Cepheid SARS-CoV-2, flu, RSV test gets EUA

written by CAP TODAY
November 19, 2020

November 2020—Cepheid received emergency use authorization from the FDA for its Xpert Xpress SARS-CoV-2/Flu/RSV, a rapid molecular diagnostic test for qualitative detection of the viruses that cause COVID-19, flu A, flu B, and RSV infections from a single patient sample.

Siemens gets EUA for semi-quantitative antibody test

written by CAP TODAY
November 19, 2020

November 2020—Siemens Healthineers received FDA emergency use authorization for the SARS-CoV-2 IgG antibody test. It is the first antibody test authorized with a semiquantitative detection claim.

Bionano Prep SP Tissue and Tumor Kit

written by CAP TODAY
November 19, 2020

N0vember 2020—Bionano Genomics has launched the Bionano Prep SP Tissue and Tumor Kit, a DNA isolation kit developed for analysis of tumors and tissue with the company's Saphyr system. The kit has been designed to simplify isolation of ultra-high-molecular-weight DNA from a variety of solid tumors and tissue types.

Thermo Fisher introduces hematology-oncology portfolio

written by CAP TODAY
November 19, 2020

November 2020—Thermo Fisher Scientific announced the availability of its Oncomine Myeloid Assay GX, the first in a series of clinical research assays available from the company's new portfolio of hematology-oncology assays for the Ion Torrent Genexus System.

EUA for personal PCR device for COVID-19 testing

written by CAP TODAY
November 19, 2020

November 2020—The FDA has issued an emergency use authorization for Visby Medical's single-use

personal PCR device, a rapid test for detecting COVID-19.

ARUP shares formula for transport media

written by CAP TODAY
November 19, 2020

November 2020—ARUP Laboratories' formula for ARUP Transport Media is now available to other laboratories. The formula is provided at the end of an article about an ARUP and University of Utah Health study in which the transport media was used for specimen collection (Hanson KE, et al. *J Clin Microbiol*. Accepted manuscript. Published online Aug. 12, 2020. doi:10.1128/JCM.01824-20).

Alpha-Tec QC1 malaria slides

written by CAP TODAY
November 19, 2020

November 2020—Alpha-Tec Systems has released quality control slides containing smears of red blood cells infected with a mixture of ring-form, trophozoite, and schizont stages of *Plasmodium falciparum*. The slides are prefixed with methanol and are ready to stain with traditional Giemsa, Wright's, or Field stains.

FDA clears Simplexa flu A/B, RSV assay

written by CAP TODAY
November 19, 2020

November 2020—DiaSorin Molecular received FDA clearance for its Simplexa Flu A/B & RSV Direct Gen II kit. The assay can be run alone or alongside the Simplexa COVID-19 Direct kit, allowing for differential diagnosis of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus.

Bio-Rad controls for COVID-19 testing

written by CAP TODAY
November 19, 2020

November 2020—Bio-Rad Laboratories launched its in vitro diagnostics Virotrol SARS-CoV-2 and Viroclear SARS-CoV-2 positive and negative quality controls for use in antibody testing of SARS-CoV-2. The serological controls are available for in vitro assay procedures in the U.S. and are CE marked for IVD markets outside the U.S.

CLSI guidelines

written by CAP TODAY
November 19, 2020

November 2020—The Clinical and Laboratory Standards Institute released two new guidelines, *MM13: Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods,* 2nd ed., and *GP42: Collection of Capillary Blood Specimens*, 7th ed.

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