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

written by CAP TODAY
April 17, 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.

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

written by CAP TODAY
April 17, 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.

Bio-Rad launches QC online learning center

written by CAP TODAY
April 17, 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.

StatLab acquires Poly Scientific R&D

written by CAP TODAY
April 17, 2024

April 2024—StatLab Medical Products announced the acquisition of Poly Scientific R&D, a manufacturer and supplier of pathology stains, reagents, and paraffin for anatomic pathology laboratories. The acquisition includes Histology Control Systems, a division of Poly Scientific that manufactures and supplies tissue control slides.

written by Keith Eilers
April 17, 2024

Register for our upcoming webinar

Virtual Roundtable: Optimizing Testing for the Diagnosis of Systemic Mastocytosis

June 25, 2024, 1:00 PM–2:00 PM ET

Webinar presenters **Robyn Scherber, MD, MPH** Hematologist UT Health SA, Medical Director Blueprint Medicines; **Anton Rets, MD, PhD** Associate Professor University of Utah, Medical Director Hematopathology and Immunohistochemistry; **Nathan A. Boggs, MD, PhD** Assistant Professor of Medicine, Uniformed Services University Allergy Division Director will discuss the barriers and possible solutions to screening for and diagnosing Systemic Mastocytosis (SM) and recommendations that will empower cross-functional laboratory stakeholders to implement changes that can help improve the diagnosis of SM.

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Confronting diagnostic gaps in fungal infection

written by CAP TODAY
April 17, 2024

April 2024—The rise in fungal infections in recent years troubles Sean Zhang, MD, PhD, for reasons near and far. It's readily apparent in the patient populations at Johns Hopkins Hospital, where he is director of the mycology laboratory. Especially concerning is the increase in *Candida auris* following the height of the COVID-19 pandemic, both in terms of colonization and infection cases, says Dr. Zhang, who is also associate professor of pathology, Division of Medical Microbiology, Department of Pathology, Johns Hopkins University School of Medicine. "Since 2022, we suddenly saw an uptick in *Candida auris* cases across the Johns Hopkins Health System." But the situation isn't unique to Johns Hopkins. Pointing to CDC figures, he notes that the tide is rising more broadly as well. The agency reports that in 2020, there were 757 clinical cases and 1,310 screening cases of *C. auris* in the United States. In 2022, there were 2,377 clinical cases and 5,754 screening cases.

Hybrid practice model beckons as solution

written by CAP TODAY
April 17, 2024

With the technology now available, could and should remote diagnostic pathology, or at least a hybrid model, become more the norm in the future? Timothy Craig Allen, MD, JD, and Casey P. Schukow …

Roche pTau217 test gets breakthrough device designation

written by CAP TODAY
April 17, 2024

April 17, 2024—Roche announced that its Elecsys pTau217 assay received breakthrough device designation from the FDA.

Need for speed in solid tumor molecular testing

written by CAP TODAY
April 17, 2024

April 2024—As the call for fast turnaround of genetic testing results in tumor profiling grows louder, the need for rapid, reliable test methods becomes more pressing. Meanwhile, with new genetic biomarkers emerging at a rapid pace, “everything has tipped the balance toward comprehensive next-generation sequencing analysis,” said Maria E. Arcila, MD, attending pathologist, molecular diagnostics and hematopathology services, Department of Pathology and Laboratory Medicine, Memorial Sloan Kettering Cancer Center. In the midst of this complexity, “the ability to provide rapid and simple results is lagging behind,” said Dr. Arcila, in addressing rapid molecular testing in solid tumors at the Association for Molecular Pathology meeting last year.

Microscope to image—big lift but also a blueprint

written by CAP TODAY
April 17, 2024

April 2024—The Food and Drug Administration in February cleared Proscia’s Concentriq AP-Dx digital pathology software for the purpose of primary diagnosis. Shortly after, Proscia cofounder and CEO David West spoke with CAP TODAY publisher Bob McGonnagle about achieving new efficiencies, elevating pathology, the heterogeneous nature of the pathology community, and being able to learn from digital pathology’s early adopters. “Laboratories and pathologists going digital don’t have to be first anymore,” West said.