EntroGen gets PMA for CRCdx RAS mutation detection kit

written by CAP TODAY
November 21, 2023

Nov. 21, 2023—The FDA has granted approval for EntroGen's CRCdx RAS mutation detection kit as a companion diagnostic for Vectibix (panitumumab).

Verichem reference materials for serum and urine testing

written by CAP TODAY
November 21, 2023

November 2023—Verichem Laboratories announced the availability of its Urine Uric Acid Standard kit, Matrix Plus Cholesterol Reference kit, and a standalone, ultra-high Matrix Plus Cholesterol Reference level F for the calibration verification testing of cholesterol and urine and serum uric acid assays. The Urine Uric Acid Standard kit is a five-level kit with uric acid concentrations ranging from 1 to 101 mg/dL. The materials feature universal testing compatibility and are composed of a biosynthetic matrix with urine-like activity. Storage temperature is −15° to −25°C and Verichem says the product can tolerate up to 10 freeze-thaw cycles with no effect on accuracy or performance. Shelf life is 19 months.

BioMérieux announces CE mark for Vidas TBI test

written by CAP TODAY
November 21, 2023

November 2023—BioMérieux announced it has received the CE mark for its Vidas TBI (GFAP, UCH-L1), a test to support the assessment of patients who have mild traumatic brain injury. The blood test measures the concentration of glial fibrillary acidic protein (GFAP) and ubiquitin C-terminal hydrolase-L1 (UCH-L1), two brain biomarkers that are released into the bloodstream during the first hour following a brain injury. It aims to fill a gap in patient screening methods by ruling out acute intracranial lesions and helping to determine if a CT scan is necessary.

FDA clears Nova Prime Plus for microcapillary sample mode

written by CAP TODAY
November 21, 2023

November 2023—Nova Biomedical announced that the FDA has granted 510(k) clearance for a microcapillary sample mode on the company's Stat Profile Prime Plus critical care blood gas analyzer.

FDA clears Thermo Fisher chromogranin A assay

written by CAP TODAY
November 21, 2023

November 2023—Thermo Fisher Scientific announced FDA clearance of its Thermo Scientific Brahms CgA II Kryptor, an automated immunofluorescent assay for the quantitative determination of the concentration of chromogranin A in human serum. The biomarker is to be used in conjunction with other clinical methods as an aid in monitoring disease progression during the course of disease and treatment in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NET), grades 1 and 2.

LGC acquires Kova International

written by CAP TODAY
November 21, 2023

November 2023—LGC Clinical Diagnostics announced the acquisition of Kova International, a developer and manufacturer of in vitro urinalysis and toxicology quality control products for clinical laboratories.

Bio SB launches TintoStainer Plus automatic IHC stainer

written by CAP TODAY
November 21, 2023

November 2023—Bio SB has launched a fully automated immunohistochemistry platform for deparaffinization and antigen retrieval and staining. Applications include immunohistochemistry, Mohs IHC, immunocytochemistry, and immunofluorescence of formalin-fixed, paraffin-embedded tissue, frozen tissue, and cell specimens.

FDA approves Qiagen CDx for GIST

written by CAP TODAY
November 21, 2023

November 2023—Qiagen announced FDA approval of its Therascreen PDGFRA RGQ PCR kit, a companion diagnostic intended for use to aid clinicians in identifying patients with gastrointestinal stromal tumors (GIST) who may be eligible for treatment with avapritinib (Ayvakit, Blueprint Medicines). Ayvakit is approved in the United States for the treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Qiagen says its kit is the first PDGFRA assay to receive FDA approval as a companion diagnostic.

FloBio bleeding risk Dx gets FDA breakthrough device designation

written by CAP TODAY
November 21, 2023

November 2023—FloBio announced that the FDA has granted breakthrough device designation for its rapid bleeding risk diagnostic test. The point-of-care test is designed for in vitro diagnostic use to determine blood clotting status and whether a patient is on a direct oral anticoagulant.

FDA clears Aptiva Connective Tissue Disease Essential reagent

written by CAP TODAY
November 21, 2023

November 2023—Werfen announced FDA 510(k) clearance of its Aptiva Connective Tissue Disease Essential reagent, to aid in diagnosing connective tissue disease. The Aptiva CTD Essential complements Werfen's previously cleared Aptiva Celiac Disease reagent.