

## List of Waived Tests and Home Testing Kits Available

The following is a list of COVID-19 tests (Molecular and Antigen) available for CLIA-waived labs (most physician's offices - and denoted by a "W" in the authorized settings column) and for at-home collection where the patient then sends in the test to a lab for analysis. Most of these at-home tests still require a prescription. A number of them are now being done entirely at home by the patient (highlighted in blue). That is, where the patient picks up or is sent the test, performs the test, and reads the result at home. Many are being marketed DTC (Direct to Consumer). That is, "ask your doctor about..." (noted). There are also a few that are available OTC (noted) without a prescription. This selection will undoubtedly grow over time.

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date of Original EUA	Attributes	Authorized Settings*	Authorization Documents
Individual EUAs for Molecular (DNA) Diagnostic Tests for SARS-CoV-2					
9/17/2020	Abbott Diagnostics Scarborough, Inc.	<a href="#">ID NOW COVID-19</a>	RT, Isothermal amplification	H, M, W	HCP, Patients, IFU
2/13/2021	Assurance Scientific Laboratories	<a href="#">Assurance SARS-CoV-2 Panel DTC</a>	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP, Individuals, EUA Summary, IFU (Home Collect)
9/21/2020	Assurance Scientific Laboratories	<a href="#">Assurance SARS-CoV-2 Panel</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
3/3/2021	Ambry Genetics Laboratory	<a href="#">Ambry COVID-19 RT-PCR Test</a>	Real-time RT-PCR, Home Collection, Saliva	H	HCP, Patients, IFU (Home Collect), EUA Summary
3/2/2021	Binx Health, Inc.	<a href="#">Binx Health At-Home Nasal Swab COVID-19 Sample Collection Kit</a>	Home Collection Kit	H	EUA Summary, IFU
12/22/2020	BioFire Diagnostics, LLC	<a href="#">BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)</a>	RT, Nested multiplex PCR, Multi-analyte	H, M, W	HCP, Patients, IFU

\*H=High Complexity Lab, M=Moderate Complexity Lab, W=Waived test. Blue highlight means may need Rx, but test is totally done at home (taken and read).

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<b>Individual EUAs for Molecular (DNA) Diagnostic Tests for SARS-CoV-2 (cont.)</b>					
1/7/2021	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2 test</a>	Real-time RT-PCR	H, M, W	HCP, Patients, IFU for Labs, <a href="#">IFU for Point-of-Care</a>
1/27/2021	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2/Flu/RSV</a>	Real-time RT-PCR, Multi-analyte	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care
12/23/2020	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2 DoD</a>	Real-time RT-PCR, Pooling	H, M, W	HCP, Patients, EUA Summary
1/19/2021	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	<a href="#">Cleveland Clinic SARS-CoV-2 Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
2/26/2021	Clinical Enterprise, Inc.	<a href="#">EmpowerDX COVID-19 Home Collection Kit DTC</a>	Home Collection Kit, Direct to Consumer (DTC), Screening	H	EUA Summary, Individuals, IFU
7/30/2020	Clinical Reference Laboratory, Inc.	<a href="#">CRL Rapid Response</a>	Real-time RT-PCR, Home Collection, Saliva	H	HCP, Patients, EUA Summary, IFU (Home Collect)
3/5/2021	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	<a href="#">CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
12/18/2020	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	<a href="#">CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
3/19/2021	Color Health, Inc.	<a href="#">Color SARS-CoV-2 RT-LAMP Diagnostic Assay</a>	RT, LAMP, Home Collection, Screening	H	HCP, Patients, EUA Summary
3/19/2021	Color Health, Inc.	<a href="#">Color COVID-19 Self-Swab Collection Kit</a>	Home Collection Kit, Screening	H	EUA Summary, IFU
3/19/2021	Color Health, Inc.	<a href="#">Color COVID-19 Self-Swab Collection Kit DTC</a>	Home Collection Kit, Direct to Consumer (DTC), Screening	H	EUA Summary, Individuals, IFU

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3/19/2021	Color Health, Inc.	<a href="#">Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC</a>	Direct to Consumer (DTC), RT, LAMP, Home Collection, Screening	H	EUA Summary, Individuals, HCP
7/13/2020	Compass Laboratory Services, LLC	<a href="#">Compass Laboratory Services SARS-CoV2 Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary
8/20/2020	Cue Health Inc.	<a href="#">Cue COVID-19 Test</a>	RT, Isothermal amplification	H, M, W	HCP, Patients, IFU
3/5/2021	Cue Health Inc.	<a href="#">Cue COVID-19 Test for Home and Over The Counter (OTC) Use</a>	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test), FAQ
2/22/2021	DxTerity Diagnostics, Inc.	<a href="#">DxTerity SARS-CoV-2 RT PCR CE Test</a>	RT-PCR, Home Collection, Saliva	H	HCP, Patients, EUA Summary, IFU (Home Collect)
9/21/2020	Ethos Laboratories	<a href="#">Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay</a>	RT-PCR and MALDI-TOF Mass Spec., Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
9/4/2020	Everlywell, Inc.	<a href="#">Everlywell COVID-19 Test Home Collection Kit</a>	Home Collection Kit	H	IFU, EUA Summary
2/13/2021	Everlywell, Inc.	<a href="#">Everlywell COVID-19 Test Home Collection Kit DTC</a>	Home Collection Kit, Direct to Consumer (DTC), Screening	H	Individuals, EUA Summary, IFU (Home Collect)
9/21/2020	Exact Sciences Laboratories	<a href="#">SARS-CoV-2 (N gene detection) Test</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
2/26/2021	Fluidigm Corporation	<a href="#">Advanta Dx SARS-CoV-2 RT-PCR Assay</a>	Real-time RT-PCR, Saliva, Home Collection	H	HCP, Patients, IFU, IFU (Home Collect)
6/15/2020	Fulgent Therapeutics, LLC	<a href="#">Fulgent COVID-19 by RT-PCR Test</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
10/17/2020	Genetrack Biolabs, Inc.	<a href="#">Genetrack SARS-CoV-2 Molecular Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)

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<b>Individual EUAs for Molecular (DNA) Diagnostic Tests for SARS-CoV-2 (cont.)</b>					
3/9/2021	GetMyDNA	<a href="#">GetMyDNA COVID-19 Test Home Collection Kit</a>	Home Collection Kit, Direct to Consumer (DTC), Screening	H	EUA Summary, Individuals, IFU
9/21/2020	Gravity Diagnostics, LLC	<a href="#">Gravity Diagnostics COVID-19 Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary
12/28/2020	Gravity Diagnostics, LLC	<a href="#">Gravity Diagnostics SARS-CoV-2 RT-PCR Assay</a>	Real-time RT-PCR, Home Collection, Screening, Saliva	H	HCP, Patients, EUA Summary
3/9/2021	Gravity Diagnostics, LLC	<a href="#">Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits</a>	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP, Individuals, EUA Summary
10/22/2020	Helix OpCo LLC	<a href="#">Helix COVID-19 Test</a>	Real-time RT-PCR, Home Collection, Screening	H	HCP, Patients, EUA Summary, IFU (Home Collect)
3/11/2021	Infinity BiologiX LLC	<a href="#">Infinity BiologiX TaqPath SARS-CoV-2 Assay</a>	Real-time RT-PCR, Home Collection, Saliva	H	HCP, Patients, IFU (Home Collect), EUA Summary
9/9/2020	Kaiser Permanente Mid-Atlantic States	<a href="#">KPMAS COVID-19 Test</a>	Real-time RT-PCR, Home Collection, Screening	H	HCP, Patients, EUA Summary, IFU (Home Collect)
12/9/2020	Laboratory Corporation of America (LabCorp)	<a href="#">COVID-19 RT-PCR Test</a>	Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP, Patients, EUA Summary, IFU LabCorp Home Collect
12/9/2020	Laboratory Corporation of America (LabCorp)	<a href="#">Pixel by LabCorp COVID-19 Test Home Collection Kit</a>	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Pooling, Screening	H	HCP, Individuals, EUA Summary, IFU (Home Collect)
3/18/2021	LetsGetChecked, Inc.	<a href="#">LetsGetChecked Coronavirus (COVID-19) Test</a>	Direct to Consumer (DTC), TMA, chemiluminescent, Home Collection, Screening	H	HCP, Individuals, EUA Summary, IFU (Home Collect)

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11/18/2020	Lucira Health, Inc.	<a href="#">Lucira COVID-19 All-In-One Test Kit</a>	Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
3/1/2021	Phosphorus Diagnostics LLC	<a href="#">Phosphorus COVID-19 RT-qPCR Test</a>	Real-time RT-PCR, Home Collection, Saliva	H	HCP, Patients, EUA Summary, IFU (Home Collect), IFU (Clinic)
2/8/2021	QDx Pathology Services	<a href="#">QDX SARS-CoV-2 Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
8/21/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics PF SARS-CoV-2 Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
11/27/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics RC SARS-CoV-2 Assay</a>	Real-time RT-PCR, Home Collection, Pooling	H	HCP, Patients, EUA Summary, IFU (Home Collect)
8/21/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics HA SARS-CoV-2 Assay</a>	TMA, chemiluminescent, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
12/4/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics RC COVID-19+Flu RT-PCR</a>	Real-time RT-PCR, Multi-analyte, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collection)
11/23/2020	RapidRona, Inc.	<a href="#">RapidRona Self-Collection Kit</a>	Home Collection Kit	H	EUA Summary, IFU (Collection)
2/12/2021	RCA Laboratory Services LLC dba GENETWORx	<a href="#">GENETWORx Covid-19 Nasal Swab Test</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
12/11/2020	ResearchDx, Inc., DBA Pacific Diagnostics	<a href="#">PacificDx Covid-19</a>	TMA, chemiluminescent, Home Collection	H	HCP, Patients, EUA Summary
11/24/2020	Stanford Health Care Clinical Virology Laboratory	<a href="#">SARS-CoV-2 RT-PCR Assay</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collection)
2/13/2021	The Kroger Co.	<a href="#">Kroger Health COVID-19 Test Home Collection Kit</a>	Home Collection Kit, Direct to Consumer (DTC), Screening	H	Individuals, IFU, EUA Summary

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2/23/2021	Thermo Fisher Scientific, Inc.	<a href="#">TaqPath COVID-19 Combo Kit</a>	Real-time RT-PCR, Home Collection	H	HCP, Patients, IFU
12/22/2020	Verily Life Sciences	<a href="#">Verily COVID-19 RT-PCR Test</a>	Real-time RT-PCR, Pooling, Home Collection	H	HCP, Patients, EUA Summary, IFU (Home Collect)
2/26/2021	Viracor Eurofins Clinical Diagnostics	<a href="#">Viracor SARS-CoV-2 assay DTC</a>	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening	H	HCP, Individuals, EUA Summary
2/8/2021	Visby Medical, Inc.	<a href="#">Visby Medical COVID-19 Point of Care Test</a>	RT-PCR	H, M, W	HCP, Patients, IFU, IFU (Collect)
10/20/2020	Wren Laboratories LLC	<a href="#">Wren Laboratories COVID-19 PCR Test</a>	Real-time RT-PCR, Home Collection, Saliva	H	HCP, Patients, EUA Summary, IFU (Home Collect)
<b>Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2</b>					
3/15/2021	Access Bio, Inc.	<a href="#">CareStart COVID-19 Antigen test</a>	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
3/1/2021	Quidel Corporation	<a href="#">QuickVue At-Home COVID-19 Test</a>	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, Patients, IFU, IFU (Home Test)
2/22/2021	Becton, Dickinson and Company (BD)	<a href="#">BD Veritor System for Rapid Detection of SARS-CoV-2</a>	Chromatographic Digital Immunoassay, Instrument Read	H, M, W	HCP, Patients, IFU
2/11/2021	Ellume Limited	<a href="#">Ellume COVID-19 Home Test</a>	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test), FAQ
2/4/2021	Princeton BioMeditech Corp.	<a href="#">Status COVID-19/Flu</a>	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP, Patients, IFU
1/26/2021	LumiraDx UK Ltd.	<a href="#">LumiraDx SARS-CoV-2 Ag Test</a>	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP, Patients, IFU

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12/22/2020	Quidel Corporation	<a href="#">QuickVue SARS Antigen Test</a>	Lateral Flow, Visual Read	H, M, W	<a href="#">HCP, Patients, IFU</a>
12/16/2020	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card</a>	Lateral Flow, Visual Read	H, M, W	<a href="#">HCP, Patients, IFU</a>
12/16/2020	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card Home Test</a>	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
12/7/2020	Luminostics, Inc.	<a href="#">Clip COVID Rapid Antigen Test</a>	Lateral flow immunoluminescent assay, instrument read	H, M, W	<a href="#">HCP, Patients, IFU</a>
10/2/2020	Quidel Corporation	<a href="#">Sofia 2 Flu + SARS Antigen FIA</a>	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W	<a href="#">HCP, Patients, IFU</a>
7/17/2020	Quidel Corporation	<a href="#">Sofia SARS Antigen FIA</a>	Lateral Flow, Fluorescence, Instrument Read	H, M, W	<a href="#">HCP, Patients, IFU</a>