

Beckman launches fully quantitative COVID-19 IgG test

written by CAP TODAY
May 20, 2021

May 20, 2021—Beckman Coulter launched its Access SARS-CoV-2 IgG (1st IS), a fully quantitative lab-based immunoglobulin G serology test that measures the quantity of antibodies against the virus that causes COVID-19.



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FDA greenlights Medbaye Clirra application

written by CAP TODAY
May 20, 2021

May 19, 2021—Medical software company Medbaye announced the availability of its Clirra application after it received clearance under the FDA's guidelines for device software functions and mobile medical applications.



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Roche launches SARS-CoV-2 variant test

written by CAP TODAY

May 20, 2021

May 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). This research use only laboratory test can be used to help scientists track mutation prevalence and to assess potential impact on diagnostics, vaccines, and therapeutics.



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Dyad COVID-19 specimen collection kits, components

written by CAP TODAY

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May 2021—Dyad Enterprise, formed in early 2020 in response to the COVID-19 pandemic, offers customizable COVID-19 kits and components based on specimen type, handling, and shipping requirements. Products include customizable nasopharyngeal and oropharyngeal COVID-19 specimen collection kits as well as saliva collection kits. COVID-19 antigen tests are also available. All products are available for immediate shipment.



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[Qiagen launches QIAcube Connect MDx](#)

written by CAP TODAY

May 20, 2021

May 2021—Qiagen announced the global launch of the CE-IVD-marked QIAcube Connect MDx, a flexible platform for automated sample processing available now to molecular diagnostic laboratories in the U.S., Canada, the European Union, and other markets worldwide.



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[Adaptive launches T-Detect COVID test](#)

written by CAP TODAY

May 20, 2021

May 2021—Adaptive Biotechnologies Corp. launched its T-Detect COVID, a clinical T-cell-based test to identify people who have evidence of a cellular immune response against SARS-CoV-2. It uses Adaptive's immunoSEQ technology to sequence T-cell receptors from a blood sample and identifies TCRs that the company has mapped for recognition of SARS-CoV-2 antigens.



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[Seegene submits EUA for SARS-CoV-2](#)

[multiplex assay](#)

written by CAP TODAY
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May 2021—Seegene announced it has submitted its Allplex SARS-CoV-2/FluA/FluB/RSV Assay to the FDA for emergency use authorization.



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[Promega launches XpressAmp Direct Amplification Reagents](#)

written by CAP TODAY
May 20, 2021

May 2021—Promega Corp. released its XpressAmp Direct Amplification Reagents. The product contains components for performing extraction-free preparation of viral samples for PCR-based amplification using commonly available PCR reagents from samples collected by nasopharyngeal swab in universal or viral transport medium. The reagents allow the user to perform direct amplification analysis in RT-qPCR following a 10-minute, room-temperature incubation.



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[Abbott's Alinity m Resp-4-Plex gets EUA](#)

written by CAP TODAY
May 20, 2021

May 2021—The FDA granted emergency use authorization for Abbott's Alinity m Resp-4-Plex molecular assay, which detects and differentiates SARS-CoV-2, influenza A and B, and respiratory syncytial virus in one test. The test is CE marked and available in countries outside the U.S.



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[Thermo Fisher launches customizable SARS-CoV-2 mutation panel](#)

written by CAP TODAY
May 20, 2021

May 2021—Thermo Fisher Scientific launched its Applied Biosystems TaqMan SARS-CoV-2 Mutation Panel, with a customizable menu of 22 verified real-time PCR assays for identification of SARS-CoV-2 mutations. The assays enable surveillance of variants that cause COVID-19 infection in specific regions globally and allow laboratories to choose which mutations to track.



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