Thermo Fisher expands hematology-oncology NGS portfolio

written by CAP TODAY
October 19, 2021

October 2021—Thermo Fisher Scientific announced a suite of Ion Torrent Oncomine immune repertoire assays designed to detect potentially malignant clones of T cells and B cells. Using proprietary Ion AmpliSeq technology, the pan-clonality assays target multiple parts of the B- and T-cell immune receptors using a single reaction with ultra-high sensitivity.

Cepheid gets EUA for Xpert Xpress CoV-2/Flu/RSV Plus

written by CAP TODAY
October 19, 2021

October 2021—Cepheid received FDA emergency use authorization for its Xpert Xpress CoV-2/Flu/RSV Plus, a rapid molecular diagnostic test for qualitative detection of the viruses causing COVID-19, flu A, flu B, and respiratory syncytial virus infections from a single patient sample. The Plus version of the test provides three gene targets for SARS-CoV-2 detection—N2, E, and RdRP. The test is designed for use on any GeneXpert system and results are delivered in about 36 minutes.

Steripath Micro available for use in children's hospitals

written by CAP TODAY
October 19, 2021

October 2021—Magnolia Medical Technologies announced the commercial availability of its Steripath Micro Initial Specimen Diversion Device designed for use in children's hospitals. Steripath Micro is an FDA 510(k)-cleared device with the specific indication to reduce blood culture contamination. The small, lightweight device requires less than 1 mL of blood for patients with limited volumes or difficult intravenous access. The company says Steripath Micro has shown a zero percent contamination rate in two leading children's hospitals during a three- month period.

LumiraDx submits SARS-CoV-2/flu A/B antigen test for EUA

written by CAP TODAY
October 19, 2021

Oct. 18, 2021—LumiraDx has submitted the LumiraDx SARS-CoV-2 & Flu A/B Test to the Food and Drug Administration for emergency use authorization.

Results release: new steps under new rules?

written by CAP TODAY
October 19, 2021

October 2021—Neither pathologists nor laboratories should panic over the new 21st Century Cures Act rules making laboratory results immediately accessible to patients, pathology leaders agree. Most laboratories already release results to electronic health records and those results are made available in patient portals, and the Cures Act will require little change in how labs send results to EHR systems. But the rules, which took effect April 5, do come with some complexities to navigate. By passing the Cures Act in 2016, Congress aimed broadly to increase interoperability across EHR platforms and to ensure that patients have full, portable, and cost-free access to their health care information. Of most direct relevance to pathology is the Cures Act's information blocking or open notes rule, mandating that lab report narratives and pathology report narratives, along with six other categories of clinical notes, be available without delay to patients in different electronic formats, including smartphones and secure online portals.

Parsing the role of race in Alzheimer's biomarkers

written by CAP TODAY
October 19, 2021

October 2021—It's not quite six degrees of Kevin Bacon, but the connection between Alzheimer's disease biomarkers and equity in medicine is real (and far more important). It's a trail researchers have been following for some time, but which has gained more prominence with the recent approval of a new drug for treating the disease (aducanumab) and the acknowledgment of racial disparities in CSF amyloid and tau biomarkers and their associated cutoffs.

AST and safety at core of microbiology checklist changes

written by CAP TODAY
October 19, 2021

October 2021—By Jan. 1, 2024, laboratories must use current breakpoints to interpret antimicrobial minimum inhibitory concentration and disk diffusion test results, according to a new requirement in the latest edition of the CAP Accreditation Programs microbiology checklist, released Sept. 22.

Up close on clonal hematopoiesis in cfDNA testing

written by CAP TODAY
October 19, 2021

October 2021—Clonal hematopoiesis is a significant biological phenomenon and denotes presence of mutations in bone marrow stem cells in the absence of a hematologic malignancy.

Molecular or morphology? Challenges in pathologic diagnoses

written by CAP TODAY
October 19, 2021

October 2021—Recent molecular genetic advances have dramatically expanded diagnostic options, thus revolutionizing the diagnosis of many tumor types, especially those of soft tissue and bone. Advances in the discovery of molecular alterations underlying neoplastic pathogenesis have also provided insights into novel therapeutic targets and prognostic biomarkers. These improvements have led to the reclassification of a growing list of previously established tumor types, resulting in significant challenges for practicing pathologists, as exemplified herein.

'Scary situation'—lab leaders on staffing and COVID

written by CAP TODAY
October 19, 2021

October 2021—Surge, supplies, staffing. Eighteen months into the pandemic, the story remains similar. Even where laboratory salaries have been bumped up or sign-on bonuses have been in place to strengthen the workforce, Compass Group members report little to no success. And on supplies: "Every week we cross our fingers and toes to see what arrives in the door, how to disperse that through the

systems, and how to continually educate the physicians on appropriate use of that limited resource," says Judy Lyzak, MD, MBA, of Alverno Laboratories. She and other laboratory leaders of the Compass Group met virtually Sept. 6 to share their latest. Of the confluence of problems laboratories face, one said: "I have never seen anything quite like this."