

FDA authorizes Beckman's IgG antibody for SARS-CoV-2

written by CAP TODAY
April 7, 2021

April 7, 2021—Beckman Coulter's Access SARS-CoV-2 IgG II antibody assay received U.S. emergency use authorization from the FDA.



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LigoLab software for supporting school surveillance testing

written by CAP TODAY
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April 6, 2021—LigoLab announced the availability of its direct-to-consumer platform TestDirectly, for clinical laboratories to use to support COVID-19 school surveillance testing.



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FDA authorizes BD combination COVID-19, flu rapid antigen test

written by CAP TODAY
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April 5, 2021—BD announced that the FDA granted emergency use authorization for its rapid antigen test that can detect SARS-CoV-2, influenza A, and influenza B in a single test.



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Diazyme obtains CE-IVD mark for SARS-CoV-2 neutralizing antibody test

written by CAP TODAY
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April 2, 2021—Diazyme Laboratories obtained CE-IVD marking for its SARS-CoV-2 neutralizing antibody test, a high-throughput chemiluminescent immunoassay.



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[**DiaSorin gets EUA for Liaison SARS-CoV-2 Ag**](#)

written by CAP TODAY
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April 1, 2021—DiaSorin received emergency use authorization from the FDA for its Liaison SARS-CoV-2 Ag.



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[**Qiagen gets EUA for NeuMoDx COVID-19 multiplex test**](#)

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March 31, 2021— Qiagen announced FDA emergency use authorization for the NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, to help identify people suspected of respiratory viral infection consistent with COVID-19.



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[**FDA authorizes Quidel QuickVue At-Home**](#)

COVID-19 test

written by CAP TODAY
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March 30, 2021—The FDA issued an emergency use authorization for the [Quidel](#) QuickVue At-Home COVID-19 test.



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Agena launches panel for SARS-CoV-2 variants

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March 29, 2021—Agena Bioscience launched its MassArray SARS-CoV-2 Variant Panel (RUO) for the detection of key SARS-CoV-2 virus strains.



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Diazyme semiquantitative SARS-CoV-2 IgG test gets EUA

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March 26, 2021—Diazyme received FDA emergency use authorization for its Semi-Quantitative DZ-Lite SARS-CoV-2 IgG CLIA test, which runs on the DZ-Lite 3000 Plus chemiluminescence analyzer.



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Roche launches SARS-CoV-2 variant test

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March 25, 2021—Roche launched the Cobas SARS-CoV-2 Variant Set 1 Test to detect and differentiate mutations found in variants that originated in the U.K. (B.1.1.7), South Africa (B.1.351), and Brazil (P.1).



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