In memoriam

written by CAP TODAY
October 20, 2023

October 2023—Thomas Dermott Trainer, MD, a member of the CAP Board of Governors from 1994 to 2000 and secretary-treasurer from 1999 to 2000, died on June 10 at age 94.

MMQCI releases BCR-ABL IS linearity panel

written by CAP TODAY
October 20, 2023

October 2023—Now available from Maine Molecular Quality Controls is the Xpert BCR-ABL IS p210 Linearity Panel C207. It's intended for use as an assayed external quality control to monitor the performance of the in vitro quantitative detection of BCR-ABL1 translocation mRNA e14a2/b3a2 transcripts and the ABL1 endogenous control mRNA transcript. It is designed to be used with the Xpert BCR-ABL Ultra assay on Cepheid GeneXpert instruments. Each kit comprises 12 bottles with two bottles of each international scale percent (%IS) value in 4 mL of synthetic BCR-ABL1 RNA transcript and synthetic ABL1 control gene RNA transcript suspended in a stabilizing matrix with a noninfectious solution of buffers and preservatives.

FDA clears PixCell HemoScreen for direct capillary sampling

written by CAP TODAY
October 20, 2023

October 2023—PixCell Medical announced that the FDA has granted 510(k) clearance for direct capillary sampling with the HemoScreen 5-part differential CBC analyzer. The clearance enables collection of a sample directly from a patient's finger without an intermediate tube. HemoScreen is also FDA cleared for point-of-care use with venous and capillary blood.

FDA approves Bosulif for pediatric patients with CML

written by CAP TODAY
October 20, 2023

October 2023—The FDA approved bosutinib (Bosulif, Pfizer) for pediatric patients who are one year old and older with chronic phase Ph+ chronic myelogenous leukemia that is newly diagnosed or resistant or intolerant to prior therapy. Efficacy was evaluated in the BCHILD trial (NCT04258943), a multicenter, nonrandomized, open-label trial conducted to identify a recommended bosutinib dose in pediatric patients with newly diagnosed chronic phase Ph+ CML and resistant or intolerant Ph+ CML; estimate the safety, tolerability, and efficacy; and evaluate bosutinib pharmacokinetics in this patient population.

Pillar Biosciences launches OncoReveal Core LBx NGS kit

written by CAP TODAY
October 20, 2023

October 2023—Pillar Biosciences announced the global launch of OncoReveal Core LBx, a research use only, liquid biopsy–based next-generation sequencing kit for pan-cancer tumor profiling. The panel interrogates 104 clinically relevant genes in one multiplex reaction, analyzes cfDNA present in plasma for genetic alterations in cancer, including assessment of microsatellite instability, and can batch more than 20 clinical samples on a single Illumina NextSeq run. Mutation detection performance is as low as 0.1 percent.

Parasitology, infectious Dx company Eiger launches

written by CAP TODAY
October 20, 2023

October 2023—Eiger Diagnostics has been formed to provide high-quality parasitology and infectious disease diagnostics worldwide. Eiger's first product releases are parasitology serology IgG and IgM ELISA assays. The company plans to add to its product portfolio this year.

Wren Labs molecular Dx predicts patient response to PRRT

written by CAP TODAY
October 20, 2023

October 2023—Wren Laboratories launched its PRRT (peptide receptor radionuclide therapy) Predictor Quotient, or PPQ, a companion diagnostic to its NETest, a liquid-biopsy neuroendocrine tumor diagnostic. The test classifies patients as either a responder, a patient who will experience disease stabilization and have a longer time to disease progression (usually greater than 18 months after the end of PRRT treatment), or as a nonresponder, who will have a shorter time until the disease progresses (usually less than 12 months after the start of PRRT). According to a research paper published in April (Bodei L, et al. *J Nucl Med*. 2023;64[9]:1329–1330), the PPQ delivers 96 percent accuracy in determining patient response to PRRT.

Primera unveils Signature EVO slide and cassette printers

written by CAP TODAY
October 20, 2023

October 2023—Primera Technology has launched its next-generation Signature EVO slide printer and Signature EVO cassette printer.

FDA clears Alinity h-series hematology system

written by CAP TODAY
October 20, 2023

October 2023—Abbott has received FDA clearance for its Alinity h-series hematology system, which includes the Alinity hq, an automated hematology analyzer, and Alinity hs, an integrated slide maker and stainer. The Alinity hq leverages multiangle polarized scatter separation (MAPPS) technology, which uses light scattering to distinguish cellular features and identify various blood cells, and processes up to 119 CBC results per hour. The system can be integrated into an existing core lab operation.

Verichem enzyme calibration verifiers for liver function testing

written by CAP TODAY
October 20, 2023

October 2023—Verichem Laboratories offers multilevel enzyme calibration verification materials for liver function testing as part of its liquid-stable Enzyme ER Verifier kit. The kit contains the enzymes alanine aminotransferase (ALT/SGPT), alkaline phosphatase (AP/ALP), aspartate aminotransferase (AST/SGOT), gamma-glutamyl transferase (GGT/GGTP), lactate dehydrogenase (LD/LDH), amylase, cholinesterase, creatine phosphokinase, and lipase. Its proprietary formulation is designed to include at least one concentration for each enzyme within the normal range. The verifiers are intended to be treated as patient specimens and are compatible with wet chemistry systems from Abbott, Beckman Coulter, Roche, and Siemens Healthineers. Shelf life is 18 months.