# Diazyme gets EUA for COVID-19 antibody test

written by CAP TODAY
August 24, 2020

Aug. 24, 2020—Diazyme Laboratories announced receiving FDA emergency use authorization for the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA test.



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# Adaptive gets expanded FDA clearance for ClonoSEQ assay

written by CAP TODAY
August 24, 2020

Aug. 20, 2020—Adaptive Biotechnologies received FDA clearance for its ClonoSEQ assay to detect and monitor minimal residual disease in blood or bone marrow from patients with chronic lymphocytic leukemia.



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# Verichem calibration verification kits,

# standards

written by CAP TODAY
August 24, 2020

August 2020—Verichem Laboratories announced the availability of its Enzyme ER Verifier Kit designed for the calibration verification of wet chemistry testing systems. The multianalyte, six-level kit of liquid stable materials is composed of nine clinical enzyme components—amylase, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, cholinesterase, creatinine kinase, gamma-glutamyl transferase, lactate dehydrogenase, and lipase—covering 54 activities.




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# Access SARS-CoV-2 IgG assay gets EUA

written by CAP TODAY
August 24, 2020

August 2020—Beckman Coulter has received FDA emergency use authorization for its Access SARS-CoV-2 IgG assay, a qualitative immunoassay that detects IgG antibodies directed to the receptor binding domain of the spike protein of the novel coronavirus. It uses immobilized virus antigens on magnetic particles to capture IgG antibodies from patient blood or serum samples. The test has a confirmed 100 percent positive percent agreement and 99.6 percent negative percent agreement.




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# Alpha-Tec launches SARS-CoV-2, HPV controls

written by CAP TODAY
August 24, 2020

August 2020—Alpha-Tec Systems has partnered with Microbix to provide whole-genome molecular REDx control products for SARS-CoV-2 and human papillomavirus to qualify and validate the elution, extraction, amplification, and detection steps of nucleic acid testing workflows.




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# Randox unveils cytokine tests

written by CAP TODAY
August 24, 2020

August 2020—Randox Laboratories has unveiled cytokine testing for COVID-19 risk stratification and treatment monitoring. The tests look for the presence of cytokines and are performed using Randox's Biochip technology, which can detect up to 12 cytokines and growth factors from a single patient sample. The testing menu includes 26 cytokines across four biochip panels.




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# Simplexa Congenital CMV Direct kit gets CE

# mark

written by CAP TODAY
August 24, 2020

August 2020—DiaSorin Molecular announced it has received the CE mark for its Simplexa Congenital CMV Direct kit. The molecular diagnostic test enables direct detection of cytomegalovirus DNA in saliva swab and urine specimens from babies up to 21 days old.




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# Illumina receives EUA for sequencing-based COVID-19 dx

written by CAP TODAY
August 24, 2020

August 2020—Illumina announced that the FDA issued an emergency use authorization for the Illumina COVIDSeq test, a high-throughput, sequencing-based, in vitro diagnostic workflow enabling the detection of SARS-CoV-2.




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# FDA issues first EUA for sample pooling in dx testing

written by CAP TODAY
August 24, 2020

August 2020—The FDA reissued on July 18 an emergency use authorization to Quest Diagnostics to authorize its Quest SARS-CoV-2 rRT-PCR test for use with pooled samples containing up to four individual swab specimens collected under observation. It is the first COVID-19 diagnostic test to be authorized for use with pooled samples.




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# BD launches POC SARS-CoV-2 antigen test

written by CAP TODAY
August 24, 2020

August 2020—Becton Dickinson announced that the FDA granted emergency use authorization to the BD Veritor Plus System for Rapid Detection of SARS-CoV-2 Assay, a point-of-care diagnostic test for use with the BD Veritor Plus System.