2021	Ellume Limited	Ellume COVID-19 Home Test (/web/20210319141203/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g IFU (Home Test) (/web/20210319141203/https://www.fda.g FAQ (/web/20210319141203/https://www.fda.g
+ 02/09/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20210319141203/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescence Immunoassay, Instrument Read	H, M	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 02/08/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20210319141203/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 02/04/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu (/web/20210319141203/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 01/26/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20210319141203/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 01/05/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20210319141203/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay	H, M	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 12/22/2020	Quidel Corporation	QuickVue SARS Antigen Test (/web/20210319141203/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 12/16/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20210319141203/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 12/16/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20210319141203/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g IFU (Home Test) (/web/20210319141203/https://www.fda.g
+ 12/07/2020	Luminostics, Inc.	Clip COVID Rapid Antigen Test (/web/20210319141203/https://www.fda.gov/media/144253/download) 12/07/2020	Lateral flow immunoluminescent assay, instrument read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 10/23/2020	Celltrion USA, Inc.	Sampinute COVID-19 Antigen MIA (/web/20210319141203/https://www.fda.gov/media/143267/download) 10/23/2020	Magnetic Force-assisted Electrochemical Sandwich Immunoassay (MESIA)	H, M	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 10/02/2020	Quidel Corporation	Sofia 2 Flu + SARS Antigen FIA (/web/20210319141203/https://www.fda.gov/media/142701/download) 10/02/2020	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g
+ 07/17/2020	Quidel Corporation	Sofia SARS Antigen FIA (/web/20210319141203/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP (/web/20210319141203/https://www.fda.g Patients (/web/20210319141203/https://www.fda.g IFU (/web/20210319141203/https://www.fda.g

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2

On August 6, 2020, based on the FDA's continued review of the scientific evidence available for Autobio Diagnostics Co. Ltd.'s Anti-SARS-CoV-2 Rapid Test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated blood (Heparin / EDTA / sodium citrate) or serum 2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20210319141203/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3306-a001.pdf), the FDA

determined that the statutory criteria for the authorization in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, the FDA determined that it is not reasonable to believe the product may be effective in detecting IgM antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. The FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20210319141203/https://www.fda.gov/media/140908/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

On June 16, 2020 (/web/20210319141203/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test), based on the FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.'s DPP COVID-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20210319141203/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3265-a001.pdf), the FDA determined that the statutory criteria for issuing an EUA in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, the FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. The FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20210319141203/https://www.fda.gov/media/139109/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

This table includes information about authorized SARS-CoV-2 serology/antibody tests and other adaptive immune response tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

For additional performance information about EUA authorized serology/antibody tests, please see the EUA Authorized Serology Test Performance (/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance) page.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/12/2021	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test (/web/20210319141203/https://www.fda.gov/media/140035/download) 07/10/2020	Total Antibody, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 03/11/2021	bioMérieux SA	VIDAS SARS-CoV-2 IgM (/web/20210319141203/https://www.fda.gov/media/140930/download) 08/06/2020	IgM, ELFA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 03/11/2021	bioMérieux SA	VIDAS SARS-CoV-2 IgG (/web/20210319141203/https://www.fda.gov/media/140934/download) 08/06/2020	IgG, ELFA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 03/09/2021	Adaptive Biotechnologies Corporation	T-Detect COVID Test (/web/20210319141203/https://www.fda.gov/media/146478/download) 03/05/2021	T-cell receptor beta (TCR β), Sequencing	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/01/2021	Abbott Laboratories Inc.	AdviseDx SARS-CoV-2 IgG II (/web/20210319141203/https://www.fda.gov/media/146368/download) 03/01/2021	IgG, CMIA, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU-ARCHITECT (/web/20210319141203/https: IFU-Alinityi (/web/20210319141203/https:
+ 02/12/2021	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack (/web/20210319141203/https://www.fda.gov/media/137360/download) 04/24/2020	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 02/10/2021	Immunodiagnostic Systems Ltd.	IDS SARS-CoV-2 IgG (/web/20210319141203/https://www.fda.gov/media/145941/download) 02/10/2021	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 02/05/2021	Nirmidas Biotech, Inc.	MidaSpot COVID-19 Antibody Combo Detection Kit (/web/20210319141203/https://www.fda.gov/media/144874/download) 12/31/2020	IgM and IgG, lateral flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/29/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (/web/20210319141203/https://www.fda.gov/media/136966/download) 04/14/2020	Total Antibody, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/19/2021	Phadia AB	EliA SARS-CoV-2-Sp1 IgG Test (/web/20210319141203/https://www.fda.gov/media/145082/download) 01/11/2021	IgG, Fluoroenzyme Immunoassay, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/15/2021	United Biomedical, Inc.	UBI SARS-CoV-2 ELISA (/web/20210319141203/https://www.fda.gov/media/145280/download) 01/15/2021	IgG, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/11/2021	ADVAITE, Inc.	RapCov Rapid COVID-19 Test (/web/20210319141203/https://www.fda.gov/media/145075/download) 01/11/2021	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/08/2021	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 IgG (CV2G) (/web/20210319141203/https://www.fda.gov/media/145012/download) 01/08/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 01/08/2021	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 IgG (COV2G) (/web/20210319141203/https://www.fda.gov/media/145017/download) 01/08/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 01/05/2021	Salofa Oy	Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette (/web/20210319141203/https://www.fda.gov/media/140079/download) 07/13/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 12/23/2020	Quanterix Corporation	Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test (/web/20210319141203/https://www.fda.gov/media/144761/download) 12/23/2020	IgG, Paramagnetic Microbead-based Sandwich ELISA, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 12/21/2020	Hangzhou Biotest Biotech Co., Ltd.	RightSign COVID-19 IgG/IgM Rapid Test Cassette (/web/20210319141203/https://www.fda.gov/media/138657/download) 06/04/2020	IgM and IgG Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 12/15/2020	ACON Laboratories, Inc.	ACON SARS-CoV-2 IgG/IgM Rapid Test (/web/20210319141203/https://www.fda.gov/media/144559/download) 12/15/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 12/02/2020	Hangzhou Laihe Biotech Co., Ltd.	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) (/web/20210319141203/https://www.fda.gov/media/139407/download) 06/19/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 12/01/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay (/web/20210319141203/https://www.fda.gov/media/137384/download) 04/26/2020	IgG, CMIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU-ARCHITECT (/web/20210319141203/https: IFU-Alinityi (/web/20210319141203/https:
+ 11/25/2020	Roche Diagnostics, Inc.	Elecsys Anti-SARS-CoV-2 S (/web/20210319141203/https://www.fda.gov/media/144034/download) 11/25/2020	Total Antibody, ECLIA, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 11/24/2020	Kantaro Biosciences, LLC	COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit (/web/20210319141203/https://www.fda.gov/media/144007/download) 11/24/2020	IgG, ELISA, Semi-quantitative	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 11/23/2020	Innovita (Tangshan) Biological Technology Co., Ltd.	Innovita 2019-nCoV Ab Test (Colloidal Gold) (/web/20210319141203/https://www.fda.gov/media/144068/download) 11/23/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 11/10/2020	Jiangsu Well Biotech Co., Ltd.	Orawell IgM/IgG Rapid Test (/web/20210319141203/https://www.fda.gov/media/142423/download) 09/23/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 11/06/2020	Xiamen Biotime Biotechnology Co., Ltd.	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test (/web/20210319141203/https://www.fda.gov/media/140440/download) 07/24/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 11/06/2020	GenScript USA Inc.	cPass SARS-CoV-2 Neutralization Antibody Detection Kit (/web/20210319141203/https://www.fda.gov/media/143584/download) 11/06/2020	Total Neutralizing Antibodies, Blocking ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/31/2020	Access Bio, Inc.	CareStart COVID-19 IgM/IgG (/web/20210319141203/https://www.fda.gov/media/140444/download) 07/24/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/30/2020	Bio-Rad Laboratories, Inc.	Platelia SARS-CoV-2 Total Ab assay (/web/20210319141203/https://www.fda.gov/media/137494/download) 04/29/2020	Total Antibody, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/30/2020	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (/web/20210319141203/https://www.fda.gov/media/138750/download) 06/08/2020	Total Antibody, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/30/2020	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (/web/20210319141203/https://www.fda.gov/media/138754/download) 06/08/2020	Total Antibody, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/28/2020	Quansys Biosciences, Inc.	Q-Plex SARS-CoV-2 Human IgG (4 Plex) (/web/20210319141203/https://www.fda.gov/media/143453/download) 10/28/2020	IgG, CLIA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/23/2020	Roche Diagnostics	Elecsys Anti-SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/media/137602/download) 05/02/2020	Total Antibody, ECLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 10/19/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG (/web/20210319141203/https://www.fda.gov/media/137356/download) 04/24/2020	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/17/2020	Biohit Healthcare (Hefei) Co. Ltd.	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (/web/20210319141203/https://www.fda.gov/media/139280/download) 06/18/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/09/2020	Abbott Laboratories Inc.	AdviseDx SARS-CoV-2 IgM (/web/20210319141203/https://www.fda.gov/media/142937/download)10/09/2020	IgM, CMIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU-ARCHITECT (/web/20210319141203/https: IFU-Alinityi (/web/20210319141203/https:
+ 10/08/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgM (/web/20210319141203/https://www.fda.gov/media/142908/download) 10/08/2020	IgM, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/08/2020	Genalyte, Inc.	Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2 (/web/20210319141203/https://www.fda.gov/media/142912/download) 10/08/2020	Total Antibody, photonic ring immunoassay	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/06/2020	Thermo Fisher Scientific	OmniPATH COVID-19 Total Antibody ELISA Test (/web/20210319141203/https://www.fda.gov/media/142697/download) 10/02/2020	Total Antibody, ELISA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 10/06/2020	ZEUS Scientific, Inc.	ZEUS ELISA SARS-CoV-2 IgG Test System (/web/20210319141203/https://www.fda.gov/media/142806/download) 10/06/2020	IgG, ELISA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/29/2020	DiaSorin, Inc.	DiaSorin LIAISON SARS-CoV-2 IgM Assay (/web/20210319141203/https://www.fda.gov/media/142549/download) 09/29/2020	IgM, Indirect CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/29/2020	NanoEntek America, Inc.	FREND COVID-19 total Ab (/web/20210319141203/https://www.fda.gov/media/142554/download) 09/29/2020	Total Antibody, FIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 09/29/2020	Nirmidas Biotech, Inc.	Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit (/web/20210319141203/https://www.fda.gov/media/142558/download) 09/29/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/25/2020	Quotient Suisse SA	MosaiQ COVID-19 Antibody Magazine (/web/20210319141203/https://www.fda.gov/media/142483/download) 09/25/2020	Total Antibody, photometric immunoassay	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/23/2020	Assure Tech. (Hangzhou Co., Ltd)	Assure COVID-19 IgG/IgM Rapid Test Device (/web/20210319141203/https://www.fda.gov/media/139789/download) 07/06/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/14/2020	Shenzhen New Industries Biomedical Engineering Co., Ltd.	MAGLUMI 2019-nCoV IgM/IgG (/web/20210319141203/https://www.fda.gov/media/142230/download) 09/14/2020	IgM and IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/09/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgM Antibody Test Kit (/web/20210319141203/https://www.fda.gov/media/141998/download) 09/09/2020	IgM, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/09/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG Antibody Test Kit (/web/20210319141203/https://www.fda.gov/media/142003/download) 09/09/2020	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 09/03/2020	Sugentech, Inc.	SGTi-flex COVID-19 IgG (/web/20210319141203/https://www.fda.gov/media/141888/download) 09/03/2020	IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 08/31/2020	TBG Biotechnology Corp.	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit (/web/20210319141203/https://www.fda.gov/media/141770/download) 08/31/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 08/31/2020	University of Arizona Genetics Core for Clinical Services	COVID-19 ELISA pan-Ig Antibody Test (/web/20210319141203/https://www.fda.gov/media/141774/download) 08/31/2020	Total Antibody, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:
+ 08/25/2020	Biocan Diagnostics Inc.	Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test - Letter of Authorization (/web/20210319141203/https://www.fda.gov/media/141547/download) 08/25/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 08/17/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG and IgM Combo Test (/web/20210319141203/https://www.fda.gov/media/141247/download) 08/17/2020	IgM and IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 08/17/2020	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit (/web/20210319141203/https://www.fda.gov/media/141252/download) 08/17/2020	IgM, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 08/05/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA (/web/20210319141203/https://www.fda.gov/media/140926/download) 08/05/2020	Total Antibody, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 IgG (COV2G) (/web/20210319141203/https://www.fda.gov/media/140700/download) 07/31/2020	IgG, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 IgG (COV2G) (/web/20210319141203/https://www.fda.gov/media/140703/download) 07/31/2020	IgG, Semi-quantitative	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 07/17/2020	Megna Health, Inc.	Rapid COVID-19 IgM/IgG Combo Test Kit (/web/20210319141203/https://www.fda.gov/media/140294/download) 07/17/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 07/16/2020	Luminex Corporation	xMAP SARS-CoV-2 Multi-Antigen IgG Assay (/web/20210319141203/https://www.fda.gov/media/140257/download) 07/16/2020	IgG, FMIA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 07/08/2020	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit (/web/20210319141203/https://www.fda.gov/media/139866/download) 07/08/2020	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 06/30/2020	InBios International, Inc.	SCoV-2 Detect IgM ELISA (/web/20210319141203/https://www.fda.gov/media/139726/download) 06/30/2020	IgM, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/26/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgG (/web/20210319141203/https://www.fda.gov/media/139624/download) 06/26/2020	IgG, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 06/23/2020	Babson Diagnostics, Inc.	Babson Diagnostics aC19G1 (/web/20210319141203/https://www.fda.gov/media/139450/download) 06/23/2020	IgG, CLIA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:
+ 06/15/2020	Emory Medical Laboratories	SARS-CoV-2 RBD IgG test (/web/20210319141203/https://www.fda.gov/media/139050/download) 06/15/2020	IgG, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:
+ 06/12/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test (/web/20210319141203/https://www.fda.gov/media/136622/download) 04/01/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210319141203/https: Patients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 06/10/2020	InBios International, Inc.	SCoV-2 Detect IgG ELISA (/web/20210319141203/https://www.fda.gov/media/138807/download) 06/10/2020	IgG, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 06/04/2020	Vibrant America Clinical Labs	Vibrant COVID-19 Ab Assay (/web/20210319141203/https://www.fda.gov/media/138626/download) 06/04/2020	IgM and IgG, CLIA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:
+ 05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (/web/20210319141203/https://www.fda.gov/media/138435/download) 05/29/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T) (/web/20210319141203/https://www.fda.gov/media/138439/download) 05/29/2020	Total Antibody, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T) (/web/20210319141203/https://www.fda.gov/media/138443/download) 05/29/2020	Total Antibody, CLIA	H, M	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:
+ 05/04/2020	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG) (/web/20210319141203/https://www.fda.gov/media/137606/download) 05/04/2020	IgG, ELISA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: IFU (/web/20210319141203/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection (/web/20210319141203/https://www.fda.gov/media/137540/download) 04/30/2020	Total Antibody, FMIA	H	HCP (/web/20210319141203/https: Recipients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:
+ 04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test (/web/20210319141203/https://www.fda.gov/media/137032/download) 04/15/2020	IgG, ELISA	H	HCP (/web/20210319141203/https: Patients (/web/20210319141203/https: EUA Summary (/web/20210319141203/https:

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay, CMIA = chemiluminescent microparticle immunoassay; ELFA = enzyme-linked fluorescence assay

Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2

On April 28, 2020, FDA issued an umbrella EUA for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by the FDA, and are confirmed by the FDA to meet the criteria set forth in the Scope of Authorization of the EUA. To date, however, no device has been added to the list of authorized devices in Appendix A of the letter of authorization.

On July 21, 2020, FDA determined, based on information and experience since issuing this EUA, that circumstances support revocation of this umbrella EUA so that FDA may issue individual EUAs. Individual EUAs will allow for broader indications and scopes of authorization, individualized conditions of authorization to address any issue unique to a specific test, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA.

Accordingly, the EUA was revoked (/web/20210319141203/https://www.fda.gov/media/140351/download) under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Individual EUAs For IVDs for Management of COVID-19 Patients

This table includes information about authorized in vitro diagnostic tests that may be used in the management of patients with COVID-19 that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Search:

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 12/18/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur IL6 assay (/web/20210319141203/https://www.fda.gov/media/144669/download) 12/18/2020	One-step Direct Chemiluminescent Immunoassay	H, M	HCP (/web/20210319141203/https://www.fda.gov/ Patients (/web/20210319141203/https://www.fda.gov/ IFU (/web/20210319141203/https://www.fda.gov/
+ 10/01/2020	Beckman Coulter, Inc.	Access IL-6 (/web/20210319141203/https://www.fda.gov/media/142597/download) 10/01/2020	One-step immunoenzymatic ("sandwich") assay, IL-6	H, M	HCP (/web/20210319141203/https://www.fda.gov/ Patients (/web/20210319141203/https://www.fda.gov/ IFU (/web/20210319141203/https://www.fda.gov/
+ 06/02/2020	Roche Diagnostics	Elecsys IL-6 (/web/20210319141203/https://www.fda.gov/media/138596/download) 06/02/2020	Immunoassay-IL-6	H, M	HCP (/web/20210319141203/https://www.fda.gov/ Patients (/web/20210319141203/https://www.fda.gov/ IFU (/web/20210319141203/https://www.fda.gov/

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20210319141203/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20210319141203/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- EUA Authorized Serology Test Performance (/web/20210319141203/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20210325011522/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic Template for Commercial Manufacturers (/web/20210325011522/https://www.fda.gov/media/135900/download) (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20210325011522/https://www.fda.gov/media/135658/download) (updated July 28, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20210325011522/https://www.fda.gov/media/138412/download) (May 29, 2020)
- Antigen Template for Test Developers (/web/20210325011522/https://www.fda.gov/media/137907/download) (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20210325011522/https://www.fda.gov/media/140615/download) (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20210325011522/https://www.fda.gov/media/146695/download) (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (/web/20210325011522/https://www.fda.gov/media/137698/download)(March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20210325011522/https://www.fda.gov/media/146746/download) (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (/web/20210325011522/https://www.fda.gov/media/143941/download) (March 24, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210325011522/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210325011522/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210325011522mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210325011522/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210325011522mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20210325011522/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210325011522/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210325011522/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210325011522mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

- Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
- Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests
- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2
- Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2
- Individual EUAs for IVDs for Management of COVID-19 Patients

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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests).

Molecular SARS-CoV-2 Diagnostic Tests for COVID-19 that have been granted a De Novo, 510(k) clearance or PMA

- BioFire Respiratory Panel 2.1 (RP2.1) - On March 17, 2021, FDA granted the first marketing authorization using the De Novo review pathway for the BioFire Respiratory Panel 2.1 (RP2.1) (https://web.archive.org/web/20210325011522/https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf) (PDF - 630 KB). The BioFire RP2.1 is for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. Also see the FDA news release: FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process (/web/20210325011522/https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process). With granting of the De Novo for the BioFire RP2.1, the FDA revoked the EUA for this device (/web/20210325011522/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations), which was initially authorized for emergency use in May 2020.

  The BioFire Respiratory Panel 2.1 (RP2.1) was reviewed under the De Novo premarket review pathway (/web/20210325011522/https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing criteria, called special controls, that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Search:

Show entries

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/23/2021	Twist Bioscience Corporation	SARS-CoV-2 NGS Assay (/web/20210325011522/https://www.fda.gov/media/146932/download) 03/23/2021	Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/22/2021	Tempus Labs, Inc.	iC SARS-CoV2 Test (/web/20210325011522/https://www.fda.gov/media/142593/download) 10/01/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (HomeCollect) (/web/20210325011522/https://www.fda
+ 03/22/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR Complete (/web/20210325011522/https://www.fda.gov/media/143059/download) 10/14/2020	RT, qSTAR amplification	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/19/2021	Color Health, Inc.	Color SARS-CoV-2 RT-LAMP Diagnostic Assay (/web/20210325011522/https://www.fda.gov/media/138248/download) 05/18/2020	RT, LAMP, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 03/19/2021	Color Health, Inc.	Color COVID-19 Self-Swab Collection Kit (/web/20210325011522/https://www.fda.gov/media/141796/download) 08/31/2020	Home Collection Kit, Screening	N/A	EUA Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/19/2021	Color Health, Inc.	Color COVID-19 Self-Swab Collection Kit DTC (/web/20210325011522/https://www.fda.gov/media/146873/download) 03/19/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/19/2021	Color Health, Inc.	Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC (/web/20210325011522/https://www.fda.gov/media/146877/download) 03/19/2021	Direct to Consumer (DTC), RT, LAMP, Home Collection, Screening	H	EUA Summary (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda HCP (/web/20210325011522/https://ww
+ 03/18/2021	LetsGetChecked, Inc.	LetsGetChecked Coronavirus (COVID-19) Test (/web/20210325011522/https://www.fda.gov/media/138405/download) 05/28/2020	Direct to Consumer (DTC), TMA, chemiluminescent, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 03/12/2021	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect (/web/20210325011522/https://www.fda.gov/media/141194/download) 08/15/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/11/2021	Infinity BiologiX LLC	Infinity BiologiX TaqPath SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/137773/download) 04/10/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 03/10/2021	Becton, Dickinson & Company	BD SARS-CoV-2 Reagents for BD MAX System (/web/20210325011522/https://www.fda.gov/media/136813/download) 04/08/2020	Real-time RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/09/2021	Quidel Corporation	Solana SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/144756/download) 12/23/2020	Isothermal Reverse Transcriptase – Helicase-Dependent Amplification (RT-HDA)	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/09/2021	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits (/web/20210325011522/https://www.fda.gov/media/145977/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 03/09/2021	GetMyDNA	GetMyDNA COVID-19 Test Home Collection Kit (/web/20210325011522/https://www.fda.gov/media/146541/download) 03/09/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/05/2021	Cue Health Inc.	Cue COVID-19 Test for Home and Over The Counter (OTC) Use (/web/20210325011522/https://www.fda.gov/media/146467/download) 03/05/2021	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Home Test) (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/05/2021	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3) (/web/20210325011522/https://www.fda.gov/media/146496/download) 03/05/2021	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 03/04/2021	Abbott Molecular Inc.	Alinity m Resp-4-Plex (/web/20210325011522/https://www.fda.gov/media/146488/download) 03/04/2021	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/03/2021	Ambry Genetics Laboratory	Ambry COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/145406/download) 01/22/2021	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 03/03/2021	Luminex Molecular Diagnostics, Inc.	NxTAG Respiratory Pathogen Panel + SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/146492/download) 03/03/2021	RT-PCR, Multi-analyte	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/02/2021	binx health, Inc.	binx health At-Home Nasal Swab COVID-19 Sample Collection Kit (/web/20210325011522/https://www.fda.gov/media/143183/download) 10/20/2020	Home Collection Kit	N/A	EUA Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 03/01/2021	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qPCR Test (/web/20210325011522/https://www.fda.gov/media/138652/download) 06/04/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda (Clinic) (/web/20210325011522/https://www.fda
+ 02/26/2021	Fluidigm Corporation	Advanta Dx SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/141538/download) 08/25/2020	Real-time RT-PCR, Saliva, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/26/2021	Clinical Enterprise, Inc.	EmpowerDX COVID-19 Home Collection Kit DTC (/web/20210325011522/https://www.fda.gov/media/143063/download) 10/15/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	EUA Summary (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/26/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay (/web/20210325011522/https://www.fda.gov/media/143070/download) 04/06/2020	Real-Time RT-PCR, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 02/26/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay DTC (/web/20210325011522/https://www.fda.gov/media/146322/download) 02/26/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 02/24/2021	Hologic, Inc.	Aptima SARS-CoV-2/Flu assay (/web/20210325011522/https://www.fda.gov/media/144587/download) 12/16/2020	Real-time TMA, chemiluminescent, Multi-analyte	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/24/2021	University of Illinois Office of the Vice President for Economic Development and Innovation	covidSHIELD (/web/20210325011522/https://www.fda.gov/media/146314/download) 02/24/2021	Real-time RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 02/23/2021	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit (/web/20210325011522/https://www.fda.gov/media/136113/download) 03/13/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/23/2021	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit (/web/20210325011522/https://www.fda.gov/media/138300/download) 05/21/2020	RT-LAMP	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/22/2021	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT PCR CE Test (/web/20210325011522/https://www.fda.gov/media/141666/download) 08/28/2020	RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/13/2021	The Kroger Co.	Kroger Health COVID-19 Test Home Collection Kit (/web/20210325011522/https://www.fda.gov/media/139681/download) 06/30/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	Individuals (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 02/13/2021	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel DTC (/web/20210325011522/https://www.fda.gov/media/145981/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/13/2021	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit DTC (/web/20210325011522/https://www.fda.gov/media/145986/download) 02/13/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/12/2021	RCA Laboratory Services LLC dba GENETWORx	GENETWORx Covid-19 Nasal Swab Test (/web/20210325011522/https://www.fda.gov/media/144550/download) 12/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/11/2021	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit (/web/20210325011522/https://www.fda.gov/media/145920/download) 02/11/2021	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 02/10/2021	Becton, Dickinson and Company (BD)	BD SARS-CoV-2/Flu for BD MAX System (/web/20210325011522/https://www.fda.gov/media/145924/download) 02/10/2021	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/10/2021	Thermo Fisher Scientific	TaqPath COVID-19, FluA, FluB Combo Kit (/web/20210325011522/https://www.fda.gov/media/145928/download) 02/10/2021	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/10/2021	Grifols Diagnostic Solutions Inc.	Procleix SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/145934/download) 02/10/2021	TMA	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/09/2021	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit (/web/20210325011522/https://www.fda.gov/media/137420/download) 04/27/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/08/2021	QDx Pathology Services	QDX SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/141542/download) 08/25/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 02/08/2021	Visby Medical, Inc.	Visby Medical COVID-19 Point of Care Test (/web/20210325011522/https://www.fda.gov/media/145914/download) 02/08/2021	RT-PCR	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Collect) (/web/20210325011522/https://www.fda
+ 02/05/2021	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit (/web/20210325011522/https://www.fda.gov/media/136407/download) 03/24/2020	Real-time RT-PCR, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/05/2021	Access Bio, Inc.	CareStart COVID-19 MDx RT-PCR (/web/20210325011522/https://www.fda.gov/media/139833/download) 07/07/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/04/2021	Quidel Corporation	Lyra SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136224/download) 03/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/04/2021	Clinomics USA Inc.	Clinomics TrioDx RT-PCR COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/145686/download) 02/04/2021	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 02/03/2021	Mesa Biotech Inc.	Accula SARS-Cov-2 Test (/web/20210325011522/https://www.fda.gov/media/136345/download) 03/23/2020	RT and amplification	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/03/2021	DiaCarta, Inc	QuantiVirus SARS-CoV-2 Test kit (/web/20210325011522/https://www.fda.gov/media/136806/download) 04/08/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/03/2021	PlexBio Co., Ltd.	IntelliPlex SARS-CoV-2 Detection Kit (/web/20210325011522/https://www.fda.gov/media/139528/download) 06/25/2020	RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 02/01/2021	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/136473/download) 03/26/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/29/2021	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test (/web/20210325011522/https://www.fda.gov/media/137737/download) 05/06/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/29/2021	Diagnostic Solutions Laboratory, LLC	DSL COVID-19 Assay (/web/20210325011522/https://www.fda.gov/media/139513/download) 06/25/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 01/29/2021	Sandia National Laboratories	SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay (/web/20210325011522/https://www.fda.gov/media/140544/download) 07/27/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 01/28/2021	Alpha Genomix Laboratories	Alpha Genomix TaqPath SARS-CoV-2 Combo Assay (/web/20210325011522/https://www.fda.gov/media/141017/download) 08/10/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 01/28/2021	BayCare Laboratories, LLC	BayCare SARS-CoV-2 RT PCR Assay (/web/20210325011522/https://www.fda.gov/media/141766/download) 08/31/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 01/27/2021	Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV (/web/20210325011522/https://www.fda.gov/media/142434/download) 09/24/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda for Labs (/web/20210325011522/https://www.fda for Point-of-Care (/web/20210325011522/https://www.fda

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+ 01/27/2021	Agena Bioscience, Inc.	MassARRAY SARS-CoV-2 Panel (/web/20210325011522/https://www.fda.gov/media/143331/download) 10/26/2020	RT-PCR, chip array and MALDI-TOF Mass Spec.	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/26/2021	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/137687/download) 05/05/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/26/2021	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (/web/20210325011522/https://www.fda.gov/media/138101/download) 05/14/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/26/2021	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138179/download) 05/18/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/22/2021	Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136153/download) 03/16/2020	Real-time RT-PCR, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/22/2021	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136566/download) 03/30/2020	RT-PCR, Collection Kit, Saliva	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Collect) (/web/20210325011522/https://www.fda
+ 01/22/2021	Hologic, Inc.	Aptima SARS-CoV-2 assay (/web/20210325011522/https://www.fda.gov/media/138097/download) 05/14/2020	TMA, chemiluminescent, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/22/2021	Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory	Express Gene 2019-nCoV RT-PCR Diagnostic Panel (/web/20210325011522/https://www.fda.gov/media/143881/download) 05/22/2020	Real-time RT-PCR, Collection Kit, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/19/2021	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	Cleveland Clinic SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140785/download) 08/03/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 01/19/2021	Hospital of the University of Pennsylvania	BD MAX COVID-19 ASSAY (Authorized by HHS/OASH) (/web/20210325011522/https://www.fda.gov/media/145675/download) 01/19/2021	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda

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+ 01/19/2021	INNO Diagnostics Reference Laboratory, Ponce Medical School	PMSF-INNO SARS-CoV-2 RT-PCR Test (Authorized by HHS/OASH) (/web/20210325011522/https://www.fda.gov/media/145679/download) 01/19/2021	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 01/15/2021	Bio-Rad Laboratories, Inc.	Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit (/web/20210325011522/https://www.fda.gov/media/145267/download) 01/15/2021	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/14/2021	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit (/web/20210325011522/https://www.fda.gov/media/137747/download) 05/06/2020	RT-LAMP, CRISPR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/13/2021	SML GENETREE Co., Ltd.	Ezplex SARS-CoV-2 G Kit (/web/20210325011522/https://www.fda.gov/media/145131/download) 01/14/2021	Real-time RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/08/2021	Centers for Disease Control and Prevention (CDC)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (/web/20210325011522/https://www.fda.gov/media/139744/download) 07/02/2020	Real-time RT-PCR, Multi-analyte	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/07/2021	Cepheid	Xpert Xpress SARS-CoV-2 test (/web/20210325011522/https://www.fda.gov/media/136316/download) 03/20/2020	Real-time RT-PCR	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda for Labs (/web/20210325011522/https://www.fda IFU for Point-of-Care (/web/20210325011522/https://www.fda
+ 01/06/2021	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit (/web/20210325011522/https://www.fda.gov/media/138819/download) 06/10/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 01/05/2021	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (/web/20210325011522/https://www.fda.gov/media/136306/download) 03/20/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/30/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit (/web/20210325011522/https://www.fda.gov/media/137781/download) 05/07/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/30/2020	Jiangsu Bioperfectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit (/web/20210325011522/https://www.fda.gov/media/139284/download) 06/18/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/30/2020	Enzo Life Sciences, Inc.	AMPIPROBE SARS-CoV-2 Test System (/web/20210325011522/https://www.fda.gov/media/139829/download) 07/07/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 12/30/2020	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/141049/download) 08/11/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patient (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit (/web/20210325011522/https://www.fda.gov/media/136787/download) 04/07/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit (/web/20210325011522/https://www.fda.gov/media/136872/download) 04/10/2020	RT, Isothermal amplification	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit (/web/20210325011522/https://www.fda.gov/media/137023/download) 04/15/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit (/web/20210325011522/https://www.fda.gov/media/137117/download) 04/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	SolGent Co., Ltd	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit (/web/20210325011522/https://www.fda.gov/media/138306/download) 05/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Omnipathology Solutions Medical Corporation	Omni COVID-19 Assay by RT-PCR (/web/20210325011522/https://www.fda.gov/media/139289/download) 06/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	Gencurix, Inc.	GenePro SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/139443/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Laboratorio Clinico Toledo	Laboratorio Clinico Toledo SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/139785/download) 07/06/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	Gene By Gene	Gene By Gene SARS-CoV-2 Detection Test (/web/20210325011522/https://www.fda.gov/media/139838/download) 07/07/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	BioSewoom, Inc.	Real-Q 2019-nCoV Detection Kit (/web/20210325011522/https://www.fda.gov/media/139938/download) 07/09/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 12/28/2020	DiaCarta, Inc.	QuantiVirus SARS-CoV-2 Multiplex Test Kit (/web/20210325011522/https://www.fda.gov/media/140355/download) 07/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Solaris Diagnostics	Solaris Multiplex SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/141013/download) 08/10/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR (/web/20210325011522/https://www.fda.gov/media/141054/download) 08/11/2020	RT, non-isothermal nucleic acid amplification qSTAR	H	HCP (/web/20210325011522/https://www.fda Patient (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Guardant Health, Inc.	Guardant-19 (/web/20210325011522/https://www.fda.gov/media/141484/download) 08/21/2020	Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	Texas Department of State Health Services, Laboratory Services Section	Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/141493/download) 08/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/28/2020	T2 Biosystems, Inc.	T2SARS-CoV-2 Panel (/web/20210325011522/https://www.fda.gov/media/141752/download) 08/31/2020	RT, amplification, T2 Magnetic resonance	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	OPTOLANE Technologies, Inc.	Kaira 2019-nCoV Detection Kit (/web/20210325011522/https://www.fda.gov/media/141792/download) 09/01/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Visby Medical, Inc.	Visby Medical COVID-19 (/web/20210325011522/https://www.fda.gov/media/142225/download) 09/16/2020	RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	Clear Labs, Inc.	Clear Dx SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/142419/download) 09/23/2020	RT-PCR and Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/28/2020	UMass Memorial Medical Center	UMass Molecular Virology Laboratory 2019-nCoV rRT-PCR Dx Panel (/web/20210325011522/https://www.fda.gov/media/142689/download) 10/01/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda

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+ 12/28/2020	Gravity Diagnostics, LLC	Gravity Diagnostics SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/143932/download) 11/23/2020	Real-time RT-PCR, Home Collection, Screening, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/23/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay (/web/20210325011522/https://www.fda.gov/media/137980/download) 05/11/2020	Real-time RT-PCR, Pooling, Screening	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/23/2020	Cepheid	Xpert Omni SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/144029/download) 11/27/2020	Real-time RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/23/2020	Cepheid	Xpert Xpress SARS-CoV-2 DoD (/web/20210325011522/https://www.fda.gov/media/144790/download) 12/23/2020	Real-time RT-PCR, Pooling	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/22/2020	Verily Life Sciences	Verily COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/141948/download) 09/08/2020	Real-time RT-PCR, Pooling, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 12/22/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) (/web/20210325011522/https://www.fda.gov/media/142693/download) 10/02/2020	RT, Nested multiplex PCR, Multi-analyte	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/18/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit (/web/20210325011522/https://www.fda.gov/media/138292/download) 05/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/18/2020	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (/web/20210325011522/https://www.fda.gov/media/139860/download) 07/08/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 12/17/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	TRUPCR SARS-CoV-2 Kit (/web/20210325011522/https://www.fda.gov/media/139293/download) 06/18/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/17/2020	Materials and Machines Corporation of America (DBA MatmaCorp, Inc.)	MatMaCorp COVID-19 2SF Test (/web/20210325011522/https://www.fda.gov/media/144656/download) 12/17/2020	RT-PCR and isothermal nucleic acid amplification	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 12/15/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B (/web/20210325011522/https://www.fda.gov/media/141884/download) 09/03/2020	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/11/2020	ResearchDx, Inc., DBA Pacific Diagnostics	PacificDx Covid-19 (/web/20210325011522/https://www.fda.gov/media/144555/download) 12/11/2020	TMA, chemiluminescent, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/10/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System (/web/20210325011522/https://www.fda.gov/media/142190/download) 09/14/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/09/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/136148/download) 03/16/2020	Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda LabCorp Home Collect (/web/20210325011522/https://www.fda
+ 12/09/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test (/web/20210325011522/https://www.fda.gov/media/137576/download) 05/01/2020	RT-droplet PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/09/2020	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/141488/download) 08/21/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 12/09/2020	Bioeksen R&D Technologies Ltd.	Bio-Speedy Direct RT-qPCR SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/141824/download) 09/02/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/09/2020	Laboratory Corporation of America (LabCorp)	Pixel by LabCorp COVID-19 Test Home Collection Kit (/web/20210325011522/https://www.fda.gov/media/144333/download) 12/09/2020	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP (/web/20210325011522/https://www.fda Individuals (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 12/07/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/139046/download) 06/15/2020	RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/04/2020	BioFire Defense, LLC	BioFire COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/136356/download) 03/23/2020	RT, Nested multiplex PCR, Pooling	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 12/04/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC COVID-19+Flu RT-PCR (/web/20210325011522/https://www.fda.gov/media/144180/download) 12/04/2020	Real-time RT-PCR, Multi-analyte, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda EUA Summary (/web/20210325011522/https://www.fda (Home Collection) (/web/20210325011522/https://www.fda
+ 12/03/2020	Rheonix, Inc.	Rheonix COVID-19 MDx Assay (/web/20210325011522/https://www.fda.gov/media/137490/download) 04/29/2020	RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 12/01/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) (/web/20210325011522/https://www.fda.gov/media/134919/download) 02/04/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/27/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics RC SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140231/download) 07/15/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 11/24/2020	Stanford Health Care Clinical Virology Laboratory	SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/136817/download) 04/08/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collection) (/web/20210325011522/https://www.fda
+ 11/23/2020	RapidRona, Inc.	RapidRona Self-Collection Kit (/web/20210325011522/https://www.fda.gov/media/143927/download) 11/23/2020	Home Collection Kit	N/A	EUA Summary (/web/20210325011522/https://www.fda (Collection) (/web/20210325011522/https://www.fda
+ 11/21/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit (/web/20210325011522/https://www.fda.gov/media/138060/download) 05/13/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/20/2020	Trax Management Services Inc.	PhoenixDx SARS-CoV-2 Multiplex (/web/20210325011522/https://www.fda.gov/media/140070/download) 07/13/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/18/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/136046/download) 03/12/2020	Real-time RT-PCR, Pooling	H, M, H-Pooling	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/18/2020	Lucira Health, Inc.	Lucira COVID-19 All-In-One Test Kit (/web/20210325011522/https://www.fda.gov/media/143810/download) 11/17/2020	Prescription Home Testing	Home, H, M, W	HCP (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Home Test) (/web/20210325011522/https://www.fda

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+ 11/13/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR (/web/20210325011522/https://www.fda.gov/media/136228/download) 03/17/2020	Real-time RT-PCR, Home Collection, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 11/10/2020	Xiamen Zeesan Biotech Co., Ltd.	SARS-CoV-2 Test Kit (Real-time PCR) (/web/20210325011522/https://www.fda.gov/media/140718/download) 07/31/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/06/2020	BioMérieux SA	SARS-COV-2 R-GENE (/web/20210325011522/https://www.fda.gov/media/137743/download) 05/06/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/04/2020	Euroimmun US, Inc.	EURORealTime SARS-Cov-2 (/web/20210325011522/https://www.fda.gov/media/138758/download) 06/08/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 11/02/2020	Seegene, Inc.	Allplex 2019-nCoV Assay (/web/20210325011522/https://www.fda.gov/media/137179/download) 04/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/31/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 RT-PCR Kit (/web/20210325011522/https://www.fda.gov/media/141994/download) 09/09/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/28/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay (/web/20210325011522/https://www.fda.gov/media/136497/download) 03/27/2020	RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/28/2020	Luminex Corporation	ARIES SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136694/download) 04/03/2020	RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/28/2020	Illumina, Inc.	Illumina COVIDSeq Test (/web/20210325011522/https://www.fda.gov/media/138778/download) 06/09/2020	Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/28/2020	DNA Genotek Inc.	ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 saliva collection devices (/web/20210325011522/https://www.fda.gov/media/143415/download) 10/28/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/28/2020	DNA Genotek Inc.	OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) saliva collection devices (/web/20210325011522/https://www.fda.gov/media/143418/download) 10/14/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 10/22/2020	Helix OpCo LLC	Helix COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/140422/download) 07/23/2020	Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 10/20/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138295/download) 05/21/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda IFU1 (Home Collect) (/web/20210325011522/https://www.fda IFU2 (Home Collect) (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 10/20/2020	Wren Laboratories LLC	Wren Laboratories COVID-19 PCR Test (/web/20210325011522/https://www.fda.gov/media/140773/download) 08/03/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 10/17/2020	Genetrack Biolabs, Inc.	Genetrack SARS-CoV-2 Molecular Assay (/web/20210325011522/https://www.fda.gov/media/142479/download) 09/25/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary, (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 10/16/2020	Spectrum Solutions LLC	SDNA-1000 Saliva Collection Device (/web/20210325011522/https://www.fda.gov/media/142906/download) 10/08/2020	Saliva Collection Device	N/A	EUA Summary (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/08/2020	University of California, Los Angeles (UCLA)	UCLA SwabSeq COVID-19 Diagnostic Platform (/web/20210325011522/https://www.fda.gov/media/142802/download) 10/06/2020	RT-PCR and Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 10/07/2020	GenMark Diagnostics, Inc.	ePlex Respiratory Pathogen Panel 2 (/web/20210325011522/https://www.fda.gov/media/142902/download) 10/07/2020	RT-PCR and electrochemical detection, Multi-analyte	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/06/2020	Detectachem Inc.	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit (/web/20210325011522/https://www.fda.gov/media/141788/download) 09/01/2020	RT-LAMP	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 10/05/2020	SEASUN BIOMATERIALS, Inc.	AQ-TOP COVID-19 Rapid Detection Kit PLUS (/web/20210325011522/https://www.fda.gov/media/142797/download) 10/05/2020	RT-LAMP	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 10/02/2020	Cuur Diagnostics	Cuur Diagnostics SARS-CoV-2 Molecular Assay (/web/20210325011522/https://www.fda.gov/media/141624/download) 08/26/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/30/2020	Aeon Global Health	Aeon Global Health SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/142532/download) 09/30/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/30/2020	Alimetrix, Inc.	Alimetrix SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/142589/download) 09/30/2020	RT-PCR, Microarray Hybridization	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/29/2020	CENTOGENE US, LLC	CentoSure SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/142536/download) 09/29/2020	Real-time RT-PCR, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/29/2020	Akron Children's Hospital	Akron Children's Hospital SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/142540/download) 09/29/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/29/2020	National Jewish Health	SARS-CoV-2 MassArray Test (/web/20210325011522/https://www.fda.gov/media/142545/download) 09/29/2020	RT-PCR and MALDI-TOF Mass Spec.	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test (/web/20210325011522/https://www.fda.gov/media/136450/download) 03/25/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/25/2020	Access Genetics, LLC	OraRisk COVID-19 RT-PCR (/web/20210325011522/https://www.fda.gov/media/140290/download) 07/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/24/2020	Acupath Laboratories, Inc.	Acupath COVID-19 Real-Time (RT-PCR) Assay (/web/20210325011522/https://www.fda.gov/media/139669/download) 06/29/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/22/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System (/web/20210325011522/https://www.fda.gov/media/136650/download) 04/02/2020	Real-time RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https:// (/web/20210325011522/https://www.fda

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+ 09/22/2020	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (/web/20210325011522/https://www.fda.gov/media/136688/download) 04/03/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/22/2020	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit (/web/20210325011522/https://www.fda.gov/media/137484/download) 04/29/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/22/2020	Quadrant Biosciences Inc.	Clarifi COVID-19 Test Kit (/web/20210325011522/https://www.fda.gov/media/142376/download) 09/22/2020	Real-time RT-PCR, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/22/2020	Vela Operations Singapore Pte. Ltd.	ViroKey SARS-CoV-2 RT-PCR Test v2.0 (/web/20210325011522/https://www.fda.gov/media/142380/download) 09/22/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/21/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel (/web/20210325011522/https://www.fda.gov/media/136569/download) 03/30/2020	Real-time RT-PCR, Multi-analyte	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/21/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/web/20210325011522/https://www.fda.gov/media/138151/download) 05/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 09/21/2020	Gravity Diagnostics, LLC	Gravity Diagnostics COVID-19 Assay (/web/20210325011522/https://www.fda.gov/media/138532/download) 06/01/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/21/2020	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138787/download) 06/09/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/21/2020	HealthQuest Esoterics	HealthQuest Esoterics TaqPath SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/139449/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/21/2020	Psomagen, Inc.	Psoma COVID-19 RT Test (/web/20210325011522/https://www.fda.gov/media/139673/download) 06/30/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda

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+ 09/21/2020	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit (/web/20210325011522/https://www.fda.gov/media/140066/download) 07/13/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/21/2020	Boston Heart Diagnostics	Boston Heart COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/140261/download) 07/16/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/21/2020	Eli Lilly and Company	Lilly SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140540/download) 07/27/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/21/2020	Ethos Laboratories	Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay (/web/20210325011522/https://www.fda.gov/media/140777/download) 08/03/2020	RT-PCR and MALDI-TOF Mass Spec., Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 09/21/2020	Exact Sciences Laboratories	SARS-CoV-2 (N gene detection) Test (/web/20210325011522/https://www.fda.gov/media/138327/download) 05/22/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect (/web/20210325011522/https://www.fda
+ 09/21/2020	Patients Choice Laboratories, LLC	PCL SARS-CoV-2 Real-Time RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/141662/download) 08/28/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 09/21/2020	KimForest Enterprise Co., Ltd.	KimForest SARS-CoV-2 Detection Kit v1 (/web/20210325011522/https://www.fda.gov/media/142360/download) 09/21/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/18/2020	GK Pharmaceuticals Contract Manufacturing Operations	GK ACCU-RIGHT SARS-CoV-2 RT-PCR KIT (/web/20210325011522/https://www.fda.gov/media/142307/download) 09/18/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 09/17/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 (/web/20210325011522/https://www.fda.gov/media/136522/download) 03/27/2020	RT, Isothermal amplification	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 09/09/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/139066/download) 06/13/2020	Real-time RT-PCR, Home Collection, Screening	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 09/04/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (/web/20210325011522/https://www.fda.gov/media/138144/download) 05/15/2020	Home Collection Kit	N/A	IFU (/web/20210325011522/https://www EUA Summary (/web/20210325011522/https://www.fda
+ 09/04/2020	BillionToOne, Inc.	qSanger-COVID-19 Assay (/web/20210325011522/https://www.fda.gov/media/141932/download) 09/04/2020	Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/31/2020	MiraDx	MiraDx SARS-CoV-2 RT-PCR assay (/web/20210325011522/https://www.fda.gov/media/141756/download) 08/31/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 08/31/2020	Mammoth Biosciences, Inc.	SARS-CoV-2 DETECTR Reagent Kit (/web/20210325011522/https://www.fda.gov/media/141762/download) 08/31/2020	RT-LAMP, CRISPR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/21/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics PF SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140226/download) 07/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 08/21/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics HA SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140236/download) 07/15/2020	TMA, chemiluminescent, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 08/20/2020	Cue Health Inc.	Cue COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/138823/download) 06/10/2020	RT, Isothermal amplification	H, M, W	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/18/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/136283/download) 03/19/2020	RT-PCR and electrochemical detection	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/17/2020	ZhuHai Sinochips Bioscience Co., Ltd.	COVID-19 Nucleic Acid RT-PCR Test Kit (/web/20210325011522/https://www.fda.gov/media/141243/download) 08/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 08/13/2020	Pro-Lab Diagnostics	Pro-AmpRT SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/141146/download) 08/13/2020	RT, Isothermal amplification	H	HCP (/web/20210325011522/https://www.fda Patient (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 08/11/2020	dba SpectronRX	Hymon SARS-CoV-2 Test Kit (/web/20210325011522/https://www.fda.gov/media/138343/download) 05/22/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/08/2020	Trax Management Services Inc.	PhoenixDx 2019-CoV (/web/20210325011522/https://www.fda.gov/media/137150/download) 04/20/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/07/2020	George Washington University Public Health Laboratory	GWU SARS-CoV-2 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/140977/download) 08/07/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 08/06/2020	Helix OpCo LLC (dba Helix)	Helix COVID-19 NGS Test (/web/20210325011522/https://www.fda.gov/media/140914/download) 08/06/2020	Sequencing	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 08/05/2020	Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/140919/download) 08/05/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 08/03/2020	Poplar Healthcare	Poplar SARS-CoV-2 TMA Pooling assay (/web/20210325011522/https://www.fda.gov/media/140789/download) 08/03/2020	TMA, chemiluminescent, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 08/03/2020	ISPM Labs, LLC dba Capstone Healthcare	Genus SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140815/download) 08/03/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 07/31/2020	University of California San Diego Health	UCSD RC SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/140714/download) 07/31/2020	Real-time RT-PCR, Pooling	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 07/30/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay (/web/20210325011522/https://www.fda.gov/media/136255/download) 03/18/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 07/30/2020	Clinical Reference Laboratory, Inc.	CRL Rapid Response (/web/20210325011522/https://www.fda.gov/media/140664/download) 07/30/2020	Real-time RT-PCR, Home Collection, Saliva	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 07/24/2020	Jiangsu CoWin Biotech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing) (/web/20210325011522/https://www.fda.gov/media/140426/download) 07/24/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 07/13/2020	Compass Laboratory Services, LLC	Compass Laboratory Services SARS-CoV2 Assay (/web/20210325011522/https://www.fda.gov/media/140074/download) 07/13/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 07/10/2020	Boston Medical Center	BMC-CReM COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/140024/download) 07/10/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 07/09/2020	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	SARS-CoV-2 RNA DETECTR Assay (/web/20210325011522/https://www.fda.gov/media/139934/download) 07/09/2020	RT-LAMP	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 07/01/2020	CENTOGENE US, LLC	CentoFast-SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/139722/download) 07/01/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/30/2020	TNS Co., Ltd (Bio TNS)	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit (/web/20210325011522/https://www.fda.gov/media/139677/download) 06/30/2020	RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 06/29/2020	LifeHope Labs	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel (/web/20210325011522/https://www.fda.gov/media/139620/download) 06/29/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/26/2020	Inform Diagnostics, Inc.	Inform Diagnostics SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/139569/download) 06/26/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/25/2020	PreciGenome LLC	FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR) (/web/20210325011522/https://www.fda.gov/media/139524/download) 06/25/2020	RT-digital droplet PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 06/24/2020	University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory	MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/139509/download) 06/24/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/23/2020	University of Alabama at Birmingham Fungal Reference Lab	FRL SARS CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/139439/download) 06/23/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/17/2020	The Ohio State University Wexner Medical Center	OSUWMC COVID-19 RT-PCR test (/web/20210325011522/https://www.fda.gov/media/139285/download) 06/17/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/138147/download) 05/15/2020	Real-time RT-PCR, Home Collection	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary, (/web/20210325011522/https://www.fda (Home Collect) (/web/20210325011522/https://www.fda
+ 06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit (/web/20210325011522/https://www.fda.gov/media/138929/download) 06/12/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 06/11/2020	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay (/web/20210325011522/https://www.fda.gov/media/137088/download) 04/16/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/10/2020	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/138815/download) 06/10/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 06/05/2020	Genetron Health (Beijing) Co., Ltd.	Genetron SARS-CoV-2 RNA Test (/web/20210325011522/https://www.fda.gov/media/138682/download) 06/05/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 06/04/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay (/web/20210325011522/https://www.fda.gov/media/136288/download) 03/19/2020	Real-time RT-PCR	H, M	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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+ 05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/web/20210325011522/https://www.fda.gov/media/137934/download) 05/11/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit (/web/20210325011522/https://www.fda.gov/media/137892/download) 05/08/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (/web/20210325011522/https://www.fda.gov/media/137652/download) 05/04/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/28/2020	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit (/web/20210325011522/https://www.fda.gov/media/136735/download) 04/06/2020	Real-time RT-digital PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/23/2020	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit (/web/20210325011522/https://www.fda.gov/media/137303/download) 04/23/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/22/2020	altona Diagnostics GmbH	RealStar SARS-CoV02 RT-PCR Kits U.S. (/web/20210325011522/https://www.fda.gov/media/137257/download) 04/22/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/18/2020	OSANG Healthcare	GeneFinder COVID-19 Plus RealAmp Kit (/web/20210325011522/https://www.fda.gov/media/137113/download) 04/18/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/16/2020	GenoSensor, LLC	GS"ç COVID-19 RT-PCR KIT (/web/20210325011522/https://www.fda.gov/media/137090/download) 04/16/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/03/2020	Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (/web/20210325011522/https://www.fda.gov/media/136684/download) 04/03/2020	RT-PCR, CoPrimer technology	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda
+ 04/01/2020	Ipsum Diagnostics, LLC	COV-19 IDx assay (/web/20210325011522/https://www.fda.gov/media/136618/download) 04/01/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda Summary (/web/20210325011522/https://www.fda
+ 03/15/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (/web/20210325011522/https://www.fda.gov/media/135661/download) 02/29/2020	Real-time RT-PCR	H	HCP (/web/20210325011522/https://www.fda Patients (/web/20210325011522/https://www.fda (/web/20210325011522/https://www.fda

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations:

- RT-PCR = reverse transcriptase polymerase chain reaction;
- RT = reverse transcriptase;
- LAMP = loop-mediated isothermal amplification;
- MALDI-TOF = Matrix Assisted Laser Desorption/Ionization - Time of Flight;
- TMA = Transcription Mediated Amplification;
- qSTAR = Selective Temperature Amplification Reaction;
- CRISPR = clustered regularly interspaced short palindromic repeats;

Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests. A manufacturer may request the addition of an eligible molecular-based LDT to Appendix A by submitting a request to CDRH-EUA-Templates@FDA.HHS.GOV (https://web.archive.org/web/20210325011522/mailto:CDRH-EUA-Templates@FDA.HHS.GOV) (https://web.archive.org/web/20210325011522mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/web/20210325011522/https://www.fda.gov/media/136598/download)
- Fact Sheet for Healthcare Providers (/web/20210325011522/https://www.fda.gov/media/136599/download)
- Fact Sheet for Patients (/web/20210325011522/https://www.fda.gov/media/136600/download)
- See Appendix A table below for a current list of included laboratories and their LTDs

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this Umbrella EUA (/web/20210325011522/https://www.fda.gov/media/136598/download) during the COVID-19 public health emergency.

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

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Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 02/03/2021	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138933/download) 06/12/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138934/download)
+ 01/29/2021	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/web/20210325011522/https://www.fda.gov/media/138529/download) 06/01/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138528/download)

Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 01/28/2021	AIT Laboratories	SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/137373/download) 04/24/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137374/download)
+ 12/28/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/137424/download) 04/27/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137423/download)
+ 12/28/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/137654/download) 05/03/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137656/download)
+ 12/28/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/web/20210325011522/https://www.fda.gov/media/137896/download) 05/07/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137897/download)
+ 09/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/web/20210325011522/https://www.fda.gov/media/137256/download) 04/22/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137255/download)
+ 09/21/2020	University of North Carolina Medical Center	UNC Health SARS-CoV-2 real-time RT-PCR test (/web/20210325011522/https://www.fda.gov/media/136879/download) 04/10/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136880/download)
+ 09/21/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test (/web/20210325011522/https://www.fda.gov/media/136943/download) 04/13/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136944/download)
+ 09/21/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136972/download) 04/14/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136971/download)
+ 09/21/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/137037/download) 04/15/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137036/download)
+ 09/21/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/137035/download) 04/15/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137034/download)
+ 09/14/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/web/20210325011522/https://www.fda.gov/media/137982/download) 05/12/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137983/download)
+ 07/29/2020	Mayo Clinic Laboratories, Rochester, MN	SARS-CoV-2 Molecular Detection Assay (/web/20210325011522/https://www.fda.gov/media/137162/download) 04/20/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137163/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138791/download) 06/10/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138790/download)
+ 06/04/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/web/20210325011522/https://www.fda.gov/media/137545/download) 04/30/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137546/download)
+ 06/04/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/web/20210325011522/https://www.fda.gov/media/136601/download) 03/31/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136602/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/web/20210325011522/https://www.fda.gov/media/138624/download) 06/04/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138625/download)

Date EUA Issued or Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV rRT Assay (/web/20210325011522/https://www.fda.gov/media/138527/download) 06/01/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138526/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/138331/download) 05/22/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138332/download)
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/web/20210325011522/https://www.fda.gov/media/138062/download) 05/13/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138063/download)
+ 05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/web/20210325011522/https://www.fda.gov/media/138064/download) 05/13/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/138065/download)
+ 04/28/2020	Biocerna	SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/137451/download) 04/28/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137450/download)
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/web/20210325011522/https://www.fda.gov/media/137371/download) 04/24/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137372/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/web/20210325011522/https://www.fda.gov/media/137369/download) 04/23/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137370/download)
+ 04/14/2020	Exact Sciences Laboratories	SARS-CoV-2 Test (/web/20210325011522/https://www.fda.gov/media/137094/download) 04/14/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/137095/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136941/download) 04/13/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136942/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/web/20210325011522/https://www.fda.gov/media/136874/download) 04/10/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/web/20210325011522/https://www.fda.gov/media/136878/download) 04/10/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136877/download)
+ 04/03/2020	Massachusetts General Hospital	MGH COVID-19 qPCR assay (/web/20210325011522/https://www.fda.gov/media/136700/download) 04/03/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136699/download)
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/web/20210325011522/https://www.fda.gov/media/136658/download) 04/02/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/web/20210325011522/https://www.fda.gov/media/136657/download) 04/02/2020	EUA Summary (/web/20210325011522/https://www.fda.gov/media/136656/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 antigen diagnostic tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests).

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20210325011522/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescence Immunoassay, Instrument Read	H, M	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g
+ 03/15/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20210325011522/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g
+ 03/01/2021	Quidel Corporation	QuickVue At-Home COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/146309/download) 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g IFU (Home Test) (/web/20210325011522/https://www.fda.g
+ 02/22/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read	H, M, W	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g
+ 02/11/2021	Ellume Limited	Ellume COVID-19 Home Test (/web/20210325011522/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g IFU (Home Test) (/web/20210325011522/https://www.fda.g FAQ (/web/20210325011522/https://www.fda.g
+ 02/04/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu (/web/20210325011522/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g
+ 01/26/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20210325011522/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20210325011522/https://www.fda.g Patients (/web/20210325011522/https://www.fda.g IFU (/web/20210325011522/https://www.fda.g

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 01/05/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20210325011522/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay	H, M	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 12/22/2020	Quidel Corporation	QuickVue SARS Antigen Test (/web/20210325011522/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 12/16/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20210325011522/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 12/16/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20210325011522/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda. IFU (Home Test) (/web/20210325011522/https://www.fda.
+ 12/07/2020	Luminostics, Inc.	Clip COVID Rapid Antigen Test (/web/20210325011522/https://www.fda.gov/media/144253/download) 12/07/2020	Lateral flow immunoluminescent assay, instrument read	H, M, W	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 10/23/2020	Celltrion USA, Inc.	Sampinute COVID-19 Antigen MIA (/web/20210325011522/https://www.fda.gov/media/143267/download) 10/23/2020	Magnetic Force-assisted Electrochemical Sandwich Immunoassay (MESIA)	H, M	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 10/02/2020	Quidel Corporation	Sofia 2 Flu + SARS Antigen FIA (/web/20210325011522/https://www.fda.gov/media/142701/download) 10/02/2020	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.
+ 07/17/2020	Quidel Corporation	Sofia SARS Antigen FIA (/web/20210325011522/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP (/web/20210325011522/https://www.fda. Patients (/web/20210325011522/https://www.fda. IFU (/web/20210325011522/https://www.fda.

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2

On August 6, 2020, based on the FDA's continued review of the scientific evidence available for Autobio Diagnostics Co. Ltd.'s Anti-SARS-CoV-2 Rapid Test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated blood (Heparin / EDTA / sodium citrate) or serum 2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20210325011522/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3306-a001.pdf), the FDA determined that the statutory criteria for the authorization in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, the FDA determined that it is not reasonable to believe the product may be effective in detecting IgM antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. The FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20210325011522/https://www.fda.gov/media/140908/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

On June 16, 2020 (/web/20210325011522/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test), based on the FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.'s DPP COVID-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2, including evidence from an NIH/NCI independent evaluation (https://web.archive.org/web/20210325011522/https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3265-a001.pdf), the FDA determined that the statutory criteria for issuing an EUA in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, the FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. The FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/web/20210325011522/https://www.fda.gov/media/139109/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

This table includes information about authorized SARS-CoV-2 serology/antibody tests and other adaptive immune response tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

For additional performance information about EUA authorized serology/antibody tests, please see the EUA Authorized Serology Test Performance (/web/20210325011522/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance) page.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/23/2021	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 IgG (sCOVG) (/web/20210325011522/https://www.fda.gov/media/146928/download) 03/23/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 03/22/2021	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit (/web/20210325011522/https://www.fda.gov/media/139866/download) 07/08/2020	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/22/2021	Beckman Coulter, Inc.	Access SARS-CoV-2 IgG II (/web/20210325011522/https://www.fda.gov/media/146898/download) 03/22/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 03/15/2021	bioMérieux SA	VIDAS SARS-CoV-2 IgM (/web/20210325011522/https://www.fda.gov/media/140930/download) 08/06/2020	IgM, ELFA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 03/15/2021	bioMérieux SA	VIDAS SARS-CoV-2 IgG (/web/20210325011522/https://www.fda.gov/media/140934/download) 08/06/2020	IgG, ELFA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 03/15/2021	Abbott Laboratories Inc.	AdviseDx SARS-CoV-2 IgG II (/web/20210325011522/https://www.fda.gov/media/146368/download) 03/01/2021	IgG, CMIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU-ARCHITECT (/web/20210325011522/https: IFU-Alinityi (/web/20210325011522/https:
+ 03/15/2021	Adaptive Biotechnologies Corporation	T-Detect COVID Test (/web/20210325011522/https://www.fda.gov/media/146478/download) 03/05/2021	T-cell receptor beta (TCR β), Sequencing	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 03/12/2021	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test (/web/20210325011522/https://www.fda.gov/media/140035/download) 07/10/2020	Total Antibody, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 02/12/2021	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack (/web/20210325011522/https://www.fda.gov/media/137360/download) 04/24/2020	IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 02/10/2021	Immunodiagnostic Systems Ltd.	IDS SARS-CoV-2 IgG (/web/20210325011522/https://www.fda.gov/media/145941/download) 02/10/2021	IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 02/05/2021	Nirmidas Biotech, Inc.	MidaSpot COVID-19 Antibody Combo Detection Kit (/web/20210325011522/https://www.fda.gov/media/144874/download) 12/31/2020	IgM and IgG, lateral flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 01/29/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (/web/20210325011522/https://www.fda.gov/media/136966/download) 04/14/2020	Total Antibody, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/19/2021	Phadia AB	EliA SARS-CoV-2-Sp1 IgG Test (/web/20210325011522/https://www.fda.gov/media/145082/download) 01/11/2021	IgG, Fluoroenzyme Immunoassay, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/15/2021	United Biomedical, Inc.	UBI SARS-CoV-2 ELISA (/web/20210325011522/https://www.fda.gov/media/145280/download) 01/15/2021	IgG, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/11/2021	ADVAITE, Inc.	RapCov Rapid COVID-19 Test (/web/20210325011522/https://www.fda.gov/media/145075/download) 01/11/2021	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/08/2021	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 IgG (CV2G) (/web/20210325011522/https://www.fda.gov/media/145012/download) 01/08/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/08/2021	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 IgG (COV2G) (/web/20210325011522/https://www.fda.gov/media/145017/download) 01/08/2021	IgG, CLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 01/05/2021	Salofa Oy	Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette (/web/20210325011522/https://www.fda.gov/media/140079/download) 07/13/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 12/23/2020	Quanterix Corporation	Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test (/web/20210325011522/https://www.fda.gov/media/144761/download) 12/23/2020	IgG, Paramagnetic Microbead-based Sandwich ELISA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 12/21/2020	Hangzhou Biotest Biotech Co., Ltd.	RightSign COVID-19 IgG/IgM Rapid Test Cassette (/web/20210325011522/https://www.fda.gov/media/138657/download) 06/04/2020	IgM and IgG Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 12/15/2020	ACON Laboratories, Inc.	ACON SARS-CoV-2 IgG/IgM Rapid Test (/web/20210325011522/https://www.fda.gov/media/144559/download) 12/15/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 12/02/2020	Hangzhou Laihe Biotech Co., Ltd.	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) (/web/20210325011522/https://www.fda.gov/media/139407/download) 06/19/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 12/01/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay (/web/20210325011522/https://www.fda.gov/media/137384/download) 04/26/2020	IgG, CMIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU-ARCHITECT (/web/20210325011522/https: IFU-Alinityi (/web/20210325011522/https:
+ 11/25/2020	Roche Diagnostics, Inc.	Elecsys Anti-SARS-CoV-2 S (/web/20210325011522/https://www.fda.gov/media/144034/download) 11/25/2020	Total Antibody, ECLIA, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 11/24/2020	Kantaro Biosciences, LLC	COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit (/web/20210325011522/https://www.fda.gov/media/144007/download) 11/24/2020	IgG, ELISA, Semi-quantitative	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 11/23/2020	Innovita (Tangshan) Biological Technology Co., Ltd.	Innovita 2019-nCoV Ab Test (Colloidal Gold) (/web/20210325011522/https://www.fda.gov/media/144068/download) 11/23/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 11/10/2020	Jiangsu Well Biotech Co., Ltd.	Orawell IgM/IgG Rapid Test (/web/20210325011522/https://www.fda.gov/media/142423/download) 09/23/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 11/06/2020	Xiamen Biotime Biotechnology Co., Ltd.	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test (/web/20210325011522/https://www.fda.gov/media/140440/download) 07/24/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 11/06/2020	GenScript USA Inc.	cPass SARS-CoV-2 Neutralization Antibody Detection Kit (/web/20210325011522/https://www.fda.gov/media/143584/download) 11/06/2020	Total Neutralizing Antibodies, Blocking ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 10/31/2020	Access Bio, Inc.	CareStart COVID-19 IgM/IgG (/web/20210325011522/https://www.fda.gov/media/140444/download) 07/24/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/30/2020	Bio-Rad Laboratories, Inc.	Platelia SARS-CoV-2 Total Ab assay (/web/20210325011522/https://www.fda.gov/media/137494/download) 04/29/2020	Total Antibody, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/30/2020	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (/web/20210325011522/https://www.fda.gov/media/138750/download) 06/08/2020	Total Antibody, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/30/2020	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (/web/20210325011522/https://www.fda.gov/media/138754/download) 06/08/2020	Total Antibody, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/28/2020	Quansys Biosciences, Inc.	Q-Plex SARS-CoV-2 Human IgG (4 Plex) (/web/20210325011522/https://www.fda.gov/media/143453/download) 10/28/2020	IgG, CLIA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/23/2020	Roche Diagnostics	Elecsys Anti-SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/media/137602/download) 05/02/2020	Total Antibody, ECLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/19/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG (/web/20210325011522/https://www.fda.gov/media/137356/download) 04/24/2020	IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/17/2020	Biohit Healthcare (Hefei) Co. Ltd.	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (/web/20210325011522/https://www.fda.gov/media/139280/download) 06/18/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/09/2020	Abbott Laboratories Inc.	AdviseDx SARS-CoV-2 IgM (/web/20210325011522/https://www.fda.gov/media/142937/download)10/09/2020	IgM, CMIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU-ARCHITECT (/web/20210325011522/https: IFU-Alinityi (/web/20210325011522/https:

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+ 10/08/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgM (/web/20210325011522/https://www.fda.gov/media/142908/download) 10/08/2020	IgM, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/08/2020	Genalyte, Inc.	Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2 (/web/20210325011522/https://www.fda.gov/media/142912/download) 10/08/2020	Total Antibody, photonic ring immunoassay	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/06/2020	Thermo Fisher Scientific	OmniPATH COVID-19 Total Antibody ELISA Test (/web/20210325011522/https://www.fda.gov/media/142697/download) 10/02/2020	Total Antibody, ELISA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 10/06/2020	ZEUS Scientific, Inc.	ZEUS ELISA SARS-CoV-2 IgG Test System (/web/20210325011522/https://www.fda.gov/media/142806/download) 10/06/2020	IgG, ELISA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/29/2020	DiaSorin, Inc.	DiaSorin LIAISON SARS-CoV-2 IgM Assay (/web/20210325011522/https://www.fda.gov/media/142549/download) 09/29/2020	IgM, Indirect CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/29/2020	NanoEntek America, Inc.	FREND COVID-19 total Ab (/web/20210325011522/https://www.fda.gov/media/142554/download) 09/29/2020	Total Antibody, FIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/29/2020	Nirmidas Biotech, Inc.	Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit (/web/20210325011522/https://www.fda.gov/media/142558/download) 09/29/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/25/2020	Quotient Suisse SA	MosaiQ COVID-19 Antibody Magazine (/web/20210325011522/https://www.fda.gov/media/142483/download) 09/25/2020	Total Antibody, photometric immunoassay	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/23/2020	Assure Tech. (Hangzhou Co., Ltd)	Assure COVID-19 IgG/IgM Rapid Test Device (/web/20210325011522/https://www.fda.gov/media/139789/download) 07/06/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/14/2020	Shenzhen New Industries Biomedical Engineering Co., Ltd.	MAGLUMI 2019-nCoV IgM/IgG (/web/20210325011522/https://www.fda.gov/media/142230/download) 09/14/2020	IgM and IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

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+ 09/09/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgM Antibody Test Kit (/web/20210325011522/https://www.fda.gov/media/141998/download) 09/09/2020	IgM, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/09/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG Antibody Test Kit (/web/20210325011522/https://www.fda.gov/media/142003/download) 09/09/2020	IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 09/03/2020	Sugentech, Inc.	SGTi-flex COVID-19 IgG (/web/20210325011522/https://www.fda.gov/media/141888/download) 09/03/2020	IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 08/31/2020	TBG Biotechnology Corp.	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit (/web/20210325011522/https://www.fda.gov/media/141770/download) 08/31/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 08/31/2020	University of Arizona Genetics Core for Clinical Services	COVID-19 ELISA pan-Ig Antibody Test (/web/20210325011522/https://www.fda.gov/media/141774/download) 08/31/2020	Total Antibody, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 08/25/2020	Biocan Diagnostics Inc.	Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test - Letter of Authorization (/web/20210325011522/https://www.fda.gov/media/141547/download) 08/25/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 08/17/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG and IgM Combo Test (/web/20210325011522/https://www.fda.gov/media/141247/download) 08/17/2020	IgM and IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 08/17/2020	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit (/web/20210325011522/https://www.fda.gov/media/141252/download) 08/17/2020	IgM, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 08/05/2020	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA (/web/20210325011522/https://www.fda.gov/media/140926/download) 08/05/2020	Total Antibody, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:

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+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 IgG (COV2G) (/web/20210325011522/https://www.fda.gov/media/140700/download) 07/31/2020	IgG, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 IgG (COV2G) (/web/20210325011522/https://www.fda.gov/media/140703/download) 07/31/2020	IgG, Semi-quantitative	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 07/17/2020	Megna Health, Inc.	Rapid COVID-19 IgM/IgG Combo Test Kit (/web/20210325011522/https://www.fda.gov/media/140294/download) 07/17/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 07/16/2020	Luminex Corporation	xMAP SARS-CoV-2 Multi-Antigen IgG Assay (/web/20210325011522/https://www.fda.gov/media/140257/download) 07/16/2020	IgG, FMIA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 06/30/2020	InBios International, Inc.	SCoV-2 Detect IgM ELISA (/web/20210325011522/https://www.fda.gov/media/139726/download) 06/30/2020	IgM, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 06/26/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgG (/web/20210325011522/https://www.fda.gov/media/139624/download) 06/26/2020	IgG, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 06/23/2020	Babson Diagnostics, Inc.	Babson Diagnostics aC19G1 (/web/20210325011522/https://www.fda.gov/media/139450/download) 06/23/2020	IgG, CLIA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 06/15/2020	Emory Medical Laboratories	SARS-CoV-2 RBD IgG test (/web/20210325011522/https://www.fda.gov/media/139050/download) 06/15/2020	IgG, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 06/12/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test (/web/20210325011522/https://www.fda.gov/media/136622/download) 04/01/2020	IgM and IgG, Lateral Flow	H, M	HCP (/web/20210325011522/https: Patients (/web/20210325011522/https: IFU (/web/20210325011522/https:

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 06/10/2020	InBios International, Inc.	SCoV-2 Detect IgG ELISA (/web/20210325011522/https://www.fda.gov/media/138807/download) 06/10/2020	IgG, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 06/04/2020	Vibrant America Clinical Labs	Vibrant COVID-19 Ab Assay (/web/20210325011522/https://www.fda.gov/media/138626/download) 06/04/2020	IgM and IgG, CLIA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (/web/20210325011522/https://www.fda.gov/media/138435/download) 05/29/2020	IgM and IgG Lateral Flow	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T) (/web/20210325011522/https://www.fda.gov/media/138439/download) 05/29/2020	Total Antibody, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T) (/web/20210325011522/https://www.fda.gov/media/138443/download) 05/29/2020	Total Antibody, CLIA	H, M	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 05/04/2020	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG) (/web/20210325011522/https://www.fda.gov/media/137606/download) 05/04/2020	IgG, ELISA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: IFU (/web/20210325011522/https:
+ 04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection (/web/20210325011522/https://www.fda.gov/media/137540/download) 04/30/2020	Total Antibody, FMIA	H	HCP (/web/20210325011522/https: Recipients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:
+ 04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test (/web/20210325011522/https://www.fda.gov/media/137032/download) 04/15/2020	IgG, ELISA	H	HCP (/web/20210325011522/https: Patients (/web/20210325011522/https: EUA Summary (/web/20210325011522/https:

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay, CMIA = chemiluminescent microparticle immunoassay; ELFA = enzyme-linked fluorescence assay

Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2

On April 28, 2020, FDA issued an umbrella EUA for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by the FDA, and are confirmed by the FDA to meet the criteria set forth in the Scope of Authorization of the EUA. To date, however, no device has been added to the list of authorized devices in Appendix A of the letter of authorization.

On July 21, 2020, FDA determined, based on information and experience since issuing this EUA, that circumstances support revocation of this umbrella EUA so that FDA may issue individual EUAs. Individual EUAs will allow for broader indications and scopes of authorization, individualized conditions of authorization to address any issue unique to a specific test, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA.

Accordingly, the EUA was revoked (/web/20210325011522/https://www.fda.gov/media/140351/download) under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Individual EUAs For IVDs for Management of COVID-19 Patients

This table includes information about authorized in vitro diagnostic tests that may be used in the management of patients with COVID-19 that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
+ 12/18/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur IL6 assay (/web/20210325011522/https://www.fda.gov/media/144669/download) 12/18/2020	One-step Direct Chemiluminescent Immunoassay	H, M	HCP (/web/20210325011522/https://www.fda.gov/ Patients (/web/20210325011522/https://www.fda.gov/ IFU (/web/20210325011522/https://www.fda.gov/
+ 10/01/2020	Beckman Coulter, Inc.	Access IL-6 (/web/20210325011522/https://www.fda.gov/media/142597/download) 10/01/2020	One-step immunoenzymatic ("sandwich") assay, IL-6	H, M	HCP (/web/20210325011522/https://www.fda.gov/ Patients (/web/20210325011522/https://www.fda.gov/ IFU (/web/20210325011522/https://www.fda.gov/
+ 06/02/2020	Roche Diagnostics	Elecsys IL-6 (/web/20210325011522/https://www.fda.gov/media/138596/download) 06/02/2020	Immunoassay-IL-6	H, M	HCP (/web/20210325011522/https://www.fda.gov/ Patients (/web/20210325011522/https://www.fda.gov/ IFU (/web/20210325011522/https://www.fda.gov/

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20210325011522/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20210325011522/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20210325011522/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- EUA Authorized Serology Test Performance (/web/20210325011522/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic Template for Commercial Manufacturers (/web/20210422185112/https://www.fda.gov/media/135900/download) (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20210422185112/https://www.fda.gov/media/135658/download) (updated July 28, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20210422185112/https://www.fda.gov/media/138412/download) (May 29, 2020)
- Antigen Template for Test Developers (/web/20210422185112/https://www.fda.gov/media/137907/download) (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20210422185112/https://www.fda.gov/media/140615/download) (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20210422185112/https://www.fda.gov/media/146695/download) (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (/web/20210422185112/https://www.fda.gov/media/137698/download)(March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20210422185112/https://www.fda.gov/media/146746/download) (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (/web/20210422185112/https://www.fda.gov/media/143941/download) (November 24, 2020)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210422185112/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to

facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210422185112/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210422185112mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210422185112/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210422185112mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20210422185112/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210422185112/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210422185112/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210422185112mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#individual-molecular)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
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- IVDs for Management of COVID-19 Patients (/web/20210422185112/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Additional Resources

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- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20210422185112/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
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Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

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- Antigen Template for Test Developers (/web/20210624112153/https://www.fda.gov/media/137907/download) (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20210624112153/https://www.fda.gov/media/140615/download) (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20210624112153/https://www.fda.gov/media/146695/download) (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (/web/20210624112153/https://www.fda.gov/media/137698/download)(March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20210624112153/https://www.fda.gov/media/146746/download) (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (/web/20210624112153/https://www.fda.gov/media/143941/download) (March 24, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210624112153/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

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Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210624112153/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210624112153mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

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    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#individual-molecular)

    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#umbrella-serological)
- IVDs for Management of COVID-19 Patients (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food

and Drug Administration Staff (/web/20210624112153/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)

- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20210624112153/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20210624112153/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

    - Revision Concerning Viral Mutation (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)

- Other Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)
    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping)
  (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
- IVDs for Management of COVID-19 Patients (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20220803233606/http://www.fda.gov/media/152768/download) (October 6, 2021)
- Molecular Diagnostic Template (/web/20220803233606/http://www.fda.gov/media/135900/download) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20220803233606/http://www.fda.gov/media/138412/download) (October 6, 2021)
- Antigen Diagnostic Template (/web/20220803233606/http://www.fda.gov/media/137907/download) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20220803233606/http://www.fda.gov/media/140615/download) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20220803233606/http://www.fda.gov/media/146695/download) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20220803233606/http://www.fda.gov/media/137698/download) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20220803233606/http://www.fda.gov/media/146746/download) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (/web/20220803233606/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20220803233606/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20220803233606mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20220803233606/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20220803233606mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20220803233606/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (/web/20220803233606/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20220803233606/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20220803233606mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20220803233606/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (/web/20220803233606/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Coronavirus (COVID-19) and Medical Devices (/web/20220803233606/http://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20220803233606/http://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20220803233606/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic Template for Commercial Manufacturers (/web/20210930092632/https://www.fda.gov/media/135900/download) (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (/web/20210930092632/https://www.fda.gov/media/135658/download) (updated July 28, 2020)
- Home Specimen Collection Molecular Diagnostic Template (/web/20210930092632/https://www.fda.gov/media/138412/download) (May 29, 2020)
- Antigen Template for Test Developers (/web/20210930092632/https://www.fda.gov/media/137907/download) (October 26, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (/web/20210930092632/https://www.fda.gov/media/140615/download) (July 29, 2020)
- Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20210930092632/https://www.fda.gov/media/146695/download) (March 16, 2021)

Serology/Antibody Templates

- Serology Template for Test Developers (/web/20210930092632/https://www.fda.gov/media/137698/download)(March 17, 2021)
- Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20210930092632/https://www.fda.gov/media/146746/download) (March 17, 2021)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (/web/20210930092632/https://www.fda.gov/media/143941/download) (March 24, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210930092632/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to

facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210930092632/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210930092632mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210930092632/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210930092632mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20210930092632/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20210930092632/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20210930092632/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20210930092632mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-

diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)

    - Revision Concerning Viral Mutations (https://web.archive.org/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
    - Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#umbrella-serological)

- IVDs for Management of COVID-19 Patients (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (/web/20210930092632/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20210930092632/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20210930092632/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)

In Vitro Diagnostics EUAs

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- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Any test developer requesting an EUA that intends to leverage data from another EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for EUA Submissions

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20211103105449/https://www.fda.gov/media/152768/download) (October 6, 2021)
- Molecular Diagnostic Template (/web/20211103105449/https://www.fda.gov/media/135900/download) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20211103105449/https://www.fda.gov/media/138412/download) (October 6, 2021)
- Antigen Diagnostic Template (/web/20211103105449/https://www.fda.gov/media/137907/download) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20211103105449/https://www.fda.gov/media/140615/download) (October 25, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20211103105449/https://www.fda.gov/media/146695/download) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20211103105449/https://www.fda.gov/media/137698/download) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20211103105449/https://www.fda.gov/media/146746/download) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (/web/20211103105449/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public Health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20211103105449/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20211103105449mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20211103105449/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20211103105449mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

    - Revision Concerning Viral Mutation (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
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- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20211103105449/https://www.fda.gov/medical-

devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)

    - Umbrella EUA for Independently Validated Serology Tests for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#umbrella-serological)

- IVDs for Management of COVID-19 Patients (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Additional Resources

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- Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy (/web/20211103105449/https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy)
- FAQs on Testing for SARS-CoV-2 (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- Emergency Use Authorization of COVID-19 Tests: Independent Assessment of the FDA's Response (/web/20211103105449/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/emergency-use-authorization-covid-19-tests-independent-assessment-fdas-response)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
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    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
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Templates for EUA Submissions

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- Molecular Diagnostic Home Specimen Collection Template (/web/20220115073527/https://www.fda.gov/media/138412/download) (October 6, 2021)
- Antigen Diagnostic Template (/web/20220115073527/https://www.fda.gov/media/137907/download) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20220115073527/https://www.fda.gov/media/140615/download) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20220115073527/https://www.fda.gov/media/146695/download) (October 25, 2021)

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Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (/web/20220115073527/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Coronavirus (COVID-19) and Medical Devices (/web/20220115073527/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20220115073527/https://www.fda.gov/media/138094/download)
- FAQs on Testing for SARS-CoV-2 (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20220115073527/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

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    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
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    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
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Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20220313065338/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20220313065338mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20220313065338/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (/web/20220313065338/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20220313065338/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20220313065338mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (/web/20220313065338/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- Coronavirus (COVID-19) and Medical Devices (/web/20220313065338/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20220313065338/https://www.fda.gov/media/138094/download)
- FAQs on Testing for SARS-CoV-2 (/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20220313065338/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
- Other Diagnostic Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-

2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)

    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)

- IVDs for Management of COVID-19 Patients (/web/20220504190144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

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- Molecular Diagnostic Home Specimen Collection Template (/web/20220504190144/https://www.fda.gov/media/138412/download) (October 6, 2021)
- Antigen Diagnostic Template (/web/20220504190144/https://www.fda.gov/media/137907/download) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20220504190144/https://www.fda.gov/media/140615/download) (November 9, 2021)

- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20220504190144/https://www.fda.gov/media/146695/download) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20220504190144/https://www.fda.gov/media/137698/download) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20220504190144/https://www.fda.gov/media/146746/download) (October 6, 2021)

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Additional Resources

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Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
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    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-

disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping) (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)

- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
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- Coronavirus (COVID-19) and Medical Devices (/web/20220613193230/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20220613193230/https://www.fda.gov/media/138094/download)
- FAQs on Testing for SARS-CoV-2 (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)

- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20220613193230/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-

devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

- Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)

- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Revision Concerning Viral Mutations (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
  - Antigen EUA Revision for Serial (Repeat) Testing (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2/latest#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)

    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping) (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
- IVDs for Management of COVID-19 Patients (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20221102225554/https://www.fda.gov/media/152768/download) (October 6, 2021)

- Molecular Diagnostic Template (/web/20221102225554/https://www.fda.gov/media/135900/download) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20221102225554/https://www.fda.gov/media/138412/download) (October 6, 2021)
- Antigen Diagnostic Template (/web/20221102225554/https://www.fda.gov/media/137907/download) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20221102225554/https://www.fda.gov/media/140615/download) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20221102225554/https://www.fda.gov/media/146695/download) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20221102225554/https://www.fda.gov/media/137698/download) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20221102225554/https://www.fda.gov/media/146746/download) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (/web/20221102225554/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov

(https://web.archive.org/web/20221102225554/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20221102225554mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20221102225554/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20221102225554mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20221102225554/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* (/web/20221102225554/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20221102225554/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20221102225554mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (/web/20221102225554/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)

- Coronavirus (COVID-19) and Medical Devices (/web/20221102225554/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20221102225554/https://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20221102225554/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-

devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

- Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20230807200412/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)

- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Revision Concerning Viral Mutations (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
  - Antigen EUA Revision for Serial (Repeat) Testing (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)

    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping) (/web/20230807200412/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-emergency-use-authorizations-euas-serology-and-other-adaptive-immune-response)
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    - Revision Concerning Viral Mutations (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
- IVDs for Management of COVID-19 Patients (/web/20230807200412/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

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- Molecular Diagnostic Template (/web/20230807200412/http://www.fda.gov/media/135900/download?attachment) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20230807200412/http://www.fda.gov/media/138412/download?attachment) (October 6, 2021)
- Antigen Diagnostic Template (/web/20230807200412/http://www.fda.gov/media/137907/download?attachment) (October 6, 2021)
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Serology/Antibody Templates

- Serology Template (/web/20230807200412/http://www.fda.gov/media/137698/download?attachment) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20230807200412/http://www.fda.gov/media/146746/download?attachment) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20230807200412/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov

(https://web.archive.org/web/20230807200412/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230807200412mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20230807200412/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

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Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20230807200412/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
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devices/coronavirus-covid-19-and-medical-devices)

- Coronavirus Testing Basics (/web/20230807200412/http://www.fda.gov/about-fda/page-not-found)
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Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-

devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

- Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)

- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Revision Concerning Viral Mutations (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
  - Antigen EUA Revision for Serial (Repeat) Testing (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)

    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping) (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-emergency-use-authorizations-euas-serology-and-other-adaptive-immune-response)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
- IVDs for Management of COVID-19 Patients (/web/20230911024212/http://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20230911024212/http://www.fda.gov/media/152768/download?attachment) (October 6, 2021)

- Molecular Diagnostic Template (/web/20230911024212/http://www.fda.gov/media/135900/download?attachment) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20230911024212/http://www.fda.gov/media/138412/download?attachment) (October 6, 2021)
- Antigen Diagnostic Template (/web/20230911024212/http://www.fda.gov/media/137907/download?attachment) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20230911024212/http://www.fda.gov/media/140615/download?attachment) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20230911024212/http://www.fda.gov/media/146695/download?attachment) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20230911024212/http://www.fda.gov/media/137698/download?attachment) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20230911024212/http://www.fda.gov/media/146746/download?attachment) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20230911024212/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov

(https://web.archive.org/web/20230911024212/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230911024212mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20230911024212/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230911024212mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20230911024212/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20230911024212/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20230911024212/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230911024212mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20230911024212/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20230911024212/http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
- Coronavirus (COVID-19) and Medical Devices (/web/20230911024212/http://www.fda.gov/medical-devices/emergency-situations-medical-

devices/coronavirus-covid-19-and-medical-devices)

- Coronavirus Testing Basics (/web/20230911024212/http://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20230911024212/http://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-

devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)

- Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)

- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Revision Concerning Viral Mutations (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
  - Antigen EUA Revision for Serial (Repeat) Testing (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)

    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping) (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
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    - Revision Concerning Viral Mutations (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
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- Molecular Diagnostic Home Specimen Collection Template (/web/20230124050005/https://www.fda.gov/media/138412/download) (October 6, 2021)
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- Serology Template (/web/20230124050005/https://www.fda.gov/media/137698/download) (October 6, 2021)
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These templates are part of the *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20230124050005/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov

(https://web.archive.org/web/20230124050005/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230124050005mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20230124050005/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20230124050005mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20230124050005/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20230124050005/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised).

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Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20230124050005/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
- Coronavirus (COVID-19) and Medical Devices (/web/20230124050005/https://www.fda.gov/medical-devices/emergency-situations-medical-

devices/coronavirus-covid-19-and-medical-devices)

- Coronavirus Testing Basics (/web/20230124050005/https://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20230124050005/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

March 24, 2023 - The FDA has finalized two guidances: *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease)* and Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease). The guidances outline the FDA's general recommendations to transition from certain policies adopted and operations implemented during the COVID-19 pandemic to normal operations, including the FDA's recommendations for:

- Developing a transition implementation plan,
- Submitting a marketing submission, and
- Taking other actions with respect to these devices.

The FDA encourages stakeholders to review the two final guidances, view the webinar, and reach out to the FDA if they have questions or concerns. In particular, for manufacturers planning to seek marketing authorization for their devices, the FDA recommends beginning work on a marketing submission, including a transition implementation plan, as described in the guidances.

Additional Resources:

- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease)
- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-

guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease)

- Webinar on Guidances on COVID-19 Transition Plans for Medical Devices - April 18, 2023 (/web/20231021022415/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-guidances-covid-19-transition-plans-medical-devices-04182023)

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Since the Secretary's declaration under section 564 of the Federal Food, Drug, and Cosmetic Act related to in vitro diagnostic tests for COVID-19, on February 4, 2020, the FDA has granted EUAs for many COVID-19 tests, based on a determination that they met the statutory criteria for EUA. EUA-authorized tests can continue to be used as long as they are available and not expired and the EUA has not been revoked. This page provides information about these EUAs.

The FDA has been working with COVID-19 test developers seeking to pursue marketing authorization through the traditional premarket review pathways, which will allow these tests to continue to be used beyond the time allowed by emergency use authorization. See COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-

medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda) for additional information on COVID-19 tests that have received traditional marketing authorizations, as well as information about the traditional premarket review and authorization process.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-

authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutations (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
    - Antigen EUA Revision for Serial (Repeat) Testing (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)

- Other Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)
    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping)
(/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#genotyping)

- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-emergency-use-authorizations-euas-serology-and-other-adaptive-immune-response)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)

    - Revision Concerning Viral Mutations (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)

- IVDs for Management of COVID-19 Patients (/web/20231021022415/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20231021022415/https://www.fda.gov/media/152768/download?attachment) (October 6, 2021)
- Molecular Diagnostic Template (/web/20231021022415/https://www.fda.gov/media/135900/download?attachment) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20231021022415/https://www.fda.gov/media/138412/download?attachment) (October 6, 2021)
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- Molecular and Antigen Home Use Test Template (/web/20231021022415/https://www.fda.gov/media/140615/download?attachment) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20231021022415/https://www.fda.gov/media/146695/download?attachment) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20231021022415/https://www.fda.gov/media/137698/download?

attachment) (October 6, 2021)

- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20231021022415/https://www.fda.gov/media/146746/download?attachment) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20231021022415/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20231021022415mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20231021022415/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20231021022415mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20231021022415/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20231021022415/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20231021022415mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20231021022415/https://www.fda.gov/medical-

devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20231021022415/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
- COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda)
- Coronavirus (COVID-19) and Medical Devices (/web/20231021022415/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20231021022415/https://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20231021022415/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

In Vitro Diagnostics EUAs

November 8, 2023 - The COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service (PHS) Act expired (https://web.archive.org/web/20231208163546/https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html) on May 11, 2023. The COVID-19 enforcement policy guidances within scope of the *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease) (see List 1) are no longer in effect.

The end of the COVID-19 PHE and certain COVID-19 enforcement policy guidances no longer being in effect do not impact the FDA's ability to authorize devices, including tests, for emergency use. Existing emergency use authorizations (EUAs) for devices relating to COVID-19 remain in effect under section 564 of the Federal Food, Drug, and Cosmetic Act. The FDA encourages manufacturers of devices issued EUAs related to COVID-19 to review the guidance: *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)* (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease) and *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19), (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease)* which outlines the FDA's recommendations and expectations to such manufacturers to transition to normal operations when the declarations that allowed for FDA to issue EUAs under section 564 of the Federal Food, Drug, and Cosmetic Act end. Additional information is provided on the page FAQs: What happens to EUAs when a public health emergency ends? (/web/20231208163546/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends)

March 24, 2023 - The FDA has finalized two guidances: *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease)* and Transition Plan for Medical

Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease). The guidances outline the FDA's general recommendations to transition from certain policies adopted and operations implemented during the COVID-19 pandemic to normal operations, including the FDA's recommendations for:

- Developing a transition implementation plan,
- Submitting a marketing submission, and
- Taking other actions with respect to these devices.

The FDA encourages stakeholders to review the two final guidances, view the webinar, and reach out to the FDA if they have questions or concerns. In particular, for manufacturers planning to seek marketing authorization for their devices, the FDA recommends beginning work on a marketing submission, including a transition implementation plan, as described in the guidances.

Additional Resources:

- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease)
- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease)
- Webinar on Guidances on COVID-19 Transition Plans for Medical Devices - April 18, 2023 (/web/20231208163546/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-guidances-covid-19-transition-plans-medical-devices-04182023)

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Since the Secretary's declaration under section 564 of the Federal Food, Drug, and Cosmetic Act related to in vitro diagnostic tests for COVID-19, on February 4, 2020, the FDA has granted EUAs for many COVID-19 tests, based on a determination that they met the statutory criteria for EUA. EUA-authorized tests can continue to be used as long as they are available and not expired and the EUA has not been revoked. This page provides information about these EUAs.

The FDA has been working with COVID-19 test developers seeking to pursue marketing authorization through the traditional premarket review pathways, which will allow these tests to continue to be used beyond the time allowed by emergency use authorization. See COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda) for additional information on COVID-19 tests that have received traditional marketing authorizations, as well as information about the traditional premarket review and authorization process.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

- Revision Concerning Viral Mutation (https://web.archive.org/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
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- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://web.archive.org/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)

- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
  - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
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  - Antigen EUA Revision for Serial (Repeat) Testing (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)
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    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping)

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Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20231208163546/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20231208163546mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20231208163546/https://www.regulations.gov/docket?

D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20231208163546/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20231208163546mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (https://web.archive.org/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20231208163546/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
- COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda)
- Coronavirus (COVID-19) and Medical Devices (/web/20231208163546/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20231208163546/https://www.fda.gov/about-fda/page-not-found)
- FAQs on Testing for SARS-CoV-2 (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20231208163546/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)

Was this helpful? Yes No

In Vitro Diagnostics EUAs

November 8, 2023 - The COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service (PHS) Act expired (https://web.archive.org/web/20250402150034/https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html) on May 11, 2023. The COVID-19 enforcement policy guidances within scope of the *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease) (see List 1) are no longer in effect.

The end of the COVID-19 PHE and certain COVID-19 enforcement policy guidances no longer being in effect do not impact the FDA's ability to authorize devices, including tests, for emergency use. Existing emergency use authorizations (EUAs) for devices relating to COVID-19 remain in effect under section 564 of the Federal Food, Drug, and Cosmetic Act. The FDA encourages manufacturers of devices issued EUAs related to COVID-19 to review the guidance: *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)* (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease) and *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19),* (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease) which outlines the FDA's recommendations and expectations to such manufacturers to transition to normal operations when the declarations that allowed for FDA to issue EUAs under section 564 of the Federal Food, Drug, and Cosmetic Act end. Additional information is provided on the page FAQs: What happens to EUAs when a public health emergency ends? (/web/20250402150034/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends)

March 24, 2023 - The FDA has finalized two guidances: *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (/web/20250402150034/https://www.fda.gov/regulatory-

information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease) and Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease). The guidances outline the FDA's general recommendations to transition from certain policies adopted and operations implemented during the COVID-19 pandemic to normal operations, including the FDA's recommendations for:

- Developing a transition implementation plan,
- Submitting a marketing submission, and
- Taking other actions with respect to these devices.

The FDA encourages stakeholders to review the two final guidances, view the webinar, and reach out to the FDA if they have questions or concerns. In particular, for manufacturers planning to seek marketing authorization for their devices, the FDA recommends beginning work on a marketing submission, including a transition implementation plan, as described in the guidances.

Additional Resources:

- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease)
- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease)
- Webinar on Guidances on COVID-19 Transition Plans for Medical Devices - April 18, 2023 (https://web.archive.org/web/20250402150034/https://public4.pagefreezer.com/browse/FDA/01-03-2024T13:19/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices-unpublished/webinar-guidances-covid-19-transition-plans-medical-devices-04182023)

(https://web.archive.org/web/20250402150034mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer)

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Since the Secretary's declaration under section 564 of the Federal Food, Drug, and Cosmetic Act related to in vitro diagnostic tests for COVID-19, on February 4, 2020, the FDA has granted EUAs for many COVID-19 tests, based on a determination that they met the statutory criteria for EUA. EUA-authorized tests can continue to be used as long as they are available and not expired and the EUA has not been revoked. This page provides information about these EUAs.

The FDA has been working with COVID-19 test developers seeking to pursue marketing authorization through the traditional premarket review pathways, which will allow these tests to continue to be used beyond the time allowed by emergency use authorization. See COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda) for additional information on COVID-19 tests that have received traditional marketing authorizations, as well as information about the traditional premarket review and authorization process.

Tables of IVD Emergency Use Authorizations:

The web pages below include tables of SARS-CoV-2 and COVID-19 related IVDs with emergency use authorizations (EUAs).

- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - Revision Concerning Viral Mutation (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#Revision)
    - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment)
    - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-eua)
    - EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#umbrella-molecular)
- Antigen Diagnostic Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
    - Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

    - Revision Concerning Viral Mutations (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Revision)
    - Antigen EUA Revision for Serial (Repeat) Testing (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting)
- Other Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2)
    - Individual EUAs for Diagnostic Breath Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-diagnostic-tests-sars-cov-2#breath)
    - Individual EUAs for Genotyping Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-other-tests-sars-cov-2#genotyping)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-emergency-use-authorizations-euas-serology-and-other-adaptive-immune-response)
    - Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological)
    - Revision Concerning Viral Mutations (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#Revision)
- IVDs for Management of COVID-19 Patients (/web/20250402150034/https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

Templates for EUA Submissions

Templates for EUA submissions for several types of COVID-19 tests are available to help facilitate the preparation, submission, and authorization of an EUA request:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (/web/20250402150034/https://www.fda.gov/media/152768/download?attachment) (October 6, 2021)
- Molecular Diagnostic Template (/web/20250402150034/https://www.fda.gov/media/135900/download?attachment) (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (/web/20250402150034/https://www.fda.gov/media/138412/download?attachment) (October 6, 2021)
- Antigen Diagnostic Template (/web/20250402150034/https://www.fda.gov/media/137907/download?attachment) (October 6, 2021)
- Molecular and Antigen Home Use Test Template (/web/20250402150034/https://www.fda.gov/media/140615/download?attachment) (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (/web/20250402150034/https://www.fda.gov/media/146695/download?attachment) (October 25, 2021)

Serology/Antibody Templates

- Serology Template (/web/20250402150034/https://www.fda.gov/media/137698/download?attachment) (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (/web/20250402150034/https://www.fda.gov/media/146746/download?attachment) (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised), which also includes additional policies specific to this public health emergency. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates

provide information and recommendations, and we plan to update them as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 tests.

Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process. The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20250402150034/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20250402150034mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20250402150034/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20250402150034mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), or they can submit comments regarding the templates to the public docket (https://web.archive.org/web/20250402150034/https://www.regulations.gov/docket?D=FDA-2020-D-0987) established for the guidance *Policy for Coronavirus Disease-2019 Tests (Revised)* (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised).

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov (https://web.archive.org/web/20250402150034/mailto:CDRH-EUA-Templates@fda.hhs.gov) (https://web.archive.org/web/20250402150034mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Any test developer requesting an EUA that intends to leverage data from another developer's EUA-authorized device must obtain a right of reference (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-development-and-review-faqs-testing-sars-cov-2#leverage) to leverage the performance data for that EUA-authorized device. The Centers for Disease Control and Prevention (CDC) has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Additional information can be found on the FAQs on Testing for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) page.

If you have a question about:	Send email to:
COVID-19 Tests	COVID19DX@fda.hhs.gov (https://web.archive.org/web/20250402150034/mailto:COVID19DX@fda.hhs.gov) (https://web.archive.org/web/20250402150034mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Additional Resources

- Policy for Coronavirus Disease-2019 Tests (Revised) (/web/20250402150034/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised)
- COVID-19 Tests Granted Traditional Marketing Authorization by the FDA (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-granted-traditional-marketing-authorization-fda)
- Coronavirus (COVID-19) and Medical Devices (/web/20250402150034/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices)
- Coronavirus Testing Basics (/web/20250402150034/https://www.fda.gov/media-base/138094)
- FAQs on Testing for SARS-CoV-2 (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests (/web/20250402150034/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests)