In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20210613103436/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210613103436/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210613103436/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)
- IVDs for Management of COVID-19 Patients (/web/20210613103436/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)

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]
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20210613103436/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20210613103436/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210613103436/https://ww Individuals (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20210613103436/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww

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]
+ 05/20/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20210613103436/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 05/11/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20210613103436/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 05/06/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20210613103436/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/20/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20210613103436/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/15/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20210613103436/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/15/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20210613103436/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/14/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20210613103436/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/13/2021	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20210613103436/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H, M	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 04/12/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20210613103436/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 04/01/2021	Quidel Corporation	Sofia SARS Antigen FIA (/web/20210613103436/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww

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]
+ 04/01/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20210613103436/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210613103436/https://ww Individuals (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 03/31/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20210613103436/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210613103436/https://ww Individuals (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test (/web/20210613103436/https://www.fda.gov/media/147256/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP (/web/20210613103436/https://ww Individuals (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww
+ 03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20210613103436/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 03/26/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20210613103436/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA	H, M	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 03/24/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B (/web/20210613103436/https://www.fda.gov/media/147013/download) 03/24/2021	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 03/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20210613103436/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescence Immunoassay, Instrument Read	H, M	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 03/01/2021	Quidel Corporation	QuickVue At-Home COVID-19 Test (/web/20210613103436/https://www.fda.gov/media/146309/download) 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww

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]
+ 02/11/2021	Ellume Limited	Ellume COVID-19 Home Test (/web/20210613103436/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/20210613103436/https://ww (/web/20210613103436/https://ww (Home Test) (/web/20210613103436/https://ww FAQ (/web/20210613103436/https://ww
+ 02/04/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu (/web/20210613103436/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 01/05/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20210613103436/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay	H, M	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww
+ 12/22/2020	Quidel Corporation	QuickVue SARS Antigen Test (/web/20210613103436/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210613103436/https://ww Patients (/web/20210613103436/https://ww (/web/20210613103436/https://ww

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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.

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

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- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210823011136/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210823011136/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)
- IVDs for Management of COVID-19 Patients (/web/20210823011136/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)

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

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To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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+ 08/10/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20210823011136/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210823011136/https://ww Individuals (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww
+ 08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20210823011136/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read	H, M	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww

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]
+ 08/02/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20210823011136/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210823011136/https://ww Individuals (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww
+ 07/28/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20210823011136/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 07/26/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20210823011136/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 07/16/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20210823011136/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 07/13/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20210823011136/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 07/12/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20210823011136/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA	H, M	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 07/08/2021	Ellume Limited	ellume.lab COVID Antigen Test (/web/20210823011136/https://www.fda.gov/media/150684/download) 07/08/2021	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 06/11/2021	Quidel Corporation	Sofia SARS Antigen FIA (/web/20210823011136/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20210823011136/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww

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+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20210823011136/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210823011136/https://ww Individuals (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20210823011136/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 05/20/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20210823011136/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 05/11/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20210823011136/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 05/06/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20210823011136/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 04/20/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20210823011136/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 04/15/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20210823011136/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 04/14/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20210823011136/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 04/13/2021	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20210823011136/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H, M	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww

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+ 03/31/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20210823011136/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210823011136/https://ww Individuals (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww
+ 03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test (/web/20210823011136/https://www.fda.gov/media/147256/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP (/web/20210823011136/https://ww Individuals (/web/20210823011136/https://ww (/web/20210823011136/https://ww (Home Test) (/web/20210823011136/https://ww
+ 03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20210823011136/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww
+ 03/24/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B (/web/20210823011136/https://www.fda.gov/media/147013/download) 03/24/2021	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte	H, M, W	HCP (/web/20210823011136/https://ww Patients (/web/20210823011136/https://ww (/web/20210823011136/https://ww

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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.

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20210916074908/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20210916074908/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20210916074908/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)
- IVDs for Management of COVID-19 Patients (/web/20210916074908/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)

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).

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 09/10/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20210916074908/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Serial Screening, Saliva	H, M	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20210916074908/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww

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]
+ 09/01/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20210916074908/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 08/24/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20210916074908/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 08/23/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20210916074908/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 08/10/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20210916074908/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20210916074908/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read	H, M	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 07/28/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20210916074908/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 07/26/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20210916074908/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 07/16/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20210916074908/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 07/13/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20210916074908/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww

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]
+ 07/12/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20210916074908/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA	H, M	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 07/08/2021	Ellume Limited	ellume.lab COVID Antigen Test (/web/20210916074908/https://www.fda.gov/media/150684/download) 07/08/2021	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 06/11/2021	Quidel Corporation	Sofia SARS Antigen FIA (/web/20210916074908/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20210916074908/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20210916074908/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20210916074908/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 05/20/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20210916074908/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 04/20/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20210916074908/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 04/15/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20210916074908/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww

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]
+ 04/14/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20210916074908/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 04/13/2021	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20210916074908/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H, M	HCP (/web/20210916074908/https://ww Patients (/web/20210916074908/https://ww (/web/20210916074908/https://ww
+ 04/12/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20210916074908/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 03/31/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20210916074908/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww
+ 03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test (/web/20210916074908/https://www.fda.gov/media/147256/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP (/web/20210916074908/https://ww Individuals (/web/20210916074908/https://ww (/web/20210916074908/https://ww (Home Test) (/web/20210916074908/https://ww

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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.

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20211006033735/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20211006033735/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211006033735/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)
- IVDs for Management of COVID-19 Patients (/web/20211006033735/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)

On This Page:

- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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]
+ 10/04/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20211006033735/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing	Home, H, M, W	HCP (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww

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]
+ 09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20211006033735/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 09/24/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20211006033735/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 09/10/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20211006033735/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Serial Screening, Saliva	H, M	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20211006033735/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 09/01/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20211006033735/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 08/24/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20211006033735/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20211006033735/https://ww Individuals (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww
+ 08/23/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20211006033735/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20211006033735/https://ww Individuals (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww

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]
+ 08/10/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20211006033735/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20211006033735/https://ww Individuals (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww
+ 08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20211006033735/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read	H, M	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 07/28/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20211006033735/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 07/26/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20211006033735/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 07/16/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20211006033735/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 07/12/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20211006033735/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA	H, M	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 07/08/2021	Ellume Limited	ellume.lab COVID Antigen Test (/web/20211006033735/https://www.fda.gov/media/150684/download) 07/08/2021	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 06/11/2021	Quidel Corporation	Sofia SARS Antigen FIA (/web/20211006033735/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww

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]
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20211006033735/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20211006033735/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP (/web/20211006033735/https://ww Individuals (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww
+ 06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20211006033735/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 05/20/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20211006033735/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 04/20/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20211006033735/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 04/15/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20211006033735/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 04/14/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20211006033735/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww
+ 04/13/2021	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20211006033735/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H, M	HCP (/web/20211006033735/https://ww Patients (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww

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]
+ 04/12/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20211006033735/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP (/web/20211006033735/https://ww IFU (/web/20211006033735/https://ww IFU (Home Test) (/web/20211006033735/https://ww

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20211006033735/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20211006033735/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20211125124414/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20211125124414/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20211125124414/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211125124414/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)
- IVDs for Management of COVID-19 Patients (/web/20211125124414/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20211125124414/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/22/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20211125124414/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20211125124414/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20211125124414/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20211125124414/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read
+ 11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20211125124414/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20211125124414/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening
+ 11/08/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20211125124414/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/05/2021	iHealth Labs, (/web/20211125124414/https://www.fda.gov/media/153925/download)Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20211125124414/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20211125124414/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20211125124414/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening
+ 10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B (/web/20211125124414/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visua Read, Multi-analyte
+ 10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20211125124414/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20211125124414/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/19/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20211125124414/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening
+ 10/12/2021	Xtrava Health	SPERA COVID-19 Ag Test (/web/20211125124414/https://www.fda.gov/media/153093/download) 10/12/2021	Lateral Flow, Visua Read
+ 09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20211125124414/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visua Read, Serial Screening
+ 09/10/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20211125124414/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20211125124414/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 09/01/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20211125124414/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visua Read, Serial Screening
+ 08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20211125124414/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flov Fluorescence, Instrument Read
+ 07/16/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20211125124414/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening
+ 07/12/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20211125124414/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA
+ 07/08/2021	Ellume Limited	ellume.lab COVID Antigen Test (/web/20211125124414/https://www.fda.gov/media/150684/download) 07/08/2021	Lateral Flow, Fluorescence, Instrument Read
+ 06/11/2021	Quidel Corporation	Sofia SARS Antigen FIA (/web/20211125124414/https://www.fda.gov/media/137886/download) 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening

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[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.

Revision Concerning Viral Mutations

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The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20211125124414/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20211125124414/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20211222003603/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20211222003603/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20211222003603/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211222003603/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)
- IVDs for Management of COVID-19 Patients (/web/20211222003603/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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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Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20211222003603/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20211222003603/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening
+ 12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20211222003603/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20211222003603/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening
+ 12/01/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20211222003603/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/30/2021	iHealth Labs, (/web/20211222003603/https://www.fda.gov/media/153925/download) Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20211222003603/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20211222003603/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20211222003603/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20211222003603/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20211222003603/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20211222003603/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20211222003603/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening
+ 11/08/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20211222003603/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20211222003603/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20211222003603/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening
+ 10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B (/web/20211222003603/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visua Read, Multi-analyte
+ 10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20211222003603/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20211222003603/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/19/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20211222003603/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening

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+ 09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20211222003603/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visua Read, Serial Screening
+ 09/10/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20211222003603/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20211222003603/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening
+ 09/01/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20211222003603/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visua Read, Serial Screening
+ 08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20211222003603/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flov Fluorescence, Instrument Read

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Viral Mutation Revision Letter – September 23, 2021 (/web/20211222003603/https://www.fda.gov/about-fda/page-not-found)

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20211231001554/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20211231001554/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20211231001554/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)
- IVDs for Management of COVID-19 Patients (/web/20211231001554/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/29/2021	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20211231001554/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/24/2021	SD Biosensor, Inc.	COVID-19 At-Home Test (/web/20211231001554/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/22/2021	iHealth Labs, (/web/20211231001554/https://www.fda.gov/media/153925/download) Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20211231001554/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20211231001554/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20211231001554/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20211231001554/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening
+ 12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20211231001554/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20211231001554/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening
+ 12/01/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20211231001554/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20211231001554/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20211231001554/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20211231001554/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20211231001554/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read
+ 11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20211231001554/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20211231001554/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening
+ 11/08/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20211231001554/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20211231001554/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20211231001554/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening
+ 10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B (/web/20211231001554/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visua Read, Multi-analyte

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20211231001554/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20211231001554/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/19/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20211231001554/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening
+ 10/12/2021	Xtrava Health	SPERA COVID-19 Ag Test (/web/20211231001554/https://www.fda.gov/media/153093/download) 10/12/2021	Lateral Flow, Visua Read
+ 09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20211231001554/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visua Read, Serial Screening
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20211231001554/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20211231001554/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20211231001554/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220109034804/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220109034804/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220109034804/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220109034804/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)
- IVDs for Management of COVID-19 Patients (/web/20220109034804/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220109034804/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/29/2021	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220109034804/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/24/2021	SD Biosensor, Inc.	COVID-19 At-Home Test (/web/20220109034804/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/22/2021	iHealth Labs, (/web/20220109034804/https://www.fda.gov/media/153925/download)Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220109034804/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20220109034804/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220109034804/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20220109034804/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening
+ 12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20220109034804/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20220109034804/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening
+ 12/01/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220109034804/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220109034804/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220109034804/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20220109034804/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20220109034804/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read
+ 11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220109034804/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20220109034804/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening
+ 11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220109034804/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220109034804/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening
+ 10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B (/web/20220109034804/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visua Read, Multi-analyte

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220109034804/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220109034804/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/19/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220109034804/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening
+ 10/12/2021	Xtrava Health	SPERA COVID-19 Ag Test (/web/20220109034804/https://www.fda.gov/media/153093/download) 10/12/2021	Lateral Flow, Visua Read
+ 09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20220109034804/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visua Read, Serial Screening
+ 09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20220109034804/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220109034804/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220109034804/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220118005025/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220118005025/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220118005025/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220118005025/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)
- IVDs for Management of COVID-19 Patients (/web/20220118005025/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)

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To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the “Date EUA Issued or Last Updated” for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20220118005025/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visua Read

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220118005025/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visua Read, Prescription Home Testing, Telehealth Proctor Supervised
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220118005025/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test (/web/20220118005025/https://www.fda.gov/media/147256/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Telehealth Proctor Supervisec Serial Screening
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20220118005025/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visua Read, Non-prescription Testin Serial Screening
+ 01/05/2022	SD Biosensor, Inc.	COVID-19 At-Home Test (/web/20220118005025/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/29/2021	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220118005025/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/22/2021	iHealth Labs, (/web/20220118005025/https://www.fda.gov/media/153925/download) Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220118005025/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20220118005025/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220118005025/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20220118005025/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening
+ 12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20220118005025/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20220118005025/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening
+ 12/01/2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220118005025/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220118005025/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220118005025/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20220118005025/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20220118005025/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read
+ 11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220118005025/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20220118005025/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening
+ 11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220118005025/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220118005025/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening
+ 10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B (/web/20220118005025/https://www.fda.gov/media/145694/download) 02/04/2021	Lateral Flow, Visua Read, Multi-analyte
+ 10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220118005025/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening
+ 10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220118005025/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220118005025/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220118005025/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220202110620/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220202110620/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220202110620/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220202110620/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)
- IVDs for Management of COVID-19 Patients (/web/20220202110620/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220202110620/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visua Read, Prescription Home Testing, Single Target
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220202110620/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220202110620/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visua Read, Serial Screening , Single Target
+ 01/25/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220202110620/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 01/22/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220202110620/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 01/19/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220202110620/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 01/14/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220202110620/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 01/14/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test Pro (/web/20220202110620/https://www.fda.gov/media/155487/download) 01/14/2022	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20220202110620/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visua Read, Single Targe

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220202110620/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visua Read, Prescription Home Testing, Telehealth Proctor Supervised , Single Target
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220202110620/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test (/web/20220202110620/https://www.fda.gov/media/147256/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening, Single Target
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20220202110620/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visua Read, Non-prescription Testing, Serial Screening, Single Target
+ 01/05/2022	SD Biosensor, Inc.	COVID-19 At-Home Test (/web/20220202110620/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 12/29/2021	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220202110620/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 12/22/2021	iHealth Labs, (/web/20220202110620/https://www.fda.gov/media/153925/download)Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220202110620/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20220202110620/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Serial Screening, Saliva, Single Targ

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220202110620/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read, Single Targe
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20220202110620/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening, Single Target
+ 12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20220202110620/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20220202110620/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220202110620/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20220202110620/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack (/web/20220202110620/https://www.fda.gov/media/145069/download) 01/11/2021	Chemiluminescenc Immunoassay, Instrument Read, Single Target
+ 11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test (/web/20220202110620/https://www.fda.gov/media/144665/download) 12/18/2020	Lateral Flow, Visua Read, Serial Screening, Single Target

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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.

Revision Concerning Viral Mutations

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The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220202110620/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220202110620/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220302093144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220302093144/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220302093144/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220302093144/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)
- IVDs for Management of COVID-19 Patients (/web/20220302093144/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220302093144/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 02/22/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220302093144/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 02/18/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220302093144/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening Single Target
+ 02/17/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220302093144/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening, Single Target
+ 02/16/2022	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20220302093144/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA, Single Target
+ 02/09/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220302093144/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 02/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20220302093144/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visua Read, Single Targe
+ 02/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220302093144/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Telehealth Proctor Supervisec Single Target
+ 02/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20220302093144/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visua Read, Non-prescription Testin Serial Screening, Single Target

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 02/01/2022	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test (/web/20220302093144/https://www.fda.gov/media/154715/download) 12/06/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220302093144/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visua Read, Prescription Home Testing, Single Target
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220302093144/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening , Single Target
+ 01/27/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220302093144/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visua Read, Serial Screening , Single Target
+ 01/25/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220302093144/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 01/22/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220302093144/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 01/19/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220302093144/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 01/14/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test Pro (/web/20220302093144/https://www.fda.gov/media/155487/download) 01/14/2022	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220302093144/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 01/05/2022	SD Biosensor, Inc.	COVID-19 At-Home Test (/web/20220302093144/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 12/22/2021	iHealth Labs, (/web/20220302093144/https://www.fda.gov/media/153925/download)Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220302093144/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test (/web/20220302093144/https://www.fda.gov/media/144925/download) 01/05/2021	Paramagnetic Microbead-based Immunoassay, Ser Screening, Saliva, Single Target
+ 12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220302093144/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visua Read, Single Targe
+ 12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (/web/20220302093144/https://www.fda.gov/media/139752/download) 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening, Single Target
+ 12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test (/web/20220302093144/https://www.fda.gov/media/142916/download) 10/08/2020	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220302093144/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 11/17/2021	GenBody Inc.	GenBody COVID-19 Ag (/web/20220302093144/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visua Read, Serial Screening, Single Target

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220302093144/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220302093144/https://www.fda.gov/media/152406/download)

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220414163950/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220414163950/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220414163950/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)
- IVDs for Management of COVID-19 Patients (/web/20220414163950/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)

On This Page:

- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220414163950/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 04/12/2022	iHealth Labs, (/web/20220414163950/https://www.fda.gov/media/153925/download) Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220414163950/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/12/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220414163950/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Telehealth Proctor Supervisec Serial Screening, Single Target
+ 04/12/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220414163950/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/07/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220414163950/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Testing, Single Target
+ 04/06/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220414163950/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Testing, Single Target
+ 04/04/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220414163950/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220414163950/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 03/30/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220414163950/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/25/2022	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220414163950/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/25/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220414163950/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220414163950/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Multiple Targets
+ 03/23/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220414163950/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/18/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220414163950/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testir Serial Screening, Single Target
+ 03/16/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220414163950/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/11/2022	Siemens Healthcare Diagnostics, Inc.	Atellica IM SARS-CoV-2 Antigen (CoV2Ag) (/web/20220414163950/https://www.fda.gov/media/156964/download) 03/11/2022	CLIA, Single Target

	Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+	03/11/2022	Siemens Healthcare Diagnostics, Inc.	ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) (/web/20220414163950/https://www.fda.gov/media/156968/download) 03/11/2022	CLIA, Single Target
+	03/04/2022	Luminostics, Inc.	Clip COVID Rapid Antigen Test (/web/20220414163950/https://www.fda.gov/media/144253/download) 12/07/2020	Lateral flow immunoluminesce assay, instrument read, Single Target
+	03/03/2022	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20220414163950/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+	02/28/2022	Oceanit Foundry LLC	ASSURE-100 Rapid COVID-19 Test (/web/20220414163950/https://www.fda.gov/media/156638/download) 02/28/2022	Lateral Flow, Visua Read, Single Targe
+	02/22/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220414163950/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+	02/18/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220414163950/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening Single Target
+	02/17/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220414163950/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening, Single Target
+	02/16/2022	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag (/web/20220414163950/https://www.fda.gov/media/147312/download) 03/26/2021	CLIA, Single Target
+	02/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card (/web/20220414163950/https://www.fda.gov/media/141567/download) 08/26/2020	Lateral Flow, Visua Read, Single Targe
+	02/04/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card (/web/20220414163950/https://www.fda.gov/media/147261/download) 03/31/2021	Lateral Flow, Visua Read, Non-prescription Testin Serial Screening, Single Target

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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.

Revision Concerning Viral Mutations

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Viral Mutation Revision Letter – September 23, 2021 (/web/20220414163950/https://www.fda.gov/media/152406/download)

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220521091049/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220521091049/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)
- Other Diagnostic Tests for SARS-CoV-2 (/web/20220521091049/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220521091049/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)
- IVDs for Management of COVID-19 Patients (/web/20220521091049/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220521091049/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 05/16/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220521091049/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visua Read, Serial Screening, Multiple Targets
+ 05/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220521091049/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 05/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220521091049/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 05/12/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220521091049/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 05/06/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220521091049/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Telehealth Proctor Supervised Serial Screening, Single Target
+ 05/05/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220521091049/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 05/05/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220521091049/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Testing, Single Target
+ 05/04/2022	Oceanit Foundry LLC	ASSURE-100 Rapid COVID-19 Test (/web/20220521091049/https://www.fda.gov/media/156638/download) 02/28/2022	Lateral Flow, Visua Read, Single Targe

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 04/29/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220521091049/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Screening Single Target
+ 04/29/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220521091049/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Testing, Single Target
+ 04/28/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220521091049/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/22/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220521091049/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/15/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220521091049/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testir Serial Screening, Single Target
+ 04/14/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220521091049/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening , Single Target
+ 04/12/2022	iHealth Labs, (/web/20220521091049/https://www.fda.gov/media/153925/download) Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220521091049/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 04/12/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220521091049/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
+ 03/30/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220521091049/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/25/2022	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test (/web/20220521091049/https://www.fda.gov/media/151771/download) 8/24/2021	Lateral Flow, Digita Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220521091049/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Multiple Targets
+ 03/23/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220521091049/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visua Read, Over the Counter (OTC) Hor Testing, Serial Screening, Single Target
+ 03/11/2022	Siemens Healthcare Diagnostics, Inc.	Atellica IM SARS-CoV-2 Antigen (CoV2Ag) (/web/20220521091049/https://www.fda.gov/media/156964/download) 03/11/2022	CLIA, Single Target
+ 03/11/2022	Siemens Healthcare Diagnostics, Inc.	ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) (/web/20220521091049/https://www.fda.gov/media/156968/download) 03/11/2022	CLIA, Single Target
+ 03/04/2022	Luminostics, Inc.	Clip COVID Rapid Antigen Test (/web/20220521091049/https://www.fda.gov/media/144253/download) 12/07/2020	Lateral flow immunoluminesce assay, instrument read, Single Target
+ 03/03/2022	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20220521091049/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visua Read, Serial Screening, Single Target
+ 02/17/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220521091049/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescen Assay, Instrument Read, Screening, Single Target

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220521091049/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220521091049/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220706015002/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220706015002/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220706015002/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)
- Other Tests for SARS-CoV-2 (/web/20220706015002/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220706015002/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)
- IVDs for Management of COVID-19 Patients (/web/20220706015002/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220706015002/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 06/29/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220706015002/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/24/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220706015002/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/24/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220706015002/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/24/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220706015002/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Individuals (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/23/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220706015002/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220706015002/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Multiple Targets	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,

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]
+ 06/23/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220706015002/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/23/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220706015002/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/21/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220706015002/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/13/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220706015002/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 06/09/2022	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220706015002/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 06/07/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220706015002/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 06/01/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220706015002/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,

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]
+ 05/27/2022	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20220706015002/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read, Single Target	H, M	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/26/2022	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test (/web/20220706015002/https://www.fda.gov/media/148349/download) 05/06/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/24/2022	Siemens Healthcare Diagnostics, Inc.	Atellica IM SARS-CoV-2 Antigen (CoV2Ag) (/web/20220706015002/https://www.fda.gov/media/156964/download) 03/11/2022	CLIA, Single Target	H, M	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/24/2022	Siemens Healthcare Diagnostics, Inc.	ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) (/web/20220706015002/https://www.fda.gov/media/156968/download) 03/11/2022	CLIA, Single Target	H, M	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/16/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220706015002/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220706015002/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 05/06/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test (/web/20220706015002/https://www.fda.gov/media/144576/download) 12/16/2020	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Individuals (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 05/05/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test (/web/20220706015002/https://www.fda.gov/media/147251/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Individuals (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,

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]
+ 05/04/2022	Oceanit Foundry LLC	ASSURE-100 Rapid COVID-19 Test (/web/20220706015002/https://www.fda.gov/media/156638/download) 02/28/2022	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Patients (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov,
+ 04/29/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220706015002/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,
+ 04/15/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220706015002/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov, FAQ (/web/20220706015002/https://www.fda.gov,
+ 04/14/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220706015002/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220706015002/https://www.fda.gov, Individuals (/web/20220706015002/https://www.fda.gov, (/web/20220706015002/https://www.fda.gov, (Home Test) (/web/20220706015002/https://www.fda.gov,

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On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is

effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220706015002/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220706015002/https://www.fda.gov/media/152406/download)

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220816155507/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220816155507/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)
- Other Tests for SARS-CoV-2 (/web/20220816155507/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220816155507/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)
- IVDs for Management of COVID-19 Patients (/web/20220816155507/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220816155507/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

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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]
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220816155507/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220816155507/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 08/11/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220816155507/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 08/10/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220816155507/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 8/5/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220816155507/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220816155507/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220816155507/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww Individuals (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220816155507/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww

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]
+ 07/29/2022	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20220816155507/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 07/22/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220816155507/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/21/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220816155507/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 07/21/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220816155507/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww Individuals (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/13/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220816155507/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/13/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220816155507/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/13/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220816155507/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww FAQ (/web/20220816155507/https://ww
+ 07/13/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220816155507/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww

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]
+ 07/08/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220816155507/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/08/2022	Watmind USA	Speedy Swab Rapid COVID-19 Antigen Self-Test (/web/20220816155507/https://www.fda.gov/media/159730/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 07/08/2022	Genabio Diagnostics Inc.	Genabio COVID-19 Rapid Self-Test Kit (/web/20220816155507/https://www.fda.gov/media/159831/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 06/29/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220816155507/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 06/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220816155507/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Multiple Targets	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 06/09/2022	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220816155507/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww
+ 06/07/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220816155507/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 06/01/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220816155507/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220816155507/https://ww (/web/20220816155507/https://ww (Home Test) (/web/20220816155507/https://ww
+ 05/27/2022	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20220816155507/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read, Single Target	H, M	HCP (/web/20220816155507/https://ww Patients (/web/20220816155507/https://ww (/web/20220816155507/https://ww

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220816155507/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220816155507/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220829071900/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220829071900/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220829071900/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)
- Other Tests for SARS-CoV-2 (/web/20220829071900/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220829071900/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)
- IVDs for Management of COVID-19 Patients (/web/20220829071900/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)

On This Page:

- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220829071900/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 08/19/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220829071900/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220829071900/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220829071900/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 08/11/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220829071900/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 08/10/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220829071900/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 8/5/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220829071900/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220829071900/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220829071900/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww Individuals (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww

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]
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220829071900/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 07/29/2022	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20220829071900/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 07/22/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220829071900/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 07/21/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220829071900/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww
+ 07/21/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220829071900/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww Individuals (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 07/13/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220829071900/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 07/13/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220829071900/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 07/13/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220829071900/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww FAQ (/web/20220829071900/https://ww

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]
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+ 07/08/2022	Watmind USA	Speedy Swab Rapid COVID-19 Antigen Self-Test (/web/20220829071900/https://www.fda.gov/media/159730/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
+ 07/08/2022	Genabio Diagnostics Inc.	Genabio COVID-19 Rapid Self-Test Kit (/web/20220829071900/https://www.fda.gov/media/159831/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220829071900/https://ww (/web/20220829071900/https://ww (Home Test) (/web/20220829071900/https://ww
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+ 05/27/2022	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen (/web/20220829071900/https://www.fda.gov/media/151380/download) 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read, Single Target	H, M	HCP (/web/20220829071900/https://ww Patients (/web/20220829071900/https://ww (/web/20220829071900/https://ww

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220829071900/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220829071900/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220831091839/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220831091839/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220831091839/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)
- Other Tests for SARS-CoV-2 (/web/20220831091839/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220831091839/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)
- IVDs for Management of COVID-19 Patients (/web/20220831091839/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)

On This Page:

- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220831091839/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 08/29/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220831091839/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/24/2022	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20220831091839/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 08/23/2022	Genabio Diagnostics Inc.	Genabio COVID-19 Rapid Self-Test Kit (/web/20220831091839/https://www.fda.gov/media/159831/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/19/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220831091839/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220831091839/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220831091839/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 08/11/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220831091839/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 08/10/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220831091839/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww

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]
+ 8/5/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220831091839/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220831091839/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220831091839/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww Individuals (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220831091839/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 07/29/2022	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20220831091839/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 07/22/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220831091839/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 07/21/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220831091839/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww
+ 07/21/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220831091839/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww Individuals (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww

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]
+ 07/13/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220831091839/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 07/13/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220831091839/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 07/13/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220831091839/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww FAQ (/web/20220831091839/https://ww
+ 07/08/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220831091839/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 07/08/2022	Watmind USA	Speedy Swab Rapid COVID-19 Antigen Self-Test (/web/20220831091839/https://www.fda.gov/media/159730/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 06/29/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220831091839/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 06/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220831091839/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Multiple Targets	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww
+ 06/09/2022	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220831091839/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220831091839/https://ww Patients (/web/20220831091839/https://ww (/web/20220831091839/https://ww

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]
+ 06/01/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220831091839/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220831091839/https://ww (/web/20220831091839/https://ww (Home Test) (/web/20220831091839/https://ww

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220831091839/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220831091839/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220927000315/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220927000315/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220927000315/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)
- Other Tests for SARS-CoV-2 (/web/20220927000315/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220927000315/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)
- IVDs for Management of COVID-19 Patients (/web/20220927000315/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)

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- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220927000315/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 09/02/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220927000315/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 09/02/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220927000315/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/29/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220927000315/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/24/2022	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20220927000315/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww
+ 08/23/2022	Genabio Diagnostics Inc.	Genabio COVID-19 Rapid Self-Test Kit (/web/20220927000315/https://www.fda.gov/media/159831/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/19/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220927000315/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220927000315/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220927000315/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww

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]
+ 08/11/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test (/web/20220927000315/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww
+ 08/10/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220927000315/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww
+ 8/5/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220927000315/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220927000315/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220927000315/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww Individuals (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220927000315/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww
+ 07/29/2022	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20220927000315/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww
+ 07/22/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220927000315/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 07/21/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220927000315/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww

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]
+ 07/21/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220927000315/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww Individuals (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 07/13/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220927000315/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 07/13/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220927000315/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww FAQ (/web/20220927000315/https://ww
+ 07/08/2022	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test (/web/20220927000315/https://www.fda.gov/media/153925/download) 11/05/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 07/08/2022	Watmind USA	Speedy Swab Rapid COVID-19 Antigen Self-Test (/web/20220927000315/https://www.fda.gov/media/159730/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 06/29/2022	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test (/web/20220927000315/https://www.fda.gov/media/154338/download) 11/22/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 06/23/2022	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220927000315/https://www.fda.gov/media/153418/download) 10/21/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Multiple Targets	Home, H, M, W	HCP (/web/20220927000315/https://ww (/web/20220927000315/https://ww (Home Test) (/web/20220927000315/https://ww
+ 06/09/2022	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220927000315/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220927000315/https://ww Patients (/web/20220927000315/https://ww (/web/20220927000315/https://ww

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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.

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://web.archive.org/web/20220927000315/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

Viral Mutation Revision Letter – September 23, 2021 (/web/20220927000315/https://www.fda.gov/media/152406/download)

The Wayback Machine - https://web.archive.org/web/20220929155820/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-v...

In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/web/20220929155820/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Molecular Diagnostic Tests for SARS-CoV-2 (/web/20220929155820/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)
- Other Tests for SARS-CoV-2 (/web/20220929155820/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)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/web/20220929155820/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)
- IVDs for Management of COVID-19 Patients (/web/20220929155820/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)

On This Page:

- Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutations

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).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/web/20220929155820/https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

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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]
+ 09/23/2022	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test (/web/20220929155820/https://www.fda.gov/media/147247/download) 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww Individuals (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 09/02/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test (/web/20220929155820/https://www.fda.gov/media/152700/download) 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 09/02/2022	Xiamen Boson Biotech Co., Ltd."	Rapid SARS-CoV-2 Antigen Test Card (/web/20220929155820/https://www.fda.gov/media/157546/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/29/2022	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test (/web/20220929155820/https://www.fda.gov/media/151245/download) 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/24/2022	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit (/web/20220929155820/https://www.fda.gov/media/152462/download) 09/24/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 08/23/2022	Genabio Diagnostics Inc.	Genabio COVID-19 Rapid Self-Test Kit (/web/20220929155820/https://www.fda.gov/media/159831/download) 07/08/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/19/2022	OSANG LLC	OHC COVID-19 Antigen Self Test (/web/20220929155820/https://www.fda.gov/media/157550/download) 04/06/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Testing, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220929155820/https://www.fda.gov/media/156956/download) 03/16/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww

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]
+ 08/12/2022	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test (/web/20220929155820/https://www.fda.gov/media/151212/download) 07/28/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 08/11/2022	Cellrion USA, Inc.	Cellrion DiaTrust COVID-19 Ag Rapid Test (/web/20220929155820/https://www.fda.gov/media/147691/download) 04/16/2021	Lateral Flow, Visual Read, Serial Screening, Multiple Targets	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 08/10/2022	GenBody Inc.	GenBody COVID-19 Ag (/web/20220929155820/https://www.fda.gov/media/150785/download) 07/13/2021	Lateral Flow, Visual Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 8/5/2022	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220929155820/https://www.fda.gov/media/155173/download) 12/29/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx (/web/20220929155820/https://www.fda.gov/media/149904/download) 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test (/web/20220929155820/https://www.fda.gov/media/149908/download) 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening , Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww Individuals (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 08/03/2022	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro (/web/20220929155820/https://www.fda.gov/media/149913/download) 06/04/2021	Lateral Flow, Visual Read, Serial Screening , Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 07/29/2022	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test (/web/20220929155820/https://www.fda.gov/media/147575/download) 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 07/22/2022	Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220929155820/https://www.fda.gov/media/155632/download) 01/19/2022	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww

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]
+ 07/21/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test (/web/20220929155820/https://www.fda.gov/media/141301/download) 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww
+ 07/13/2022	SD Biosensor, Inc.	Pilot COVID-19 At-Home Test (/web/20220929155820/https://www.fda.gov/media/155123/download) 12/24/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww
+ 07/13/2022	Ellume Limited	Ellume COVID-19 Home Test (/web/20220929155820/https://www.fda.gov/media/144457/download) 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Serial Screening, Single Target	Home, H, M, W	HCP (/web/20220929155820/https://ww (/web/20220929155820/https://ww (Home Test) (/web/20220929155820/https://ww FAQ (/web/20220929155820/https://ww
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+ 06/09/2022	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (/web/20220929155820/https://www.fda.gov/media/149056/download) 05/20/2021	Lateral Flow, Visual Read, Single Target	H, M, W	HCP (/web/20220929155820/https://ww Patients (/web/20220929155820/https://ww (/web/20220929155820/https://ww

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[1] Authorized settings include the following:

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Viral Mutation Revision Letter – September 23, 2021 (/web/20220929155820/https://www.fda.gov/media/152406/download)