| **Date EUA Issued or Last Updated** | **Entity** | **Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued** | | | **Attributes** | **Authorized Setting(s)**[**1**](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#iaft1) | | **Authorization Documents**[**2**](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#iaft2) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01/14/2022 | PHASE Scientific International, Ltd. | [INDICAID COVID-19 Rapid Antigen Test](https://www.fda.gov/media/151212/download) 07/28/2021 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/151213/download), [Patients](https://www.fda.gov/media/151214/download), [IFU](https://www.fda.gov/media/151215/download) |
| 01/14/2022 | iHealth Labs, Inc. | [iHealth COVID-19 Antigen Rapid Test Pro](https://www.fda.gov/media/155487/download) 01/14/2022 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/155488/download), [Patients](https://www.fda.gov/media/155489/download), [IFU](https://www.fda.gov/media/155490/download) |
| 01/07/2022 | Abbott Diagnostics Scarborough, Inc. | [BinaxNOW COVID-19 Ag Card](https://www.fda.gov/media/141567/download) 08/26/2020 | | | Lateral Flow, Visual Read | H, M, W | | [HCP](https://www.fda.gov/media/141568/download), [Patients](https://www.fda.gov/media/141569/download), [IFU](https://www.fda.gov/media/141570/download) |
| 01/07/2022 | Abbott Diagnostics Scarborough, Inc. | [BinaxNOW COVID-19 Ag Card Home Test](https://www.fda.gov/media/144576/download) 12/16/2020 | | | Lateral Flow, Visual Read, Prescription Home Testing, Telehealth Proctor Supervised | Home, H, M, W | | [HCP](https://www.fda.gov/media/144573/download), [IFU](https://www.fda.gov/media/144574/download), [IFU (Home Test)](https://www.fda.gov/media/144575/download) |
| 01/07/2022 | Abbott Diagnostics Scarborough, Inc. | [BinaxNOW COVID-19 Antigen Self Test](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](https://www.fda.gov/media/147252/download), [Individuals](https://www.fda.gov/media/147253/download), [IFU](https://www.fda.gov/media/147254/download), [IFU (Home Test)](https://www.fda.gov/media/147255/download) |
| 01/07/2022 | Abbott Diagnostics Scarborough, Inc. | [BinaxNOW COVID-19 Ag Card 2 Home Test](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](https://www.fda.gov/media/147257/download), [Individuals](https://www.fda.gov/media/147258/download), [IFU](https://www.fda.gov/media/147259/download), [IFU (Home Test)](https://www.fda.gov/media/147260/download) |
| 01/07/2022 | Abbott Diagnostics Scarborough, Inc. | [BinaxNOW COVID-19 Ag 2 Card](https://www.fda.gov/media/147261/download) 03/31/2021 | | | Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/147262/download), [Patients](https://www.fda.gov/media/147263/download), [IFU](https://www.fda.gov/media/147264/download) |
| 01/05/2022 | SD Biosensor, Inc. | [COVID-19 At-Home Test](https://www.fda.gov/media/155123/download) 12/24/2021 | | | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening | Home, H, M, W | | [HCP](https://www.fda.gov/media/155124/download), [IFU](https://www.fda.gov/media/155125/download), [IFU (Home Test)](https://www.fda.gov/media/155126/download) |
| 12/29/2021 | Siemens Healthineers | [CLINITEST Rapid COVID-19 Antigen Self-Test](https://www.fda.gov/media/155173/download) 12/29/2021 | | | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening | Home, H, M, W | | [HCP](https://www.fda.gov/media/155174/download), [IFU](https://www.fda.gov/media/155175/download), [IFU (Home Test)](https://www.fda.gov/media/155176/download) |
| 12/22/2021 | iHealth Labs,Inc. | [iHealth COVID-19 Antigen Rapid Test](https://www.fda.gov/media/153925/download) 11/05/2021 | | | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening | Home, H, M, W | | [HCP](https://www.fda.gov/media/153922/download), [IFU](https://www.fda.gov/media/153923/download), [IFU (Home Test)](https://www.fda.gov/media/153924/download) |
| 12/17/2021 | Salofa Oy | [Sienna-Clarity COVID-19 Antigen Rapid Test Cassette](https://www.fda.gov/media/149056/download) 05/20/2021 | | | Lateral Flow, Visual Read | H, M, W | | [HCP](https://www.fda.gov/media/149054/download), [Patients](https://www.fda.gov/media/149057/download), [IFU](https://www.fda.gov/media/149055/download) |
| 12/10/2021 | Becton, Dickinson and Company (BD) | [BD Veritor System for Rapid Detection of SARS-CoV-2](https://www.fda.gov/media/139752/download) 07/02/2020 | | | Chromatographic Digital Immunoassay, Instrument Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/139753/download), [Patients](https://www.fda.gov/media/139754/download), [IFU](https://www.fda.gov/media/139755/download) |
| 12/06/2021 | Nano-Ditech Corp. | [Nano-Check COVID-19 Antigen Test](https://www.fda.gov/media/154715/download) 12/06/2021 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/154716/download), [Patients](https://www.fda.gov/media/154717/download), [IFU](https://www.fda.gov/media/154718/download) |
| 12/02/2021 | Access Bio, Inc. | [CareStart COVID-19 Antigen test](https://www.fda.gov/media/142916/download) 10/08/2020 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/142917/download), [Patients](https://www.fda.gov/media/142918/download), [IFU](https://www.fda.gov/media/142919/download) |
| 12/01/2021 | Access Bio, Inc. | [*CareStart* COVID-19 Antigen Home Test](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](https://www.fda.gov/media/151246/download), [IFU](https://www.fda.gov/media/151248/download), [IFU (Home Test)](https://www.fda.gov/media/152188/download) |
| 11/23/2021 | Becton, Dickinson and Company (BD) | [BD Veritor At-Home COVID-19 Test](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](https://www.fda.gov/media/151760/download), [Individuals](https://www.fda.gov/media/151770/download), [IFU](https://www.fda.gov/media/151761/download), [IFU (Home Test)](https://www.fda.gov/media/151763/download) |
| 11/22/2021 | InBios International Inc. | [SCoV-2 Ag Detect Rapid Self-Test](https://www.fda.gov/media/154338/download) 11/22/2021 | | | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening | Home, H, M, W | | [HCP](https://www.fda.gov/media/154335/download), [IFU](https://www.fda.gov/media/154336/download), [IFU (Home Test)](https://www.fda.gov/media/154337/download) |
| 11/17/2021 | GenBody Inc. | [GenBody COVID-19 Ag](https://www.fda.gov/media/150785/download) 07/13/2021 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/150786/download), [Patients](https://www.fda.gov/media/150787/download), [IFU](https://www.fda.gov/media/150788/download) |
| 11/09/2021 | Quidel Corporation | [QuickVue SARS Antigen Test](https://www.fda.gov/media/144665/download) 12/18/2020 | | | Lateral Flow, Visual Read, Serial Screening | H, M, W | | [HCP](https://www.fda.gov/media/144666/download), [Patients](https://www.fda.gov/media/144667/download), [IFU](https://www.fda.gov/media/144668/download) |
| 11/01/2021 | OraSure Technologies, Inc. | [InteliSwab COVID-19 Rapid Test](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](https://www.fda.gov/media/149909/download), [Individuals](https://www.fda.gov/media/149910/download), [IFU](https://www.fda.gov/media/149911/download), [IFU (Home Test)](https://www.fda.gov/media/149912/download) |
| 10/29/2021 | LumiraDx UK Ltd. | [LumiraDx SARS-CoV-2 Ag Test](https://www.fda.gov/media/141301/download) 08/18/2020 | | | Microfluidic Immunofluorescence Assay, Instrument Read, Screening | H, M, W | | [HCP](https://www.fda.gov/media/141302/download), [Patients](https://www.fda.gov/media/141303/download), [IFU](https://www.fda.gov/media/141304/download) |
| 10/27/2021 | Princeton BioMeditech Corp. | [Status COVID-19/Flu A&B](https://www.fda.gov/media/145694/download) 02/04/2021 | | | Lateral Flow, Visual Read, Multi-analyte | H, M, W | | [HCP](https://www.fda.gov/media/145695/download), [Patients](https://www.fda.gov/media/145696/download), [IFU](https://www.fda.gov/media/145697/download) |
| 10/21/2021 | Celltrion USA, Inc. | [Celltrion DiaTrust COVID-19 Ag Home Test](https://www.fda.gov/media/153418/download) 10/21/2021 | | | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening | Home, H, M, W | | [HCP](https://www.fda.gov/media/153419/download), [IFU](https://www.fda.gov/media/153420/download), [IFU (Home Test)](https://www.fda.gov/media/153421/download) |
| 10/21/2021 | Quidel Corporation | | [QuickVue At-Home OTC COVID-19 Test](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](https://www.fda.gov/media/147248/download), [Individuals](https://www.fda.gov/media/147249/download), [IFU](https://www.fda.gov/media/147265/download), [IFU (Home Test)](https://www.fda.gov/media/147250/download) |
| 10/19/2021 | ACON Laboratories, Inc | | [Flowflex COVID-19 Antigen Home Test](https://www.fda.gov/media/152700/download) 10/04/2021 | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Screening | | | Home, H, M, W | [HCP](https://www.fda.gov/media/152697/download), [IFU](https://www.fda.gov/media/152698/download), [IFU (Home Test)](https://www.fda.gov/media/152699/download) |
| 10/12/2021 | Xtrava Health | | [SPERA COVID-19 Ag Test](https://www.fda.gov/media/153093/download) 10/12/2021 | Lateral Flow, Visual Read | | | H, M, W | [HCP](https://www.fda.gov/media/153094/download), [Patients](https://www.fda.gov/media/153095/download), [IFU](https://www.fda.gov/media/153096/download) |
| 09/24/2021 | ANP Technologies, Inc | | [NIDS COVID-19 Antigen Rapid Test Kit](https://www.fda.gov/media/152462/download) 09/24/2021 | Lateral Flow, Visual Read, Serial Screening | | | H, M, W | [HCP](https://www.fda.gov/media/152463/download), [Patients](https://www.fda.gov/media/152465/download), [IFU](https://www.fda.gov/media/152464/download) |
| 09/03/2021 | InBios International, Inc. | | [SCoV-2 Ag Detect Rapid Test](https://www.fda.gov/media/148349/download) 05/06/2021 | Lateral Flow, Visual Read, Serial Screening | | | H, M, W | [HCP](https://www.fda.gov/media/148350/download), [Patients](https://www.fda.gov/media/148352/download), [IFU](https://www.fda.gov/media/148353/download) |
| 09/01/2021 | Celltrion USA, Inc. | | [Celltrion DiaTrust COVID-19 Ag Rapid Test](https://www.fda.gov/media/147691/download) 04/16/2021 | Lateral Flow, Visual Read, Serial Screening | | | H, M, W | [HCP](https://www.fda.gov/media/147692/download), [Patients](https://www.fda.gov/media/147693/download), [IFU](https://www.fda.gov/media/147694/download) |
| 07/08/2021 | Ellume Limited | | [ellume.lab COVID Antigen Test](https://www.fda.gov/media/150684/download) 07/08/2021 | Lateral Flow, Fluorescence, Instrument Read | | | H, M, W | [HCP](https://www.fda.gov/media/150685/download), [Patients](https://www.fda.gov/media/150686/download), [IFU](https://www.fda.gov/media/150687/download) |
| 06/11/2021 | Quidel Corporation | | [Sofia SARS Antigen FIA](https://www.fda.gov/media/137886/download) 05/08/2020 | Lateral Flow, Fluorescence, Instrument Read, Serial Screening | | | H, M, W | [HCP](https://www.fda.gov/media/137884/download), [Patients](https://www.fda.gov/media/137887/download), [IFU](https://www.fda.gov/media/137885/download) |
| 06/04/2021 | OraSure Technologies, Inc. | | [InteliSwab COVID-19 Rapid Test Rx](https://www.fda.gov/media/149904/download) 06/04/2021 | Lateral Flow, Visual Read, Prescription Home Testing | | | Home, H, M, W | [HCP](https://www.fda.gov/media/149905/download), [IFU](https://www.fda.gov/media/149906/download), [IFU (Home Test)](https://www.fda.gov/media/149907/download) |
| 06/04/2021 | OraSure Technologies, Inc. | | [InteliSwab COVID-19 Rapid Test Pro](https://www.fda.gov/media/149913/download) 06/04/2021 | Lateral Flow, Visual Read, Serial Screening | | | H, M, W | [HCP](https://www.fda.gov/media/149915/download), [Patients](https://www.fda.gov/media/149917/download), [IFU](https://www.fda.gov/media/149918/download) |
| 03/24/2021 | Becton, Dickinson and Company (BD) | | [BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B](https://www.fda.gov/media/147013/download) 03/24/2021 | Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte | | | H, M, W | [HCP](https://www.fda.gov/media/147014/download), [Patients](https://www.fda.gov/media/147015/download), [IFU](https://www.fda.gov/media/147016/download) [Viral Mutation Revision Letter - September 23, 2021](https://www.fda.gov/media/152406/download) |
| 03/01/2021 | Quidel Corporation | | [QuickVue At-Home COVID-19 Test](https://www.fda.gov/media/146309/download) 03/01/2021 | Lateral Flow, Visual Read, Prescription Home Testing | | | Home, H, M, W | [HCP](https://www.fda.gov/media/146310/download), [Patients](https://www.fda.gov/media/146311/download), [IFU](https://www.fda.gov/media/146312/download), [IFU (Home Test)](https://www.fda.gov/media/146313/download) |
| 02/11/2021 | Ellume Limited | | [Ellume COVID-19 Home Test](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](https://www.fda.gov/media/144591/download), [IFU](https://www.fda.gov/media/144592/download), [IFU (Home Test)](https://www.fda.gov/media/144593/download), [FAQ](https://www.fda.gov/media/144747/download) |
| 12/07/2020 | Luminostics, Inc. | | [Clip COVID Rapid Antigen Test](https://www.fda.gov/media/144253/download) 12/07/2020 | Lateral flow immunoluminescent assay, instrument read | | | H, M, W | [HCP](https://www.fda.gov/media/144254/download), [Patients](https://www.fda.gov/media/144255/download), [IFU](https://www.fda.gov/media/144256/download) |
| 10/02/2020 | Quidel Corporation | | [Sofia 2 Flu + SARS Antigen FIA](https://www.fda.gov/media/142701/download) 10/02/2020 | Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte | | | H, M, W | [HCP](https://www.fda.gov/media/142702/download), [Patients](https://www.fda.gov/media/142703/download), [IFU](https://www.fda.gov/media/142704/download) |