FDA approves liquid biopsy NGS CDx

written by CAP TODAY
October 1, 2020

Oct. 1, 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.

Siemens, CDC to develop process to standardize SARS-CoV-2 assays

written by CAP TODAY
October 1, 2020

Sept. 29, 2020—Siemens Healthineers will collaborate with the Centers for Disease Control and Prevention and the Joint Research Centre of the European Commission on a research project to develop a novel process for standardizing SARS-CoV-2 assays.

FDA issues EUA for Yale's SalivaDirect

written by CAP TODAY
October 1, 2020

Sept. 28, 2020—The FDA issued an emergency use authorization to Yale School of Public Health for its SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection, the agency says.

FDA approves expanded use of CINtec Plus Cytology

written by CAP TODAY
October 1, 2020

Sept. 25, 2020—Roche announced FDA approval for the expanded use of CINtec Plus Cytology, a triage test based on biomarker technology for women whose cervical cancer screening results are positive for high-risk types of human papillomavirus.

Accumen releases EUA COVID-19 saliva testing kits

written by CAP TODAY
October 1, 2020

Sept. 24, 2020—Accumen announced a partnership with medical equipment manufacturer Spectrum Solutions to provide saliva testing kits for detecting COVID-19.

ARUP shares formula for transport media

written by CAP TODAY
October 1, 2020

Sept. 23, 2020—ARUP Laboratories' formula for ARUP Transport Media is now available to other laboratories.

Qiagen fully acquires NeuMoDx Molecular

written by CAP TODAY
October 1, 2020

Sept. 22, 2020—Qiagen has acquired the remaining 80.1 percent of NeuMoDx Molecular for $248 million in cash.

Bruker introduces MALDI-2 source on TimsTOF Flex

written by CAP TODAY
October 1, 2020

September 2020—Bruker announced an advance in matrix-assisted laser desorption ionization with the launch of its MALDI-2 post-ionization (PI) source, now available as an option on the TimsTOF Flex ESI/MALDI mass spectrometer. The MALDI-2 technology can offer one or two orders of magnitude higher sensitivity for many small molecules and lipids, Bruker said. MALDI-2 increases the applications range of MALDI mass spectrometry and imaging even further. Bruker launched additional TIMS/PASEF-enabled 4D proteomics methods that leverage the large-scale, real-time availability of accurate collision cross sections (CCS) for thousands of measured peptides per 4D nanoLC-CCS-MS/MS run.

Power of Process, LabVine offer online lab program

written by CAP TODAY
October 1, 2020

September 2020—Power of Process, an international learning and development company, and LabVine have partnered to provide an online laboratory performance improvement program, hosted on Labvinelearning.com. The program consists of the Power of Process Champion and Power of Process Master courses followed by a three-month workplace component to embed learning.

Luminex receives EUA for COVID-19 antibody test

written by CAP TODAY
October 1, 2020

September 2020—Luminex Corp. announced that the FDA issued an emergency use authorization for the company's xMAP SARS-CoV-2 Multi-Antigen IgG Assay. The assay demonstrated specificity of 100 percent in human serum and greater than 99 percent in human plasma, with sensitivity greater than 96 percent for human serum and plasma (>14 days post-symptom onset) in clinical studies.