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| 11/19/2021 | | | | Sugentech, Inc. | | | | | [SGTi-flex COVID-19 IgG](https://www.fda.gov/media/141888/download) 09/03/2020 | | | | | | | | | IgG, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | H, M, W | | |  | | | | | | | |
| 11/02/2021 | | | Nirmidas Biotech, Inc. | | | | | | | | | | | | [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 | | | | | H, M, W | | | | | | |
| 09/22/2021 | | | | | | | | NOWDiagnostics, Inc. | | | | | | | | [ADEXUSDx COVID-19 Test](https://www.fda.gov/media/149438/download) 05/24/2021 | | | | | | | Total Antibody, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | H, M, W | | | | | |
| 08/24/2021 | | | | | | InBios International, Inc | | | | | | | | | | | [SCoV-2 Detect IgG Rapid Test](https://www.fda.gov/media/151818/download) 08/24/2021 | | | | | | | IgG, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | H, M, W | | | | |
| 08/12/2021 | | | Access Bio, Inc. | | | | | | | | | | [*CareStart* COVID-19 IgM/IgG](https://www.fda.gov/media/140444/download) 07/24/2020 | | | | | | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | H, M, W | |  | | | | | | | |
| 08/10/2021 | | | Diabetomics, Inc. | | | | | | | | | | [CovAb SARS-CoV-2 Ab Test](https://www.fda.gov/media/149940/download) 06/04/2021 | | | | | | Total Antibody, Lateral Flow, Oral Fluid | | | | | | | | | | H, M, W | |  | | | | | | | |
| 08/02/2021 | | | | LumiraDx UK Ltd. | | | | | | | [LumiraDx SARS-CoV-2 Ab Test](https://www.fda.gov/media/151249/download) 08/02/2021 | | | | | | | | | | Total Antibody, Fluorescence Immunoassay, Fingerstick Whole Blood | | | | | | | | | | | | | | H, M, W | | | |
| 7/12/2021 | | Salofa Oy | | | | | [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 | | | | | | | | | | | H, M, W | | |
| 06/24/2021 | | | | | Access Bio, Inc. | | | | | | | [CareStart EZ COVID-19 IgM/IgG](https://www.fda.gov/media/150422/download) 06/24/2021 | | | | | | | | | | IgM and IgG, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | | | | | | H, M, W | |
| 4/26/2021 | | | ADVAITE, Inc. | | | | | | | [RapCov Rapid COVID-19 Test](https://www.fda.gov/media/145075/download) 01/11/2021 | | | | | | | | | | IgG, Lateral Flow, Fingerstick Whole Blood | | | | | | | | | | H, M, W |  | | | | | | | |
| 04/22/2021 | | | Megna Health, Inc. | | | | | | | [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 | | | | | | | | | | H, M, W |  | | | | | | | |
| 2/21/2020 | Hangzhou Biotest Biotech Co., Ltd. | | | | | | | | | | | | | [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 | | | | | | | | | | | | H, M, W |
| 09/23/2020 | Assure Tech. (Hangzhou Co., Ltd) | | | | | | | | | | | | | [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 | | | | | | | | | | | | H, M, W |