Quantimetrix Dipper POCT now with integrated barcode

written by CAP TODAY
April 18, 2024

April 18, 2024—Quantimetrix announced that its Dipper POCT urinalysis dipstick control pouches now include a barcode.

FDA approves test to screen for malaria in blood donors

written by CAP TODAY
April 18, 2024

April 2024—Roche announced FDA approval of the Cobas Malaria test, a qualitative in vitro nucleic acid screening test for the direct detection of *Plasmodium* RNA and DNA in whole blood samples from individual human donors. The test can be performed with other routine blood donor screening tests and is designed for use on the Cobas 6800/8800 systems in the United States.

FDA clears Diasorin Liaison Plex system

written by CAP TODAY
April 18, 2024

April 2024—Diasorin announced FDA 510(k) clearance for its Liaison Plex platform and Flex respiratory assay. The fully automated, sample-to-answer system uses room-temperature–stable consumables and has a hands-on time of two minutes per sample. Results are available in less than two hours. Diasorin says Flex testing allows users to generate and pay for a subset of specific results based on a patient's clinical picture.

Bio-Rad launches QC online learning center

written by CAP TODAY
April 18, 2024

April 2024—Bio-Rad Laboratories has launched its online Quality Controls Learning Center, a free resource designed to provide laboratories with the educational resources needed to maintain quality control patient test results. The site provides a library of articles and best practices on quality control process and design, laboratory management, quality control data management, quality control troubleshooting and solutions, and the benefits of independent quality control.

Sekisui gets EUA for Osom flu, SARS-CoV-2 test

written by CAP TODAY
April 18, 2024

April 2024—Sekisui Diagnostics has received emergency use authorization for its Osom Flu SARS-CoV-2 Combo test for use in professional and home testing settings. The lateral flow immunochromatographic assay is intended for the qualitative detection and differentiation of influenza A and B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen. The test is for in vitro diagnostic use.

SpotFire R/ST panel gets 510(k) clearance, CLIA waiver

written by CAP TODAY
April 18, 2024

April 2024—BioMérieux has received FDA 510(k) clearance and CLIA waiver approval for the BioFire SpotFire Respiratory/Sore Throat (R/ST) panel. The multiplex PCR test is for the detection and identification of nucleic acids from up to 15 of the most common bacteria, viruses, and viral subtypes responsible for respiratory or sore throat infections. Samples can be taken from a nasopharyngeal swab when a respiratory tract infection is suspected or from a throat swab in case of a pharyngitis syndrome. Results are available in about 15 minutes on the BioFire SpotFire system.

Verichem releases microprotein reference materials

written by CAP TODAY
April 18, 2024

April 2024—Verichem Laboratories offers a multilevel set of clinical reference materials intended for the calibration verification of clinical systems testing for total protein and albumin in urine and cerebrospinal fluid samples. The liquid-stable and ready-to-use materials are suitable for use with turbidimetric and colorimetric test methods and incorporate human protein components.

De novo classification granted for ADAMTS13 activity test

written by CAP TODAY
April 18, 2024

April 2024—Technoclone and its distributor in the United States, DiaPharma Group, announced that the FDA has granted de novo classification for the Technozym ADAMTS13 Activity ELISA. The assay is intended for the qualitative determination of ADAMTS13 activity in platelet poor human citrated plasma and indicated for use in conjunction with other clinical and laboratory findings as an aid in diagnosing thrombotic thrombocytopenic purpura in adult and pediatric patients being evaluated for thrombotic microangiopathy.

Bayer, Thermo Fisher to develop NGS CDx assays

written by CAP TODAY
April 18, 2024

April 2024—Bayer and Thermo Fisher Scientific announced that they will develop next-generation sequencing–based companion diagnostic assays to help identify patients who may benefit from Bayer's precision cancer therapies. The assays will be developed using Thermo Fisher's Oncomine Dx Express test on the Ion Torrent Genexus Dx system. The Genexus Dx instrument and Oncomine Dx Express test are CE-IVD marked and only available in countries that accept the CE mark.

Bio-Rad gets My Green Lab certification

written by CAP TODAY
April 18, 2024

April 2024—Bio-Rad Laboratories announced it received My Green Lab certification for its R&D facilities in Irvine, Calif. It has been certified at My Green Lab's highest rating, green, which reflects the percentage of possible green lab best practices that have been adopted and the extent to which they have been adopted by the lab.