



## Point-of-Care Tests for COVID-19

### Molecular Diagnostic Tests for SARS-CoV-2

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes <sup>3</sup>	Authorized Setting(s) <sup>1</sup>	Authorization Documents <sup>2</sup>
03/21/2022	Quest Diagnostics Nichols Institute	<a href="#">Quest COVID-19 PCR Test Home Collection Kit</a> 03/21/2022	Direct to Consumer (DTC), Home Collection Kit	N/A	<a href="#">EUA Summary</a> , <a href="#">IFU</a> , <a href="#">Individuals</a>
03/03/2022	Diversified Medical Healthcare	<a href="#">RapidRona Self-Collection Kit</a> 11/23/2020	Home Collection Kit	N/A	<a href="#">EUA Summary</a> , <a href="#">IFU (Collection)</a>
03/01/2022	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	<a href="#">SalivaDirect At-Home Collection Kit</a> 04/09/2021	Home Collection Kit, Saliva, Screening	N/A	<a href="#">EUA Summary</a> , <a href="#">IFU-1</a> , <a href="#">IFU-2</a>
02/23/2022	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	<a href="#">SalivaDirect DTC Saliva Collection Kit</a> 08/27/2021	Direct to Consumer (DTC), Home Collection Kit, Saliva, Screening	N/A	<a href="#">Individual</a> , <a href="#">IFU-1</a> , <a href="#">IFU-2</a> , <a href="#">EUA Summary</a>

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01/31/2022	Color Health, Inc.	<a href="#">Color COVID-19 Self-Swab Collection Kit with Saline</a> 04/14/2021	Home Collection Kit, Screening	N/A	<a href="#">EUA Summary, IFU</a>
01/26/2022	Color Health, Inc.	<a href="#">Color COVID-19 Self-Swab Collection Kit</a> 08/31/2020	Home Collection Kit, Screening, Multiple Targets	N/A	<a href="#">EUA Summary, IFU</a>
01/26/2022	Color Health, Inc.	<a href="#">Color COVID-19 Self-Swab Collection Kit DTC</a> 03/19/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	<a href="#">EUA Summary, Individuals, IFU</a>
12/14/2021	Quest Diagnostics Nichols Institute	<a href="#">Quest Diagnostics Collection Kit for COVID-19</a> 10/08/2021	Home Collection Kit	N/A	<a href="#">EUA Summary, IFU</a>
11/30/2021	Audere	<a href="#">HealthPulse@home</a> 11/30/2021	Home Collection Kit, Screening, Single Target	N/A	<a href="#">EUA Summary, IFU</a>

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11/29/2021	Kwokman Diagnostics, LLC	<a href="#">Kwokman Diagnostics COVID-19 Home Collection Kit</a> 08/13/2021	Home Collection Kit	N/A	<a href="#">IFU, EUA Summary</a>
08/13/2021	binx health, Inc.	<a href="#">binx health At-Home Nasal Swab COVID-19 Sample Collection Kit</a> 10/20/2020	Home Collection Kit	N/A	<a href="#">EUA Summary, IFU</a>
08/04/2021	Spectrum Solutions LLC	<a href="#">SDNA-1000 Saliva Collection Device</a> 10/08/2020	Saliva Collection Device	N/A	<a href="#">EUA Summary, IFU</a>
07/01/2021	Everlywell, Inc.	<a href="#">Everlywell COVID-19 Test Home Collection Kit DTC</a> 02/13/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	<a href="#">Individuals, EUA Summary, IFU (Home Collect)</a>
07/01/2021	Everlywell, Inc.	<a href="#">Everlywell COVID-19 &amp; Flu Test Home Collection Kit</a> 07/01/2021	Home Collection Kit, Multi-analyte	N/A	<a href="#">IFU, EUA Summary</a>

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06/17/2021	WREN Laboratories LLC	<a href="#">WREN Laboratories COVID-19 Saliva Test Collection Kit DTC</a> 06/17/2021	Direct to Consumer (DTC), Home Collection Kit, Saliva, Screening, Multiple Targets	N/A	<a href="#">Individuals, EUA Summary, IFU</a>
06/10/2021	Clinical Enterprise, Inc.	<a href="#">EmpowerDX COVID-19 Home Collection Kit DTC</a> 10/15/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	<a href="#">EUA Summary, Individuals, IFU</a>
06/03/2021	Everlywell, Inc.	<a href="#">Everlywell COVID-19 Test Home Collection Kit</a> 05/15/2020	Home Collection Kit	N/A	<a href="#">IFU, EUA Summary</a>
05/26/2021	GetMyDNA	<a href="#">GetMyDNA COVID-19 Test Home Collection Kit</a> 03/09/2021	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	<a href="#">EUA Summary, Individuals, IFU</a>
05/19/2021	The Kroger Co.	<a href="#">Kroger Health COVID-19 Test Home Collection Kit</a> 06/30/2020	Home Collection Kit, Direct to Consumer (DTC), Screening	N/A	<a href="#">Individuals, IFU, EUA Summary</a>

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05/17/2021	Phosphorus Diagnostics LLC	<a href="#">Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC</a> 05/17/2021	Direct to Consumer (DTC), Home Collection Kit, Saliva, Screening, Multiple Targets	N/A	<a href="#">Individual</a> , <a href="#">EUA Summary</a> , <a href="#">IFU</a>
10/28/2020	DNA Genotek Inc.	<a href="#">ORAcollection-RNA OR-100 and ORAcollection-RNA ORE-100 saliva collection devices</a> 10/28/2020	Saliva Collection Device	N/A	<a href="#">EUA Summary</a> , <a href="#">IFU</a>
10/28/2020	DNA Genotek Inc.	<a href="#">OMNIgene-ORAL OM-505 and OME-505 (OMNIgene-ORAL) saliva collection devices</a> 10/14/2020	Saliva Collection Device	N/A	<a href="#">EUA Summary</a> , <a href="#">IFU</a>
04/11/2022	Detect, Inc.	<a href="#">Detect Covid-19 Test</a> 10/28/2021	RT, LAMP, Lateral Flow Strips, Over the Counter (OTC) Home Testing, Serial	Home, H, M, W	<a href="#">HCP</a> , <a href="#">Individuals</a> , <a href="#">IFU</a> , <a href="#">IFU (Home Test)</a>

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			Screening, Single Target		
03/31/2022	Lucira Health, Inc.	<a href="#">Lucira CHECK-IT COVID-19 Test Kit</a> 04/09/2021	RT, LAMP, Over the Counter (OTC) Home Testing, Screening, Multiple Targets	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
02/09/2022	Cue Health Inc.	<a href="#">Cue COVID-19 Test for Home and Over The Counter (OTC) Use</a> 03/05/2021	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening, Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test), FAQ</a>
11/18/2020	Lucira Health, Inc.	<a href="#">Lucira COVID-19 All-In-One Test Kit</a> 11/17/2020	Prescription Home Testing, Multiple Targets	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
03/25/2022	Uh-Oh Labs Inc.	<a href="#">UOL COVID-19 Test</a> 02/08/2022	RT-LAMP, Single Target	H, M, W	<a href="#">HCP, Patients, IFU</a>

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03/24/2022	Roche Molecular Systems, Inc.	<a href="#">cobas SARS-CoV-2 &amp; Influenza A/B Nucleic Acid Test for use on the cobas Liat System</a> 09/14/2020	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
03/15/2022	Minute Molecular Diagnostics, Inc.	<a href="#">DASH SARS-CoV-2/S Test</a> 03/15/2022	Real-time RT-PCR, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
03/01/2022	Cue Health Inc.	<a href="#">Cue COVID-19 Test</a> 06/10/2020	RT, Isothermal amplification, Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
01/04/2022	Roche Molecular Systems	<a href="#">cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2)</a> 06/17/2021	Real-time RT-PCR, Screening, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>

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11/10/2021	Talis Biomedical Corporation	<a href="#">Talis One COVID-19 Test System</a> 11/05/2021	RT, Isothermal amplification, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
10/20/2021	Cepheid	<a href="#">Xpert Xpress CoV-2/Flu/RSV plus</a> 09/10/2021	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU for Labs</a> , <a href="#">IFU for Point-of-Care</a>
08/30/2021	BioFire Diagnostics, LLC	<a href="#">BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)</a> 10/02/2020	RT, Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
08/27/2021	Abbott Diagnostics Scarborough, Inc.	<a href="#">ID NOW COVID-19</a> 03/27/2020	RT, Isothermal amplification, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
02/08/2021	Visby Medical, Inc.	<a href="#">Visby Medical COVID-19 Point of Care Test</a> 02/08/2021	RT-PCR, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a> , <a href="#">IFU (Collect)</a>
02/03/2021	Mesa Biotech Inc.	<a href="#">Accula SARS-Cov-2 Test</a> 03/23/2020	RT and amplification, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>



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01/27/2021	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2/Flu/RSV</a> 09/24/2020	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	<a href="#">HCP, Patients, IFU for Labs, IFU for Point-of-Care</a>
01/07/2021	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2 test</a> 03/20/2020	Real-time RT-PCR, Multiple Targets	H, M, W	<a href="#">HCP, Patients, IFU for Labs, IFU for Point-of-Care</a>
12/23/2020	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2 DoD</a> 12/23/2020	Real-time RT-PCR, Pooling, Multiple Targets	H, M, W	<a href="#">HCP, Patients, EUA Summary</a>

## Antigen Diagnostic Tests for SARS-CoV-2

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04/12/2022	iHealth Labs, Inc.	<a href="#">iHealth COVID-19 Antigen Rapid Test</a> 11/05/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
04/12/2022	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card Home Test</a> 12/16/2020	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test)</a>
04/12/2022	InBios International Inc.	<a href="#">SCoV-2 Ag Detect Rapid Self-Test</a> 11/22/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
04/07/2022	Xiamen Boson Biotech Co., Ltd.”	<a href="#">Rapid SARS-CoV-2 Antigen Test Card</a> 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>

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04/06/2022	OSANG LLC	<a href="#">OHC COVID-19 Antigen Self Test</a> 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
04/04/2022	SD Biosensor, Inc.	<a href="#">Pilot COVID-19 At-Home Test</a> 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
04/04/2022	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Antigen Self Test</a> 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test)</a>
03/30/2022	Maxim Biomedical, Inc.	<a href="#">MaximBio ClearDetect COVID-19 Antigen Home Test</a> 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>

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03/25/2022	Becton, Dickinson and Company (BD)	<a href="#">BD Veritor At-Home COVID-19 Test</a> 8/24/2021	Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test)</a>
03/25/2022	Access Bio, Inc.	<a href="#">CareStart COVID-19 Antigen Home Test</a> 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
03/23/2022	Celltrion USA, Inc.	<a href="#">Celltrion DiaTrust COVID-19 Ag Home Test</a> 10/21/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Multiple Targets	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
03/23/2022	Siemens Healthineers	<a href="#">CLINITEST Rapid COVID-19 Antigen Self-Test</a> 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>

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03/18/2022	Ellume Limited	<a href="#">Ellume COVID-19 Home Test</a> 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a> , <a href="#">FAQ</a>
03/16/2022	PHASE Scientific International, Ltd.	<a href="#">INDICAID COVID-19 Rapid Antigen At-Home Test</a> 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
02/18/2022	ACON Laboratories, Inc	<a href="#">Flowflex COVID-19 Antigen Home Test</a> 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Screening, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
01/27/2022	OraSure Technologies, Inc.	<a href="#">InteliSwab COVID-19 Rapid Test Rx</a> 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	<a href="#">HCP, IFU, IFU (Home Test)</a>
01/27/2022	OraSure Technologies, Inc.	<a href="#">InteliSwab COVID-19 Rapid Test</a> 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test)</a>

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10/21/2021	Quidel Corporation	<a href="#">QuickVue At-Home OTC COVID-19 Test</a> 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	<a href="#">HCP, Individuals, IFU, IFU (Home Test)</a>
03/01/2021	Quidel Corporation	<a href="#">QuickVue At-Home COVID-19 Test</a> 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	<a href="#">HCP, Patients, IFU, IFU (Home Test)</a>
03/04/2022	Luminostics, Inc.	<a href="#">Clip COVID Rapid Antigen Test</a> 12/07/2020	Lateral flow immunoluminescent assay, instrument read, Single Target	H, M, W	<a href="#">HCP, Patients, IFU</a>
03/03/2022	InBios International, Inc.	<a href="#">SCoV-2 Ag Detect Rapid Test</a> 05/06/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP, Patients, IFU</a>
02/28/2022	Oceanit Foundry LLC	<a href="#">ASSURE-100 Rapid COVID-19 Test</a> 02/28/2022	Lateral Flow, Visual Read, Single Target	H, M, W	<a href="#">HCP, Patients, IFU</a>

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02/22/2022	PHASE Scientific International, Ltd.	<a href="#">INDICAID COVID-19 Rapid Antigen Test</a> 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
02/17/2022	LumiraDx UK Ltd.	<a href="#">LumiraDx SARS-CoV-2 Ag Test</a> 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
02/04/2022	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag Card</a> 08/26/2020	Lateral Flow, Visual Read, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
02/04/2022	Abbott Diagnostics Scarborough, Inc.	<a href="#">BinaxNOW COVID-19 Ag 2 Card</a> 03/31/2021	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
02/01/2022	Nano-Ditech Corp.	<a href="#">Nano-Check COVID-19 Antigen</a>	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>

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		<a href="#">Test</a> 12/06/2021			
01/27/2022	OraSure Technologies, Inc.	<a href="#">InteliSwab COVID-19 Rapid Test Pro</a> 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
01/14/2022	iHealth Labs, Inc.	<a href="#">iHealth COVID-19 Antigen Rapid Test Pro</a> 01/14/2022	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
12/17/2021	Salofa Oy	<a href="#">Sienna-Clarity COVID-19 Antigen Rapid Test Cassette</a> 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
12/10/2021	Becton, Dickinson and	<a href="#">BD Veritor System for Rapid Detection of SARS-</a>	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>



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	Company (BD)	<a href="#">CoV-2</a> 07/02/2020			
12/02/2021	Access Bio, Inc.	<a href="#">CareStart COVID-19 Antigen test</a> 10/08/2020	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
11/17/2021	GenBody Inc.	<a href="#">GenBody COVID-19 Ag</a> 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
11/09/2021	Quidel Corporation	<a href="#">QuickVue SARS Antigen Test</a> 12/18/2020	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
10/27/2021	Princeton BioMeditech Corp.	<a href="#">Status COVID-19/Flu A&amp;B</a> 02/04/2021	Lateral Flow, Visual Read, Multi-analyte, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>

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10/12/2021	Xtrava Health	<a href="#">SPERA COVID-19 Ag Test</a> 10/12/2021	Lateral Flow, Visual Read, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
09/24/2021	ANP Technologies, Inc	<a href="#">NIDS COVID-19 Antigen Rapid Test Kit</a> 09/24/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
09/01/2021	Celltrion USA, Inc.	<a href="#">Celltrion DiaTrust COVID-19 Ag Rapid Test</a> 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
07/08/2021	Ellume Limited	<a href="#">ellume.lab COVID Antigen Test</a> 07/08/2021	Lateral Flow, Fluorescence, Instrument Read, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>
06/11/2021	Quidel Corporation	<a href="#">Sofia SARS Antigen FIA</a> 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening, Single Target	H, M, W	<a href="#">HCP</a> , <a href="#">Patients</a> , <a href="#">IFU</a>

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03/24/2021	Becton, Dickinson and Company (BD)	<a href="#">BD Veritor System for Rapid Detection of SARS-CoV-2 &amp; Flu A+B</a> 03/24/2021	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte, Single Target	H, M, W	<a href="#">HCP, Patients, IFU Viral Mutation Revision Letter - September 23, 2021</a>
10/02/2020	Quidel Corporation	<a href="#">Sofia 2 Flu + SARS Antigen FIA</a> 10/02/2020	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte, Single Target	H, M, W	<a href="#">HCP, Patients, IFU</a>

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

<b>Date EUA Issued or Last Updated</b>	<b>Entity</b>	<b>Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued</b>	<b>Attributes<sup>3</sup></b>	<b>Authorized Setting(s)<sup>1</sup></b>	<b>Authorization Documents<sup>2</sup></b>
03/09/2022	Megna Health, Inc.	<a href="#">Rapid COVID-19 IgM/IgG Combo Test Kit</a> 07/17/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
02/01/2022	NOWDiagnostics, Inc.	<a href="#">ADEXUSDx COVID-19 Test</a> 05/24/2021	Total Antibody, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
01/31/2022	Assure Tech. (Hangzhou Co., Ltd)	<a href="#">Assure COVID-19 IgG/IgM Rapid Test Device</a> 07/06/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
11/19/2021	Sugentech, Inc.	<a href="#">SGTi-flex COVID-19 IgG</a> 09/03/2020	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
11/02/2021	Nirmidas Biotech, Inc.	<a href="#">MidaSpot COVID-19 Antibody Combo Detection Kit</a> 12/31/2020	IgM and IgG, lateral flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
08/24/2021	InBios International, Inc	<a href="#">SCoV-2 Detect IgG Rapid Test</a> 08/24/2021	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>

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08/12/2021	Access Bio, Inc.	<a href="#">CareStart COVID-19 IgM/IgG</a> 07/24/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
08/10/2021	Diabetomics, Inc.	<a href="#">CovAb SARS-CoV-2 Ab Test</a> 06/04/2021	Total Antibody, Lateral Flow, Oral Fluid	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
08/02/2021	LumiraDx UK Ltd.	<a href="#">LumiraDx SARS-CoV-2 Ab Test</a> 08/02/2021	Total Antibody, Fluorescence Immunoassay, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
07/12/2021	Salofa Oy	<a href="#">Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette</a> 07/13/2020	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
06/24/2021	Access Bio, Inc.	<a href="#">CareStart EZ COVID-19 IgM/IgG</a> 06/24/2021	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>
04/26/2021	ADVAITE, Inc.	<a href="#">RapCov Rapid COVID-19 Test</a> 01/11/2021	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes <sup>3</sup>	Authorized Setting(s) <sup>1</sup>	Authorization Documents <sup>2</sup>
12/21/2020	Hangzhou Biotest Biotech Co., Ltd.	<a href="#">RightSign COVID-19 IgG/IgM Rapid Test Cassette</a> 06/04/2020	IgM and IgG Lateral Flow, Fingerstick Whole Blood	H, M, W	<a href="#">HCP</a> , <a href="#">Recipients</a> , <a href="#">IFU</a>