

# **COVID-19, flu, RSV test available from ARUP**

written by CAP TODAY  
December 17, 2020

December 2020—ARUP Laboratories announced the availability of a combined test to detect and differentiate COVID-19, influenza, and/or respiratory syncytial virus in individuals with respiratory symptoms consistent with COVID-19. The test can be performed on specimens collected using a deep nasal swab or on specimens collected from the back of the throat and the front of both nostrils.



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# **Siemens, Novartis to develop assays**

written by CAP TODAY  
December 17, 2020

December 2020—Siemens Healthineers announced a master collaboration agreement with Novartis Pharma to design, develop, and commercialize diagnostic tests for therapeutic products across Novartis' therapeutic pipeline. The initial program will focus on developing a serum neurofilament light chain immunoassay for patients with multiple sclerosis and other neurological diseases.



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# **FDA approves first treatment for COVID-19**

written by CAP TODAY  
December 17, 2020

December 2020—The FDA approved Gilead Sciences' antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should be administered only in a hospital or health care setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval.



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# **PCR Biosystems kit for Illumina NGS systems**

written by CAP TODAY  
December 17, 2020

December 2020—PCR Biosystems has introduced its NGSBIO Library Quant Kit for Illumina. The kit contains all the components necessary for accurate and sensitive quantification of DNA libraries prior to next-generation sequencing with Illumina platforms. The kit contains five DNA standards, primers specific to the p5 and p7 Illumina adapter sequences, a library dilution buffer, and qPCRBIO SyGreen Mix or qPCRBIO SyGreen Blue Mix. The blue qPCR mix contains a nonreactive dye to improve reaction mix visibility and is useful when using small reaction volumes or white plates.



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# [Thermo Fisher monitoring service for ULT freezers](#)

written by CAP TODAY  
December 17, 2020

December 2020—Thermo Fisher Scientific introduced a service designed to enable its team of technical experts to monitor Wi-Fi-connected Thermo Scientific TSX series ultra-low temperature freezers.



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# [Fabric Genomics launches GEM algorithm for genetic disease dx](#)

written by CAP TODAY  
December 17, 2020

December 2020—Fabric Genomics launched Fabric GEM, a novel algorithm that identifies the likely genetic cause of rare diseases using next-generation sequencing.



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# **SARS-CoV-2 assay for BD Veritor Plus gets CE mark**

written by CAP TODAY  
December 17, 2020

December 2020—BD announced its rapid, point-of-care, SARS-CoV-2 antigen test for use on the BD Veritor Plus system has been CE marked to the IVD directive. The test delivers results in 15 minutes and has been authorized by the FDA under an EUA for use by authorized laboratories.



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# **Genalyte rapid COVID-19 antibody test obtains EUA**

written by CAP TODAY  
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December 2020—Genalyte announced that its SARS-CoV-2 Multi-Antigen Serology Panel received emergency use authorization from the FDA. The panel tests for IgM and IgG antibodies against 13 unique viral antigens and runs on the company's Maverick diagnostic system, which provides results in 20 minutes. The test demonstrated 98 percent specificity and 96 percent sensitivity.



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# [Agena granted EUA for SARS-CoV-2 panel](#)

written by CAP TODAY  
December 17, 2020

December 2020—Agena Bioscience's MassArray SARS-CoV-2 Panel for qualitative detection of the SARS-CoV-2 coronavirus has been granted emergency use authorization from the FDA.



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# [FDA approves liquid biopsy NGS CDx](#)

written by CAP TODAY  
December 17, 2020

December 2020—The FDA approved the Guardant360 CDx assay (Guardant Health), a liquid biopsy companion diagnostic that also uses next-generation sequencing technology to identify patients with specific types of mutations of the epidermal growth factor receptor gene in a deadly form of metastatic non-small cell lung cancer. This is the first approval to combine NGS and liquid biopsy in one diagnostic test in order to guide treatment decisions.



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