Siemens IL-6 test receives emergency use authorization

written by CAP TODAY
January 7, 2021

Jan. 7, 2021–The FDA has issued an emergency use authorization for Siemens Healthineers' laboratory-based IL-6 assay to measure the presence of interleukin-6 in human serum or plasma.

UnitedHealth to acquire Change Healthcare

written by CAP TODAY
January 7, 2021

Jan. 6, 2021—Optum, a part of UnitedHealth Group, and Change Healthcare have agreed to combine. Change Healthcare will join with the OptumInsight business to provide software and data analytics, technology-enabled services and research, and advisory and revenue cycle management offerings.

Quidel gets EUA for Solana SARS molecular

test

written by CAP TODAY
January 7, 2021

Dec. 29, 2020—Quidel received emergency use authorization from the FDA to market its Solana SARS-CoV-2 assay

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CompuGroup Medical purchases eMDs

written by CAP TODAY
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Dec. 28, 2020—CompuGroup Medical has acquired eMDs, a provider of ambulatory information systems and outsourcing services for medical accounting, for approximately $240 million.

FDA approves new indication for Tagrisso

written by CAP TODAY
January 7, 2021

Dec. 23, 2020—AstraZeneca's Tagrisso (osimertinib) has been FDA approved for the adjuvant treatment of adult patients with early-stage epidermal growth factor receptor-mutated non-small cell lung cancer after tumor resection with curative intent.

Quidel gets EUA for QuickVue SARS rapid antigen test

written by CAP TODAY
January 7, 2021

Dec. 22, 2020 —Quidel announced it received emergency use authorization from the FDA to market its QuickVue SARS Antigen test, a point-of-care assay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares swab specimens from people who are suspected of COVID-19 by their health care provider within the first five days of the onset of symptoms.

Reduced TAT for Vivalytic SARS-CoV-2 positive samples

written by CAP TODAY
January 7, 2021

Dec. 21, 2020—Randox announced that its improved software for the Vivalytic analysis device enables

its CE-marked Vivalytic SARS-CoV-2 rapid coronavirus test to deliver results for positive samples in less than 30 minutes.

Beckman launches $4, high-throughput COVID-19 antigen test

written by CAP TODAY
January 7, 2021

Dec. 18, 2020—Beckman Coulter launched the Access SARS-CoV-2 Antigen assay, a high-throughput COVID-19 test available in the U.S., priced at $4 to health care providers, including public and private institutions, governments, and nonprofits.

Verichem Labs reference materials

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December 2020—Protein-based, ready-to-use liquid Matrix Plus Cholesterol Reference kits are available from Verichem Laboratories. The kits are designed to support overall system quality control and CLIA compliance and are for the calibration or calibration verification of cholesterol and uric acid wet assays on clinical testing systems. The materials contain esterified and free cholesterol from bovine serum. The standard kit with the sixth level F covers 12 concentration points; cholesterol concentrations range

from 40 to 750 mg/dL and uric acid concentrations from 2 to 30 mg/dL. Active components are verified using standard reference materials from the National Institute of Standards and Technology. Shelf life is 21 months from the date of manufacture. Ready-to-use, liquid Total Protein and Albumin reference materials are also available. The combined Total Protein/Albumin Standard kit, along with the optional standalone Total Protein/Albumin Standard level F, are designed for the calibration and calibration verification of albumin and total protein assays on a wide number of clinical testing systems. The standards are prepared with human serum albumin and gamma-globulin serum proteins in a saline-based solution. Shelf life is 24 months from the manufacturing date.

COVID-19, flu, RSV test available from ARUP

written by CAP TODAY
January 7, 2021

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.