ZeptoMetrix launches NATtrol MS2 bacteriophage stock

written by CAP TODAY
January 11, 2023

January 2023—ZeptoMetrix launched its NATtrol MS2 bacteriophage quantitative stock, intended for use as an internal process control for rt-PCR assays.

FDA clears HemoSonics Quantra with QStat cartridge

written by CAP TODAY
January 11, 2023

January 2023—HemoSonics has received FDA 510(k) clearance for the Quantra hemostasis system with QStat cartridge. The clearance of the QStat cartridge expands the Quantra system's indications for use to include trauma and liver transplant procedures.

On display: pathology resident's art in honor of friend

written by CAP TODAY
January 11, 2023

The photography collection of Leonard Yenwongfai, MD, MS, a third-year pathology resident at the University of Kentucky College of Medicine, was selected for display at the Arts in HealthCare North Gallery located in the Kentucky Clinic, part of the UK hospital. His collection of flowers and insect life is titled "Patterns and Pollinators" and was born of concern for a friend who had been diagnosed in 2020 at UK with bulbar amyotrophic lateral sclerosis and missed spending time outdoors. Read the UK HealthCare article here.

Primary medical care in transition

written by CAP TODAY
January 11, 2023

Bruce A. Friedman, MD, emeritus professor of informatics, Department of Pathology, University of Michigan Medical School, and member of LigoLab Information Systems' advisory board, has written an opinion piece titled "Primary Medical Care in Transition: Effects on the Lab Test Ordering Market." Read the piece here.

Qiagen, Helix partner to advance CDx for hereditary diseases

written by CAP TODAY
January 11, 2023

Jan. 6, 2023—Qiagen announced an exclusive strategic partnership with Helix to advance companion diagnostics for hereditary diseases.

Xifin white paper: a guide to molecular Dx market-share expansion

written by CAP TODAY
January 11, 2023

Xifin released a white paper titled "The Executive's Guide to Molecular Diagnostic Market-Share Expansion: Critical Success Factors for Maximizing Revenue, Patient Access, and Physician Engagement." Authors Kyle Fetter, chief operating officer, and Harley Ross, chief commercial officer, offer practical approaches, process enhancements, and payor strategies essential to growing novel diagnostic market share through proactive, purposeful, and technologically enabled engagements with patients, physicians, and payors. Download the white paper here.

FDA approves FoundationOne Liquid CDx for a group of TKIs

written by CAP TODAY
January 11, 2023

Dec. 28, 2022—The FDA has approved Foundation Medicine's FoundationOne Liquid CDx as a companion diagnostic to identify patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitutions and are appropriate for treatment with a group of tyrosine kinase inhibitors approved by the FDA for this indication

Hologic awarded contract from BARDA

written by CAP TODAY
January 11, 2023

December 2022—Hologic has been awarded a $19 million contract from the Biomedical Advanced Research and Development Authority. The funding will help bring Hologic's Panther Fusion SARS-CoV-2/Flu A/B/RSV and Aptima SARS-CoV-2 assays in line with the FDA's in vitro diagnostic standards and support clinical efforts to obtain claims for nasal samples using the Panther Fusion as well as market authorization for COVID-19 testing of asymptomatic individuals who have reason to be tested. The Aptima SARS-CoV-2 assay received EUA in May 2020, and the CE-marked Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is under development in the United States. The project has been funded with federal funds from the U.S. Department of Health and Human Services, the Administration for Strategic Preparedness and Response, and BARDA.

Sebia acquires Zeus Scientific

written by CAP TODAY
January 11, 2023

December 2022—Sebia announced the acquisition of Zeus Scientific, an in vitro diagnostic company based in Branchburg, NJ. Sebia, headquartered in Lisses, France, says the acquisition will expand its capabilities and product portfolio in autoimmunity and reinforce its operations and footprint in the United States. Financial terms of the agreement are undisclosed.

FDA authorizes Abbott monkeypox test

written by CAP TODAY
January 11, 2023

December 2022—The FDA issued emergency use authorization to Abbott Molecular for the Alinity m MPXV, a real-time polymerase chain reaction test intended to detect monkeypox DNA using lesion swab specimens from individuals suspected of monkeypox virus infection. The test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of PCR and in vitro diagnostic procedures. Testing is limited to CLIA-certified laboratories that meet the requirements to perform moderate- or high-complexity tests.