Cepheid gets CLIA waiver for Xpert Xpress MVP

written by CAP TODAY
January 19, 2024

Jan. 19, 2024—Cepheid announced it has received FDA clearance with a CLIA waiver for the Xpert Xpress MVP, a multiplex vaginal panel that can now be performed in near-patient settings.

More progress, fewer barriers for PGx testing

written by CAP TODAY
January 19, 2024

January 2024—Sometimes even superb ideas can also turn out to be quite, well, bothersome. Zoom meetings. Bridal showers. Bike lanes. Parking apps. QR menu codes. And—if laboratories aren't careful—the same can be true of pharmacogenomic testing. Just ask Ann Moyer, MD, PhD, associate professor, laboratory medicine and pathology, Mayo Clinic. When it comes to pharmacogenomic testing, laboratory medicine brings significant expertise to the table. But in clinical settings, physicians who prescribe the medications need to be familiar with how to use the test results. They also need to work with the lab to decide which tests, for which genes or gene-drug pairs, will be most helpful for their patients, she says. "Especially if you're going to start incorporating clinical support alerts into the EHR," adds Dr. Moyer, who was chair of (until Dec. 31; she is now advisor to) the CAP/ACMG Biochemical and Molecular Genetics Committee. "If the practice doesn't actually want them, then you're just going to end up annoying them."

The who, when, and why of thrombophilia testing

written by CAP TODAY
January 19, 2024

January 2024—Thrombophilia testing has been shown to be performed far more often than indicated in thromboembolic events, at significant cost to the patient and hospital.

Lab-developed test proposal reflections and predictions

written by CAP TODAY
January 19, 2024

January 2024—The Food and Drug Administration's proposed rule on laboratory-developed tests would phase out its existing enforcement discretion approach for oversight of LDTs. Instead, the FDA would classify in vitro diagnostics offered as LDTs as class I, II, or III medical devices depending on their risk to patients.

A scan of studies on HER2-low breast cancer scoring

written by CAP TODAY
January 19, 2024

January 2024—Much has been said and written about scoring HER2-low breast cancer, and it has its difficulties. But there are steps and tools to support scoring, and Savitri Krishnamurthy, MD, last fall shined a light on them and several HER2-low breast cancer-related studies.

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7 pointers for POC cardiac troponin measurement

written by CAP TODAY
January 19, 2024

January 2024—Seven recommendations for the use of cardiac troponin measurement at the point of care were published last year and reported in a session at the Association for Diagnostics and Laboratory Medicine annual meeting, shortly after the recommendations appeared in print.

Thoracic SMARCA4-deficient undifferentiated tumor

written by CAP TODAY
January 19, 2024

January 2024—Thoracic SMARCA4-deficient undifferentiated tumor (TSDUT), formerly known as SMARCA4-deficient thoracic sarcoma and SMARCA4-deficient thoracic sarcomatoid tumor, is a relatively newly defined entity with a distinct clinical history, morphology, immunohistochemical profile, molecular findings, and clinical behavior.

Bethesda System for Reporting Thyroid Cytopathology

written by CAP TODAY
January 19, 2024

January 2024—The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) is a widely endorsed and globally adapted standardized reporting system of thyroid fine-needle aspiration specimens.

Reporting urine cytology: how Paris 2.0 differs from 1.0

written by CAP TODAY
January 19, 2024

January 2024—Urinary cytology is widely used to screen for high-grade urothelial carcinoma (HGUC) and to monitor for recurrence. Several reporting systems have been proposed over the past few decades, but The Paris System (TPS) for Reporting Urinary Cytology is the most widely applied worldwide.

Panelists on viscoelastic and other coag assays

written by CAP TODAY
January 19, 2024

January 2024—Viscoelastic assays and other coagulation tests were front and center when CAP TODAY publisher Bob McGonnagle on Nov. 20 convened seven people in an online roundtable. Oksana Volod, MD, and Eric Salazar, MD, PhD, and five company representatives weighed in on, among other things, appropriate test use, automation, and laboratory-developed tests. What they said begins here.