FDA authorizes Ortho quantitative serology test

written by CAP TODAY
September 17, 2021

September 2021—The FDA issued an emergency use authorization to Ortho Clinical Diagnostics for its Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative test.

FDA approves pembrolizumab plus lenvatinib

written by CAP TODAY
September 17, 2021

September 2021—The Food and Drug Administration approved pembrolizumab (Keytruda, Merck) in combination with lenvatinib (Lenvima, Eisai) for patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

Inova announces FDA 510(k) clearance for Aptiva

written by CAP TODAY
September 17, 2021

September 2021—Inova Diagnostics announced FDA 510(k) clearance of its Aptiva system and Aptiva Celiac Disease IgA assay. Aptiva is a fully automated digital multianalyte system for the clinical laboratory. Aptiva received the CE mark in August 2020.

Medicare issues LCD for Biocept's Target Selector assay

written by CAP TODAY
September 17, 2021

September 2021—Biocept received a positive final local coverage determination that expands Medicare coverage for use of its Target Selector assay to identify the HER2 biomarker from circulating tumor cells. The coverage determination from the Centers for Medicare and Medicaid Services molecular diagnostics program was effective July 4.

Immunovia pancreatic cancer test gets CLIA approval

written by CAP TODAY
September 17, 2021

September 2021—Immunovia has received approval to begin patient testing for the IMMray PanCan-d blood test for the early detection of pancreatic cancer. Approval was received Aug. 3 from the Massachusetts Department of Public Health, and the company received its CLIA Certificate of Registration on June 21.

Sarstedt lithium heparin gel tubes

written by CAP TODAY
September 17, 2021

September 2021—Sarstedt introduced S-Monovette Lithium-Heparin Gel blood collection tubes, which feature a polymer-based gel layer with improved rheological properties to reduce centrifugation time. Tubes can be centrifuged in as few as four minutes to yield properly separated and stable plasma ready for immediate testing, the company says. The tubes are offered in three volume and size options: 2.7 mL (13 × 75 mm), 4 mL (13 × 75 mm), and 4.9 mL (13 × 90 mm).

FDA approves avapritinib for advanced systemic mastocytosis

written by CAP TODAY
September 17, 2021

September 2021—Blueprint Medicines announced that the FDA approved Ayvakit (avapritinib) for the treatment of adult patients with advanced systemic mastocytosis, including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia. Advanced systemic mastocytosis patients can now receive a targeted therapy designed to potently and selectively inhibit D816V mutant KIT.

In coag collections, every detail counts

written by CAP TODAY
September 17, 2021

September 2021—Rare wine? Delectable. Rara avis? Magnificent. Rare blue-top collection tube? Uh oh. For Richard Marlar, PhD, coming across a non-FDA-approved tube was an unhappy discovery. Dr. Marlar, medical director, coagulation laboratory, University of New Mexico Hospital, says his lab was among the first to encounter one of these rogue tubes, available for purchase on the internet and likely taking wing due to pandemic supply shortages. When the tube arrived for testing, it quickly kindled concerns, says Dr. Marlar. “It’s a tube we had never seen before. It looks like it has a CE mark on it, and the Europeans don’t know anything about it. It has a label on it that suggests it’s FDA approved—but the FDA is not aware of it,” he says, adding that his lab has spoken with the agency. It feels like a “CSI”-tinged moment in a venue that labs would prefer to keep drama-free. It also points to the ongoing need to keep a keen eye on what passes through coagulation laboratories. It’s not so much that the devil is in the details; rather, that’s where accurate results lie.

Gastric HER2, hsALK to join monitored PT list

written by CAP TODAY
September 17, 2021

September 2021—Beginning next year, CAP-accredited laboratories that perform HER2 immunohistochemistry in gastroesophageal adenocarcinoma or highly sensitive (hs) ALK in non-small cell lung cancer will be required to enroll in proficiency testing for those analytes.

Metagenomic NGS: More pros than cons?

written by CAP TODAY
September 17, 2021

September 2021—A stem cell transplant patient at Lurie Children's Hospital in Chicago had a disseminated fungal infection by every clinical criterion, but no conventional method had detected it.