**Quick Reference of Antibody Tests Emergency Use Authorized**

**Source:** <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#isft1>

**Disclaimers:**

This list is not an exhaustive list and is current as of the date posted. For a complete list of assays, go visit the [FDA website](https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices). Projects must execute the EUA instructions exactly as stated in the FDA authorization letter and IFU (information for use).

\* Please refer to FDA communications (found [here](https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls)) for applicable recalls or FDA notices on certain assays.

**Date: 03/24/2022**

| **Date EUA Issued or Last Updated** | **Entity** | **RAD-Tech/ATP** | **Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued** | **Attributes**[**3**](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#isft3) | **N or S protein** | **Authorized Setting(s)**[**1**](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#isft1) | **Authorization Documents**[**2**](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#isft2) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 03/29/2021 | Ortho Clinical Diagnostics, Inc. | No | [VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack](https://www.fda.gov/media/136966/download)  04/14/2020 | Total Antibody, CLIA | S | H, M | [HCP](https://www.fda.gov/media/136970/download), [Recipients](https://www.fda.gov/media/136969/download),  [IFU](https://www.fda.gov/media/136967/download) |
| 07/29/2021 | Nirmidas Biotech, Inc. | No | [MidaSpot COVID-19 Antibody Combo Detection Kit](https://www.fda.gov/media/144874/download)  12/31/2020 | IgM and IgG, lateral flow, Fingerstick Whole Blood | S | H, M, W | [HCP](https://www.fda.gov/media/144875/download), [Recipients](https://www.fda.gov/media/144876/download),  [IFU](https://www.fda.gov/media/144877/download) |
| 01/19/2021 | Phadia AB | No | [EliA SARS-CoV-2-Sp1 IgG Test](https://www.fda.gov/media/145082/download)  01/11/2021 | IgG, Fluoroenzyme Immunoassay, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/145085/download), [Recipients](https://www.fda.gov/media/145087/download),  [IFU](https://www.fda.gov/media/145089/download) |
| 01/15/2021 | United Biomedical, Inc. | No | [UBI SARS-CoV-2 ELISA](https://www.fda.gov/media/145280/download)  01/15/2021 | IgG, ELISA | S/N | H | [HCP](https://www.fda.gov/media/145275/download), [Recipients](https://www.fda.gov/media/145281/download),  [IFU](https://www.fda.gov/media/145277/download) |
| 04/26/2021 | ADVAITE, Inc. | No | [RapCov Rapid COVID-19 Test](https://www.fda.gov/media/145075/download)  01/11/2021 | IgG, Lateral Flow, Fingerstick Whole Blood | N | H, M, W | [HCP](https://www.fda.gov/media/145077/download), [Recipients](https://www.fda.gov/media/145078/download),  [IFU](https://www.fda.gov/media/145080/download) |
| 4/02/2021 | Siemens Healthcare Diagnostics Inc. | No | [Dimension EXL SARS‑CoV‑2 IgG (CV2G)](https://www.fda.gov/media/145012/download)  01/08/2021 | IgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/145013/download), [Recipients](https://www.fda.gov/media/145014/download),  [IFU](https://www.fda.gov/media/145015/download) |
| 4/02/2021 | Siemens Healthcare Diagnostics Inc. | No | [Dimension Vista SARS‑CoV‑2 IgG (COV2G)](https://www.fda.gov/media/145017/download)  01/08/2021 | IgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/145018/download), [Recipients](https://www.fda.gov/media/145019/download),  [IFU](https://www.fda.gov/media/145020/download) |
| 07/12/2021 | Salofa Oy | No | [Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette](https://www.fda.gov/media/140079/download)  07/13/2020 | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | S | H, M, W | [HCP](https://www.fda.gov/media/140080/download), [Recipients](https://www.fda.gov/media/140081/download),  [IFU](https://www.fda.gov/media/140082/download) |
| 04/15/2021 | Quanterix Corporation | No | [Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test](https://www.fda.gov/media/144761/download)  12/23/2020 | IgG, Paramagnetic Microbead-based Sandwich ELISA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/144762/download), [Recipients](https://www.fda.gov/media/144763/download),  [IFU](https://www.fda.gov/media/144764/download) |
| 12/21/2020 | Hangzhou Biotest Biotech Co., Ltd. | No | [RightSign COVID-19 IgG/IgM Rapid Test Cassette](https://www.fda.gov/media/138657/download)  06/04/2020 | IgM and IgG Lateral Flow, Fingerstick Whole Blood | S | H, M, W | [HCP](https://www.fda.gov/media/138658/download), [Recipients](https://www.fda.gov/media/138659/download),  [IFU](https://www.fda.gov/media/138660/download) |
| 08/06/2021 | ACON Laboratories, Inc. | No | [ACON SARS-CoV-2 IgG/IgM Rapid Test](https://www.fda.gov/media/144559/download)  12/15/2020 | IgM and IgG, Lateral Flow | Not listed | H, M | [HCP](https://www.fda.gov/media/144560/download), [Recipients](https://www.fda.gov/media/144561/download),  [IFU](https://www.fda.gov/media/144562/download) |
| 12/02/2020 | Hangzhou Laihe Biotech Co., Ltd. | No | [LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)](https://www.fda.gov/media/139407/download)  06/19/2020 | IgM and IgG Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/139409/download), [Recipients](https://www.fda.gov/media/139408/download),  [IFU](https://www.fda.gov/media/139410/download) |
| 01/14/2021 | Abbott Laboratories Inc. | No | [SARS-CoV-2 IgG assay](https://www.fda.gov/media/137384/download)  04/26/2020 | IgG, CMIA | N | H, M | [HCP](https://www.fda.gov/media/137381/download), [Recipients](https://www.fda.gov/media/137382/download),  [IFU-ARCHITECT](https://www.fda.gov/media/137383/download), [IFU-Alinityi](https://www.fda.gov/media/137910/download) |
| 03/15/2021 | Abbott Laboratories Inc. | No | [AdviseDX SARS-CoV-2 IgG II](https://www.fda.gov/media/146368/download)  3/01/2021 | IgG, CMIA, Semi-quantitative | S | H,M | [HCP](https://www.fda.gov/media/146369/download), [Recipients](https://www.fda.gov/media/146370/download), [IFU-ARCHITECT](https://www.fda.gov/media/146371/download), [IFU-Alinityi](https://www.fda.gov/media/146372/download) |
| 05/06/2021 | Roche Diagnostics, Inc. | No | [Elecsys Anti-SARS-CoV-2 S](https://www.fda.gov/media/144034/download)  11/25/2020 | Total Antibody, ECLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/144035/download), [Recipients](https://www.fda.gov/media/144036/download),  [IFU](https://www.fda.gov/media/144037/download) |
| 11/24/2020 | Kantaro Biosciences, LLC | No | [COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit](https://www.fda.gov/media/144007/download)  11/24/2020 | IgG, ELISA, Semi-quantitative | S | H | [HCP](https://www.fda.gov/media/144008/download), [Recipients](https://www.fda.gov/media/144009/download),  [IFU](https://www.fda.gov/media/144010/download) |
| 11/23/2020 | Innovita (Tangshan) Biological Technology Co., Ltd. | No | [Innovita 2019-nCoV Ab Test (Colloidal Gold)](https://www.fda.gov/media/144068/download)  11 /23/2020 | IgM and IgG, Lateral Flow | S/N | H, M | [HCP](https://www.fda.gov/media/144069/download), [Recipients](https://www.fda.gov/media/144070/download),  [IFU](https://www.fda.gov/media/144071/download) |
| 11/10/2020 | Jiangsu Well Biotech Co., Ltd. | No | [Orawell IgM/IgG Rapid Test](https://www.fda.gov/media/142423/download)  09/23/2020 | IgM and IgG, Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/142421/download), [Recipients](https://www.fda.gov/media/142424/download),  [IFU](https://www.fda.gov/media/142422/download) |
| 11/06/2020 | Xiamen Biotime Biotechnology Co., Ltd. | No | [BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test](https://www.fda.gov/media/140440/download)  07/24/2020 | IgM and IgG, Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/140441/download), [Recipients](https://www.fda.gov/media/140442/download),  [IFU](https://www.fda.gov/media/140443/download) |
| 11/12/2020 | GenScript USA Inc. | No | [cPass SARS-CoV-2 Neutralization Antibody Detection Kit](https://www.fda.gov/media/143584/download)  11/06/2020 | Total Neutralizing Antibodies, Blocking ELISA | S | H | [HCP](https://www.fda.gov/media/143582/download), [Recipients](https://www.fda.gov/media/143585/download),  [IFU](https://www.fda.gov/media/143583/download) |
| 08/12/2021 | Access Bio, Inc. | No | [CareStart COVID-19 IgM/IgG](https://www.fda.gov/media/140444/download)  07/24/2020 | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | N/S | H, M, W | [HCP](https://www.fda.gov/media/140445/download), [Recipients](https://www.fda.gov/media/140446/download),  [IFU](https://www.fda.gov/media/140447/download) |
| 10/30/2020 | Bio-Rad Laboratories, Inc. | No | [Platelia SARS-CoV-2 Total Ab assay](https://www.fda.gov/media/137494/download)  04/29/2020 | Total Antibody, ELISA | N | H | [HCP](https://www.fda.gov/media/137492/download), [Recipients](https://www.fda.gov/media/137495/download),  [IFU](https://www.fda.gov/media/137493/download) |
| 10/30/2020 | Siemens Healthcare Diagnostics Inc. | No | [Dimension Vista SARS-CoV-2 Total antibody assay (COV2T)](https://www.fda.gov/media/138750/download)  06/08/2020 | Total Antibody, CLIA | S | H, M | [HCP](https://www.fda.gov/media/138751/download), [Recipients](https://www.fda.gov/media/138752/download),  [IFU](https://www.fda.gov/media/138753/download) |
| 10/30/2020 | Siemens Healthcare Diagnostics Inc. | No | [Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)](https://www.fda.gov/media/138754/download)  06/08/2020 | Total Antibody, CLIA | S | H, M | [HCP](https://www.fda.gov/media/138755/download), [Recipients](https://www.fda.gov/media/138756/download),  [IFU](https://www.fda.gov/media/138757/download) |
| 10/28/2020 | Quansys Biosciences, Inc. | No | [Q-Plex SARS-CoV-2 Human IgG (4 Plex)](https://www.fda.gov/media/143453/download)  10/28/2020 | IgG, CLIA | S | H | [HCP](https://www.fda.gov/media/143451/download), [Recipients](https://www.fda.gov/media/143454/download),  [IFU](https://www.fda.gov/media/143452/download) |
| 02/12/2021 | Ortho-Clinical Diagnostics, Inc. | No | [VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack](https://www.fda.gov/media/137360/download)  04/24/2020 | IgG, CLIA | S | H, M | [HCP](https://www.fda.gov/media/137361/download), [Recipients](https://www.fda.gov/media/137362/download),  [IFU](https://www.fda.gov/media/137363/download) |
| 07/13/2021 | Roche Diagnostics | No | [Elecsys Anti-SARS-CoV-2](https://www.fda.gov/media/137602/download)  05/02/2020 | Total Antibody, ECLIA | N | H, M | [HCP](https://www.fda.gov/media/137603/download), [Recipients](https://www.fda.gov/media/137604/download),  [IFU](https://www.fda.gov/media/137605/download) |
| 10/07/2020 | DiaSorin Inc. | No | [LIAISON SARS-CoV-2 S1/S2 IgG](https://www.fda.gov/media/153016/download)  04/24/2020 | IgG, CLIA | S | H, M | [HCP](https://www.fda.gov/media/137357/download), [Recipients](https://www.fda.gov/media/137358/download),  [IFU](https://www.fda.gov/media/137359/download) |
| 10/17/2020 | Biohit Healthcare (Hefei) Co. Ltd. | No | [Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit](https://www.fda.gov/media/139280/download)  06/18/2020 | IgM and IgG Lateral Flow | N | H, M | [HCP](https://www.fda.gov/media/139281/download), [Recipients](https://www.fda.gov/media/139282/download),  [IFU](https://www.fda.gov/media/139283/download) |
| 10/01/2021 | Abbott Laboratories Inc. | No | [AdviseDx SARS-CoV-2 IgM](https://www.fda.gov/media/142937/download)  10/09/2020 | IgM, CMIA | S | H, M | [HCP](https://www.fda.gov/media/142938/download), [Recipients](https://www.fda.gov/media/142939/download),    [IFU-ARCHITECT](https://www.fda.gov/media/142940/download), [IFU-Alinityi](https://www.fda.gov/media/142941/download) |
| 10/08/2020 | Beckman Coulter, Inc. | No | [Access SARS-CoV-2 IgM](https://www.fda.gov/media/142908/download)  10/08/2020 | IgM, CLIA | S | H, M | [HCP](https://www.fda.gov/media/142909/download), [Recipients](https://www.fda.gov/media/142910/download),  [IFU](https://www.fda.gov/media/142911/download) |
| 10/08/2020 | Genalyte, Inc. | No | [Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2](https://www.fda.gov/media/142912/download)  10/08/2020 | Total Antibody, photonic ring immunoassay | N/S | H, M | [HCP](https://www.fda.gov/media/142913/download), [Recipients](https://www.fda.gov/media/142914/download),  [IFU](https://www.fda.gov/media/142915/download) |
| 10/06/2020 | Thermo Fisher Scientific | No | [OmniPATH COVID-19 Total Antibody ELISA Test](https://www.fda.gov/media/142697/download)  10/02/2020 | Total Antibody, ELISA | S | H, M | [HCP](https://www.fda.gov/media/142698/download), [Recipients](https://www.fda.gov/media/142699/download),  [IFU](https://www.fda.gov/media/142700/download) |
| 05/12/2021 | ZEUS Scientific, Inc. | No | [ZEUS ELISA SARS-CoV-2 IgG Test System](https://www.fda.gov/media/142806/download)  10/06/2020 | IgG, ELISA | S/N | H, M | [HCP](https://www.fda.gov/media/142807/download), [Recipients](https://www.fda.gov/media/142808/download),  [IFU](https://www.fda.gov/media/142809/download) |
| 09/29/2020 | DiaSorin, Inc. | No | [DiaSorin LIAISON SARS-CoV-2 IgM Assay](https://www.fda.gov/media/142549/download)  09/29/2020 | IgM, Indirect CLIA | S | H, M | [HCP](https://www.fda.gov/media/142550/download), [Recipients](https://www.fda.gov/media/142551/download),  [IFU](https://www.fda.gov/media/142552/download) |
| 09/29/2020 | NanoEntek America, Inc. | No | [FREND COVID-19 total Ab](https://www.fda.gov/media/142554/download)  09/29/2020 | Total Antibody, FIA | N | H, M | [HCP](https://www.fda.gov/media/142555/download), [Recipients](https://www.fda.gov/media/142556/download),  [IFU](https://www.fda.gov/media/142557/download) |
| 09/29/2020 | Nirmidas Biotech, Inc. | No | [Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit](https://www.fda.gov/media/142558/download)  09/29/2020 | IgM and IgG, Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/142559/download), [Recipients](https://www.fda.gov/media/142560/download),  [IFU](https://www.fda.gov/media/142561/download) |
| 04/27/2021 | Quotient Suisse SA | No | [MosaiQ COVID-19 Antibody Magazine](https://www.fda.gov/media/142483/download)  09/25/2020 | Total Antibody, photometric immunoassay | S | H | [HCP](https://www.fda.gov/media/142484/download), [Recipients](https://www.fda.gov/media/142485/download),  [IFU](https://www.fda.gov/media/142486/download) |
| 09/23/2020 | Assure Tech. (Hangzhou Co., Ltd) - Distributed by MPBio | No | [Assure COVID-19 IgG/IgM Rapid Test Device](https://www.fda.gov/media/139789/download)  07/06/2020 | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | S/N | H, M, W | [HCP](https://www.fda.gov/media/139790/download), [Recipients](https://www.fda.gov/media/139791/download),  [IFU](https://www.fda.gov/media/139792/download) |
| 09/14/2020 | Shenzhen New Industries Biomedical Engineering Co., Ltd. | No | [MAGLUMI 2019-nCoV IgM/IgG](https://www.fda.gov/media/142230/download)  09/14/2020 | IgM and IgG, CLIA | S/N | H, M | [HCP](https://www.fda.gov/media/142231/download), [Recipients](https://www.fda.gov/media/142232/download),  [IFU](https://www.fda.gov/media/142233/download) |
| 09/09/2020 | BioCheck, Inc. | No | [BioCheck SARS-CoV-2 IgM Antibody Test Kit](https://www.fda.gov/media/141998/download)  09/09/2020 | IgM, CLIA | S | H, M | [HCP](https://www.fda.gov/media/141999/download), [Recipients](https://www.fda.gov/media/142000/download),  [IFU](https://www.fda.gov/media/142002/download) |
| 09/09/2020 | BioCheck, Inc. | No | [BioCheck SARS-CoV-2 IgG Antibody Test Kit](https://www.fda.gov/media/142003/download)  09/09/2020 | IgG, CLIA | S | H, M | [HCP](https://www.fda.gov/media/142004/download), [Recipients](https://www.fda.gov/media/142005/download),  [IFU](https://www.fda.gov/media/142006/download) |
| 08/11/2021 | Sugentech, Inc. | No | [SGTi-flex COVID-19 IgG](https://www.fda.gov/media/141888/download)  09/03/2020 | IgG, Lateral Flow, Fingerstick Whole Blood | S/N | H, M, W | [HCP](https://www.fda.gov/media/141889/download), [Recipients](https://www.fda.gov/media/141890/download),  [IFU](https://www.fda.gov/media/141891/download) |
| 08/31/2020 | TBG Biotechnology Corp. | No | [TBG SARS-CoV-2 IgG / IgM Rapid Test Kit](https://www.fda.gov/media/141770/download)  08/31/2020 | IgM and IgG, Lateral Flow | S/N | H, M | [HCP](https://www.fda.gov/media/141771/download), [Recipients](https://www.fda.gov/media/141772/download),  [IFU](https://www.fda.gov/media/141773/download) |
| 08/31/2020 | University of Arizona Genetics Core for Clinical Services | No | [COVID-19 ELISA pan-Ig Antibody Test](https://www.fda.gov/media/141774/download)  08/31/2020 | Total Antibody, ELISA | S | H | [HCP](https://www.fda.gov/media/141775/download), [Recipients](https://www.fda.gov/media/141776/download),  [EUA Summary](https://www.fda.gov/media/141777/download) |
| 08/25/2020 | Biocan Diagnostics Inc. | No | [Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test](https://www.fda.gov/media/141547/download)  08/25/2020 | IgM and IgG, Lateral Flow | S/N | H, M | [HCP](https://www.fda.gov/media/141548/download), [Recipients](https://www.fda.gov/media/141549/download),  [IFU](https://www.fda.gov/media/141550/download) |
| 08/17/2020 | BioCheck, Inc. | No | [BioCheck SARS-CoV-2 IgG and IgM Combo Test](https://www.fda.gov/media/141247/download)  08/17/2020 | IgM and IgG, CLIA | S | H, M | [HCP](https://www.fda.gov/media/141248/download), [Recipients](https://www.fda.gov/media/141249/download),  [IFU](https://www.fda.gov/media/141251/download) |
| 08/17/2020 | Diazyme Laboratories, Inc. | No | [Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit](https://www.fda.gov/media/141252/download)  08/17/2020 | IgM, CLIA | Not listed | H, M | [HCP](https://www.fda.gov/media/141253/download), [Recipients](https://www.fda.gov/media/141254/download),  [IFU](https://www.fda.gov/media/141255/download) |
| 03/15/2021 | bioMérieux SA | No | [VIDAS SARS-CoV-2 IgM](https://www.fda.gov/media/140930/download)  08/06/2020 | IgM, ELFA | S | H, M | [HCP](https://www.fda.gov/media/140931/download), [Recipients](https://www.fda.gov/media/140932/download),  [IFU](https://www.fda.gov/media/140933/download) |
| 03/15/2021 | bioMérieux SA | No | [VIDAS SARS-CoV-2 IgG](https://www.fda.gov/media/140934/download)  08/06/2020 | IgG, ELFA | S | H, M | [HCP](https://www.fda.gov/media/140935/download), [Recipients](https://www.fda.gov/media/140936/download),  [IFU](https://www.fda.gov/media/140937/download) |
| 08/05/2020 | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. | No | [WANTAI SARS-CoV-2 Ab ELISA](https://www.fda.gov/media/140926/download)  08/05/2020 | Total Antibody, ELISA | S | H | [HCP](https://www.fda.gov/media/140927/download), [Recipients](https://www.fda.gov/media/140928/download),  [IFU](https://www.fda.gov/media/140929/download) |
| 07/31/2020 | Siemens Healthcare Diagnostics Inc. | No | [Atellica IM SARS-CoV-2 IgG (COV2G)](https://www.fda.gov/media/140700/download)  07/31/2020 | IgG, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/140698/download), [Recipients](https://www.fda.gov/media/140701/download),  [IFU](https://www.fda.gov/media/140699/download) |
| 07/31/2020 | Siemens Healthcare Diagnostics Inc. | No | [ADVIA Centaur SARS-CoV-2 IgG (COV2G)](https://www.fda.gov/media/140703/download)  07/31/2020 | IgG, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/140702/download), [Recipients](https://www.fda.gov/media/140705/download),  [IFU](https://www.fda.gov/media/140704/download) |
| 08/10/2021 | Siemens Healthcare Diagnostics Inc. | No | [ADVIA Centaur SARS-CoV-2 IgG (sCOVG)](https://www.fda.gov/media/150235/download)  06/17/2021 | IgG, CLIA,Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/150236/download), [Recipients](https://www.fda.gov/media/150237/download), [IFU](https://www.fda.gov/media/150238/download) |
| 04/22/2021 | Megna Health, Inc. | No | [Rapid COVID-19 IgM/IgG Combo Test Kit](https://www.fda.gov/media/140294/download)  07/17/2020 | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | N | H, M, W | [HCP](https://www.fda.gov/media/140295/download), [Recipients](https://www.fda.gov/media/140296/download),  [IFU](https://www.fda.gov/media/140297/download) |
| 07/16/2020 | Luminex Corporation | No | [xMAP SARS-CoV-2 Multi-Antigen IgG Assay](https://www.fda.gov/media/140257/download)  07/16/2020 | IgG, FMIA | S | H | [HCP](https://www.fda.gov/media/140255/download), [Recipients](https://www.fda.gov/media/140258/download),  [IFU](https://www.fda.gov/media/140256/download) |
| 03/12/2021 | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. | No | [WANTAI SARS-CoV-2 Ab Rapid Test](https://www.fda.gov/media/140035/download)  07/10/2020 | Total Antibody, Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/140028/download), [Recipients](https://www.fda.gov/media/140037/download),  [IFU](https://www.fda.gov/media/140030/download) |
| 03/22/2021 | Diazyme Laboratories, Inc. | No | [Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit](https://www.fda.gov/media/139866/download)  07/08/2020 | IgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/139863/download), [Recipients](https://www.fda.gov/media/139867/download),  [IFU](https://www.fda.gov/media/139865/download) |
| 03/25/2021 | InBios International, Inc. | No | [SCoV-2 Detect IgM ELISA](https://www.fda.gov/media/139726/download)  06/30/2020 | IgM, ELISA | N | H | [HCP](https://www.fda.gov/media/139727/download), [Recipients](https://www.fda.gov/media/139729/download),  [IFU](https://www.fda.gov/media/139730/download) |
| 06/26/2020 | Beckman Coulter, Inc. | No | [Access SARS-CoV-2 IgG](https://www.fda.gov/media/139624/download)  06/26/2020 | IgG, CLIA | S | H, M | [HCP](https://www.fda.gov/media/139625/download), [Recipients](https://www.fda.gov/media/139626/download),  [IFU](https://www.fda.gov/media/139627/download) |
| 06/23/2020 | Babson Diagnostics, Inc. | No | [Babson Diagnostics aC19G1](https://www.fda.gov/media/139450/download)  06/23/2020 | IgG, CLIA | S | H | [HCP](https://www.fda.gov/media/139447/download), [Recipients](https://www.fda.gov/media/139448/download),  [EUA Summary](https://www.fda.gov/media/139446/download) |
| 06/15/2020 | Emory Medical Laboratories | No | [SARS-CoV-2 RBD IgG test](https://www.fda.gov/media/139050/download)  06/15/2020 | IgG, ELISA | S | H | [HCP](https://www.fda.gov/media/139051/download), [Recipients](https://www.fda.gov/media/139052/download),  [EUA Summary](https://www.fda.gov/media/139053/download) |
| 06/12/2020 | Cellex Inc. | No | [qSARS-CoV-2 IgG/IgM Rapid Test](https://www.fda.gov/media/136622/download)  04/01/2020 | IgM and IgG, Lateral Flow | S/N | H, M | [HCP](https://www.fda.gov/media/136623/download), [Patients](https://www.fda.gov/media/136624/download), [IFU](https://www.fda.gov/media/136625/download) |
| 05/14/2021 | InBios International, Inc. | No | [SCoV-2 Detect IgG ELISA](https://www.fda.gov/media/138807/download)  06/10/2020 | IgG, ELISA | Not listed | H, M | [HCP](https://www.fda.gov/media/138808/download), [Recipients](https://www.fda.gov/media/138809/download),  [IFU](https://www.fda.gov/media/138810/download) |
| 06/04/2020 | Vibrant America Clinical Labs | No | [Vibrant COVID-19 Ab Assay](https://www.fda.gov/media/138626/download)  06/04/2020 | IgM and IgG, CLIA | S/N | H | [HCP](https://www.fda.gov/media/138627/download), [Recipients](https://www.fda.gov/media/138628/download),  [EUA Summary](https://www.fda.gov/media/138629/download) |
| 05/29/2020 | Healgen Scientific LLC | No | [COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)](https://www.fda.gov/media/138435/download)  05/29/2020 | IgM and IgG Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/138436/download), [Recipients](https://www.fda.gov/media/138437/download),  [IFU](https://www.fda.gov/media/138438/download) |
| 06/01/2021 | Siemens Healthcare Diagnostics Inc. | No | [Atellica IM SARS-CoV-2 Total (COV2T)](https://www.fda.gov/media/138439/download)  05/29/2020 | Total Antibody, CLIA | S | H, M | [HCP](https://www.fda.gov/media/138440/download), [Recipients](https://www.fda.gov/media/138441/download),  [IFU](https://www.fda.gov/media/138442/download) |
| 09/14/2021 | Siemens Healthcare Diagnostics Inc. | No | [ADVIA Centaur SARS-CoV-2 Total (COV2T)](https://www.fda.gov/media/138443/download)  05/29/2020 | Total Antibody, CLIA | S | H, M | [HCP](https://www.fda.gov/media/138444/download), [Recipients](https://www.fda.gov/media/138445/download),  [IFU](https://www.fda.gov/media/138446/download) |
| 05/04/2020 | EUROIMMUN US Inc. | No | [Anti-SARS-CoV-2 ELISA (IgG)](https://www.fda.gov/media/137606/download)  05/04/2020 | IgG, ELISA | S | H | [HCP](https://www.fda.gov/media/137607/download), [Recipients](https://www.fda.gov/media/137608/download),  [IFU](https://www.fda.gov/media/137609/download) |
| 04/30/2020 | Wadsworth Center, New York State Department of Health | No | [New York SARS-CoV Microsphere Immunoassay for Antibody Detection](https://www.fda.gov/media/137540/download)  04/30/2020 | Total Antibody, FMIA | N | H | [HCP](https://www.fda.gov/media/137542/download), [Recipients](https://www.fda.gov/media/137543/download),  [EUA Summary](https://www.fda.gov/media/137541/download) |
| 04/15/2020 | Mount Sinai Laboratory | No | [COVID-19 ELISA IgG Antibody Test](https://www.fda.gov/media/137032/download)  04/15/2020 | IgG, ELISA | S | H | [HCP](https://www.fda.gov/media/137030/download), [Patients](https://www.fda.gov/media/137033/download),  [EUA Summary](https://www.fda.gov/media/137029/download) |
| 02/10/2021 | Immunodiagnostics Systems LTD | No | [IDS SARS-COV-2 lgG](https://www.fda.gov/media/145941/download)  02/10/2021 | IgG, CLIA | N, S | H, M | [HCP](https://www.fda.gov/media/145942/download), [Recipients](https://www.fda.gov/media/145943/download), [IFU](https://www.fda.gov/media/145944/download) |
| 06/24/2021 | Symbiotica Inc. | No | [COVID-19 Self-Collected Antibody Test System](https://www.fda.gov/media/147365/download)  04/05/2021 | IgG, ELISA, Home Collection, Fingerstick Dried Blood Spot | Not listed/ ”structural proteins” | H | [HCP](https://www.fda.gov/media/147366/download), [Recipient](https://www.fda.gov/media/147367/download), [EUA Summary](https://www.fda.gov/media/147368/download), [IFU (Home Collect)](https://www.fda.gov/media/147369/download) |
| 04/19/2021 | Inova Diagnostics, Inc. | No | [QUANTA Flash SARS-CoV-2 IgG](https://www.fda.gov/media/147805/download)  04/19/2021 | lgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/147806/download), [Recipients](https://www.fda.gov/media/147807/download), [IFU](https://www.fda.gov/media/147808/download) |
| 05/11/2021 | QIAGEN, GmbH | No | [QIAreach Anti-SARS-CoV-2 Total Test](https://www.fda.gov/media/148559/download)  05/11/2021 | Total Antibody, Digital Lateral Flow | S | H, M | [HCP](https://www.fda.gov/media/148560/download), [Recipients](https://www.fda.gov/media/148561/download), [IFU](https://www.fda.gov/media/148562/download) |
| 05/11/2021 | Zeus scientific Inc | No | [ZEUS ELISA SARS-CoV-2 Total Antibody Test System](https://www.fda.gov/media/148554/download)  05/11/2021 | Total Antibody, ELISA | S, N | H, M | [HCP](https://www.fda.gov/media/148555/download), [Recipients](https://www.fda.gov/media/148556/download), [IFU](https://www.fda.gov/media/148557/download) |
| 05/19/2021 | DiaSorin, Inc. | No | [LIAISON SARS-CoV-2 TrimericS IgG](https://www.fda.gov/media/149060/download)  05/19/2021 | IgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/149058/download), [Recipients](https://www.fda.gov/media/149061/download), [IFU](https://www.fda.gov/media/149059/download) |
| 09/22/2021 | NOWDiagnostics Inc. | No | [ADexusDx COVID-19 Test](https://www.fda.gov/media/149438/download)  05/24/2021 | Total Antibody, Lateral Flow, Fingerstick Whole Blood | S(RBD) | H, M, W | [HCP](https://www.fda.gov/media/149439/download), [Recipients](https://www.fda.gov/media/149440/download), [IFU](https://www.fda.gov/media/149441/download) |
| 08/10/2021 | Diabetomics Inc | No | [CovAb SARS-CoV-2 Ab Test](https://www.fda.gov/media/149940/download)  06/04/2021 | Total Antibody, Lateral Flow, Oral Fluid (gingival crevicular fluid) | S (S1 domain of spike protein) | H, M, W | [HCP](https://www.fda.gov/media/149941/download), [Recipients](https://www.fda.gov/media/149942/download), [IFU](https://www.fda.gov/media/149943/download) |
| 09/08/2021 | Ortho-Clinical Diagnostics, Inc. | No | [VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti- SARS-CoV-2 IgG Quantitative Calibrator](https://www.fda.gov/media/150672/download)  07/09/2021 | IgG, CLIA, Quantitative | S | H, M | [HCP](https://www.fda.gov/media/150673/download), [Recipients](https://www.fda.gov/media/150674/download), [IFU](https://www.fda.gov/media/150675/download) |
| 07/01/2021 | Bio-Rad Laboratories | No | [BioPlex 2200 SARS-CoV-2 IgG](https://www.fda.gov/media/150550/download)  07/01/2021 | IgG, Bead-based Fluorescent Immunoassay, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/150551/download), [Recipients](https://www.fda.gov/media/150552/download), [IFU](https://www.fda.gov/media/150553/download) |
| 08/02/2021 | LumiraDx UK Ltd. | No | [LumiraDx SARS-CoV-2 Ab Test](https://www.fda.gov/media/151249/download)  08/02/2021 | Total Antibody, Fluorescence Immunoassay, Fingerstick Whole Blood | S | H, M, W, | [HCP](https://www.fda.gov/media/151250/download), [Recipients](https://www.fda.gov/media/151251/download), [IFU](https://www.fda.gov/media/151252/download) |
| 08/18/2021 | Beckman Coulter, Inc. | No | [Access SARS-CoV-2 IgG II](https://www.fda.gov/media/146898/download)  03/22/2021 | IgG, CLIA, Semi-quantitative | S (RBD domain) | H, M | [HCP,](https://www.fda.gov/media/146899/download) [Recipients](https://www.fda.gov/media/146900/download), [IFU](https://www.fda.gov/media/146901/download) |
| 08/24/2021 | InBios International, Inc. | No | [SCoV-2 Detect IgG Rapid Test](https://www.fda.gov/media/151818/download)  08/24/2021 | IgG, Lateral Flow, Fingerstick Whole Blood | S | H, M, W | [HCP](https://www.fda.gov/media/151816/download), [Recipients](https://www.fda.gov/media/151819/download), [IFU](https://www.fda.gov/media/151817/download) |
| 10/06/2021 | EUROIMMUN US, Inc. | No | [EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)](https://www.fda.gov/media/152748/download)  10/06/2021 | IgG, ELISA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/152746/download), [Recipients](https://www.fda.gov/media/152749/download), [IFU](https://www.fda.gov/media/152747/download) |
| 06/24/2021 | Access Bio, Inc. | No | [CareStart EZ COVID-19 IgM/IgG](https://www.fda.gov/media/150422/download)  06/24/2021 | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | N, S (S1 RBD) | H, M, W | [HCP](https://www.fda.gov/media/150423/download), [Recipients](https://www.fda.gov/media/150424/download), [IFU](https://www.fda.gov/media/150425/download) |
| 09/01/2021 | Siemens Healthcare Diagnostics Inc. | No | [Atellica IM SARS-CoV-2 IgG (sCOVG)](https://www.fda.gov/media/146928/download)  03/23/2021 | IgG, CLIA, Semi-quantitative | S | H, M | [HCP](https://www.fda.gov/media/146929/download), [Recipients](https://www.fda.gov/media/146930/download), [IFU](https://www.fda.gov/media/146931/download) |
| 07/22/2021 | Ortho-Clinical Diagnostics, Inc. | No | [VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators](https://www.fda.gov/media/151024/download)  07/22/2021 | Total Antibody, CLIA | N | H, M | [HCP](https://www.fda.gov/media/151025/download), [Recipients](https://www.fda.gov/media/151026/download), [IFU](https://www.fda.gov/media/151027/download) |
| 10/22/2021 | InBios International, Inc. | No | [SCoV-2 Detect Neutralizing Ab ELISA](https://www.fda.gov/media/153501/download)  10/22/2021 | Total Neutralizing Antibodies, Elisa | Anti-SARS-CoV-2 S protein antibodies (Total neutralizing antibodies to SARS-CoV-2) | H | [HCP](https://www.fda.gov/media/153502/download), [Recipients](https://www.fda.gov/media/153503/download), [IFU](https://www.fda.gov/media/153504/download) |

**Disclaimer**: This list is not an exhaustive list and is current as of the date posted. For a complete list of assays, go to: [https: //www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas](http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas). Projects must execute the EUA instructions exactly as stated in the FDA authorization letter and IFU (information for use). **\***Please refer to FDA communications (i.e. <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls> ) for applicable recalls or FDA notices on certain assays.

**Abbreviations:**

* 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.