Abbott’s STI assay gets FDA clearance

written by CAP TODAY
May 13, 2022

May 13, 2022—Abbott has received FDA clearance for its Alinity m STI assay.

Put It on the Board

written by CAP TODAY
May 13, 2022

May 2022—The Department of Health and Human Services and the Centers for Medicare and Medicaid Services should engage laboratory stakeholders early and across the spectrum of care delivery environments before laboratory policies are implemented in public health emergencies, the Association for Molecular Pathology says in a report released April 19 titled “Economics of Testing During a Public Health Emergency: Lessons Learned from Two Years of COVID-19.”

FDA authorizes Fujirebio test for Alzheimer

disease

written by CAP TODAY
May 13, 2022

May 11, 2022—Fujirebio Diagnostics announced that the FDA has granted de novo marketing authorization for its Lumipulse G β-Amyloid Ratio (1-42/1-40) in vitro diagnostic test for assessing β-amyloid pathology in patients who are being evaluated for Alzheimer's disease and other causes of cognitive decline.

BioFire joint infection panel gets de novo authorization

written by CAP TODAY
May 13, 2022

May 9, 2022—BioMérieux's BioFire joint infection panel has received FDA de novo authorization.

Tribun Health enters pharmaceutical market

written by CAP TODAY
May 13, 2022

April 27, 2022—Tribun Health, formerly Tribvn Healthcare, announced its expansion into the pharmaceutical market with the appointment of Loic Dartois as vice president of pharma.

Accelerate Diagnostics presents performance data at ECCMID

written by CAP TODAY
May 13, 2022

April 22, 2022—Accelerate Diagnostics announced the release of new performance data on the Accelerate Arc module and blood culture kit.

Versant Dx launches strategy to accelerate digital pathology

written by CAP TODAY
May 13, 2022

April 21, 2022—Versant Diagnostics has announced a strategy to “drive the digital revolution in pathology,” with a focus on anatomic pathology, precision medicine, and the digital transformation of the industry.

PreciseDx AI-enabled digital pathology detects Parkinson's

written by CAP TODAY
May 13, 2022

April 20, 2022—PreciseDx today announced its artificial intelligence–enabled digital pathology technology can accurately diagnose Parkinson's disease in patients prior to the severe onset of symptoms.

Paragon Genomics unveils CleanPlex Emerging Variant Add-on V2

written by CAP TODAY
May 13, 2022

April 2022—Paragon Genomics announced the release of its Emerging Variant Add-on V2. The panel is designed to be used with existing CleanPlex SARS-CoV-2 products, the company says, to maintain high coverage for variant calling and identification as the virus evolves. It includes added primers for enhanced coverage of critical variants, such as alpha, beta, delta, mu, and omicron, and has been confirmed in silico to cover the defining and characteristic mutations of the omicron sublineages, BA.1, BA.2, and BA.3.

Thermo Fisher RT-LAMP tests for ID surveillance

written by CAP TODAY
May 13, 2022

April 2022—Thermo Fisher Scientific has launched two reverse transcription loop-mediated isothermal amplification (RT-LAMP)–based solutions for research use only. The Invitrogen Colorimetric ReadiLAMP Kit, SARS-CoV-2, is an off-the-shelf assay designed to provide accurate, robust detection of SARS-CoV-2 from saliva, nasal, or nasopharyngeal swab samples. The kit includes two protocols, one for crude sample types with a 30-minute turnaround time and one for increased sensitivity with purified RNA sample types that has a one-hour turnaround time.

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