FDA clears Avails Medical AST system

written by CAP TODAY
March 19, 2024

March 2024—Avails Medical announced it has received FDA 510(k) clearance for its Equant system, an automated lab inoculation preparation system that consists of a single module instrument that holds a cuvette with an electrical sensor. It is intended for use with positive blood cultures samples for direct antimicrobial susceptibility testing without the traditional overnight subculture. The system works by preparing samples for direct susceptibility testing by manual agar disk diffusion.

Randox releases bladder cancer array

written by CAP TODAY
March 19, 2024

March 2024—Randox has released its female bladder cancer array, designed to help clinicians stratify patients presenting with hematuria. The array detects interleukin-12p70, interleukin-13, midkine, and clusterin from a single urine sample to determine an individual's biomarker risk score. A person's risk for developing bladder cancer is determined by combining the biomarker risk score with clinical risk scores generated using the company's algorithms.

FDA clears EDTA cartridges for SeptiCyte Rapid

written by CAP TODAY
March 19, 2024

March 2024—Immunexpress announced FDA clearance of EDTA blood compatible cartridges for use with the SeptiCyte Rapid test. SeptiCyte Rapid is a sample-to-answer, cartridge-based, host response molecular test for sepsis using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes isolated from whole blood. It is intended for in vitro diagnostic use and runs on the Biocartis Idylla platform.

Binx, Cardinal Health enter into distribution agreement

written by CAP TODAY
March 19, 2024

March 2024—Binx Health announced it has entered into a national distribution agreement with Cardinal Health to expand access to care with its CLIA-waived, FDA-cleared Binx IO. The molecular point-of-care platform is used to detect chlamydia and gonorrhea in male and female patient samples and provides results in about 30 minutes.

Roche to acquire LumiraDx's POC technology

written by CAP TODAY
March 19, 2024

March 2024—Roche has entered into a definitive agreement to acquire select parts of the LumiraDx group related to LumiraDx's point-of-care technology. The transaction is expected to close by the middle of this year, after which the acquired entities will be fully integrated into Roche Diagnostics.

Bruker to acquire EliTechGroup

written by CAP TODAY
March 19, 2024

March 2024—Bruker Corp. has entered into a definitive share purchase agreement to acquire EliTechGroup for €870 million (about $940 million) in cash, excluding EliTech's clinical chemistry business. Bruker expects to close the transaction in the second quarter of this year.

Cepheid gets CLIA waiver for Xpert Xpress MVP

written by CAP TODAY
March 19, 2024

March 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. The test is intended to aid in the diagnosis of bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis from a single specimen. It runs on Cepheid's GeneXpert Xpress instruments and provides results within an hour.

Copan gets third clearance for Colibrí system

written by CAP TODAY
March 19, 2024

March 2024—Copan Diagnostics announced the third FDA 510(k) clearance for its Colibrí automated ID/AST preparation instrument. The in vitro diagnostic specimen preparation system has been cleared to prepare MALDI-TOF targets for qualitative identification and microbial suspension for the Beckman Coulter MicroScan WalkAway antimicrobial susceptibility testing system for qualitative testing of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media.

OGT expands NGS operations in the U.K.

written by CAP TODAY
March 19, 2024

March 2024—OGT announced the opening of state-of-the-art facilities in Oxford Technology Park in the U.K. The facilities will drive development of OGT's SureSeq next-generation sequencing product portfolio, as well as deliver expert-led training and opportunities for collaboration. Customers can receive face-to-face support with OGT's field application specialists at the new facility and in-depth demonstrations of the company's NGS and FISH products.

Qiagen Digital Insights launches NGS analysis for somatic cancer

written by CAP TODAY
March 19, 2024

March 2024—Qiagen Digital Insights announced its enhanced CLC Genomics Workbench Premium with LightSpeed technology now supports next-generation sequencing for somatic cancer secondary analysis. The software accelerator converts raw sequencing data in FASTQ files to interpretable lists of genetic variants in variant call format files. Qiagen says LightSpeed can analyze a 275-gene comprehensive cancer panel at 3377× coverage in six minutes for less than $0.72 per test within standard cloud environments, or laboratories can run the Qiagen CLC LightSpeed technology on existing local hardware with similar performance.