Tox testing challenges in adolescents, young adults

written by CAP TODAY
March 18, 2021

March 2021—Synthetic cannabinoids. Toxic household substances. Over-the-counter medicine. These and other drug and non-drug substances are favored by adolescents and young adults and tough to detect, and the pandemic has exacerbated their use. “Many drugs that are of interest for this age group are household substances, things they can get their hands on easily, and often those tests are not available as immunoassays,” said Sarah E. Wheeler, PhD, medical director of the automated laboratory, University of Pittsburgh Medical Center Children’s Hospital of Pittsburgh, and assistant professor of pathology, University of Pittsburgh, in a session on adolescent and young adult substance abuse testing at AACC’s virtual annual meeting last year.

Rapid ID from positive blood culture: Labs tally gains

written by CAP TODAY
March 18, 2021

March 2021—Fresh from its Dec. 27, 2020 FDA clearance, the Bruker MALDI Sepsityper Kit US IVD promises to provide microbiology laboratories with a universal, rapid sepsis identification solution. With the Bruker MALDI Biotyper platform’s reference library covering 491 organisms, the Sepsityper’s ability to identify pathogens directly from positive blood cultures in suspected bacterial or fungal sepsis cases delivers an “order of magnitude increase” in the number of microorganisms that can be identified through PCR detection, said Wolfgang Pusch, Bruker Daltonics executive vice president of microbiology and diagnostics, in a company statement.

AMP case report: A CLL/SLL case with distinctive molecular and cytogenetic changes during different stages of disease progression

written by CAP TODAY
March 18, 2021

March 2021—Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is one of the most common lymphoproliferative diseases. It is a CD5-positive B-cell neoplasm of monomorphic small mature B cells. One of the characteristics of CLL/SLL is its heterogeneity, not only among individuals but also within individual patients.[1] The cytogenetic and molecular variants are dynamic during disease progression and in response to targeted therapies.

Oxford Immunotec submits EUA for T-SPOT.COVID test

written by CAP TODAY
March 18, 2021

March 17, 2021—Oxford Immunotec has released the T-SPOT.COVID test, a CE-marked ELISpot-based test intended for qualitative detection of T-cell immune response to SARS-CoV-2 in human whole blood.

From the President's Desk: Lab quality in times of COVID-19

written by CAP TODAY
March 18, 2021

March 2021—I inspected my first lab as a pathology resident in 1988. Robert Baisden, MD, head of clinical pathology at Medical College of Georgia at the time, handed me a checklist one day and said we were going to do a laboratory inspection. Like that of so many pathologists, my introduction to the CAP came through the Laboratory Accreditation Program. The Laboratory Improvement Program, LIP, is an essential component in the CAP's efforts to ensure laboratory quality.

Q&A column

written by CAP TODAY
March 18, 2021

Q. In our hospital, respiratory therapy runs most of the blood gas tests on instruments in centralized locations. Staff are able to enter into the blood gas instrument, which is connected to the LIS, to whom they gave critical results. However, staff do not have a way to document that a result was read back. The majority of these critical results happen in the neonatal intensive care and intensive care units, where respiratory therapy is a part of the care team, so results are given in person. Is documenting a read-back necessary when critical results are communicated verbally? How does the CAP checklist COM.30100 relate to point-of-care testing? Read answer.

Clinical pathology selected abstracts

written by CAP TODAY
March 18, 2021

March 2021—Convalescent plasma, with neutralizing and non-neutralizing anti-viral antibodies, has been used to treat COVID-19 patients. Plasma is collected from people who have recovered from the disease and transfused to those who are infected. Data have shown improvements in patients with severe infections who are transfused with COVID-19 convalescent plasma. The majority of people who have COVID-19 will demonstrate IgM and IgG antibodies within two weeks of symptom onset. These antibodies have specificity toward the receptor-binding domain (RBD) and spike protein viral epitopes that correspond to virus neutralization.

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Anatomic pathology selected abstracts

written by CAP TODAY
March 18, 2021

March 2021—Prostatic-type differentiation in the lower female genital tract is rarely encountered and its causes and clinical associations are not well established. Reports have invariably described ectopic prostatic-type differentiation within the vagina as restricted to the lamina propria. The authors encountered a patient receiving testosterone for gender dysphoria whose vaginectomy specimen showed a prostatic glandular proliferation within the surface epithelium. To elucidate its potential association with androgen exposure, they sought similar lesions, resected during a 26-year period, from patients with exogenous or endogenous androgen excess. Thirteen cases, involving the vagina (n=12)

and exocervix (n=1), were identified.

Pathology informatics selected abstracts

written by CAP TODAY
March 18, 2021

March 2021—A significant benefit of whole slide imaging is the ability to view digital slides remotely. This benefit has been reinforced during the COVID pandemic as pathologists render pathology diagnoses from home. At the same time, the FDA has temporarily relaxed regulations for modifying FDA-cleared digital pathology devices and the marketing of devices that are not FDA 510(k) cleared. This contrasts with previous requirements that various digital pathology systems use computer displays with specifications that have satisfied regulatory or institutional approval, or both. This, in turn, raises concern about pathologists working in unregulated home settings where they use a variety of monitors that vary in visual quality and, therefore, in image clarity.

Molecular pathology selected abstracts

written by CAP TODAY
March 18, 2021

March 2021—High tumor mutational burden in certain cancers has become an established biomarker for predicting a response to immune checkpoint inhibitor therapy and longer overall survival after such treatment. The immune checkpoint inhibitor (ICI) pembrolizumab, for example, has recently been

approved by the FDA for patients whose solid tumors, regardless of histology, have a high tumor mutational burden (TMB), defined as 10 or more mutations per megabase. TMB, assessed by next-generation sequencing, varies considerably among cancers and can range from 0.01 to more than 1,000 somatic mutations per megabase of sequenced genome. The presumed mechanism for the enhanced responsiveness to immunotherapy associated with high TMB is the creation, by somatic mutation, of potentially immunogenic neoantigens that facilitate an enhanced antitumor immune response. Given this presumed mechanism, the authors addressed whether high TMB levels, which are associated with better cancer outcomes in patients treated with immune checkpoint inhibitors, might also lead to better outcomes for patients treated with other anti-cancer therapies.