FDA approves therapy for myelodysplastic syndromes

written by CAP TODAY
December 27, 2023

December 2023—The FDA has approved ivosidenib (Tibsovo, Servier Pharmaceuticals) for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes with an isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test. The agency also approved the Abbott RealTime IDH1 assay as a companion diagnostic for the selection of R/R MDS patients with an IDH1 mutation.

FoundationOne CDx approved for capivasertib plus fulvestrant

written by CAP TODAY
December 27, 2023

December 2023—Foundation Medicine has received FDA approval for its FoundationOne CDx to be used as a companion diagnostic for capivasertib (Truqap, AstraZeneca) in combination with fulvestrant, which has been contemporaneously approved for the treatment of adult patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Tosoh G8 now connects to Sysmex XN-9000, XN-9100 systems

written by CAP TODAY
December 27, 2023

Dec. 27, 2023—Tosoh Bioscience has entered into an agreement with Sysmex America in which its HLC-723G8 automated glycohemoglobin analyzers can now be connected to Sysmex XN-9000 and XN-9100 automated hematology systems in the United States, Latin America, and Canada.

FDA clears QuidelOrtho Savanna platform, HSV 1+2/VZV assay

written by CAP TODAY
December 27, 2023

Dec. 21, 2023—QuidelOrtho has received FDA 510(k) clearance for its Savanna PCR platform and Savanna HSV 1+2/VZV in vitro diagnostic test for the detection and differentiation of herpes simplex virus types 1 and 2 and varicella zoster virus nucleic acids isolated and purified from swabs obtained from cutaneous or mucocutaneous lesion specimens from symptomatic patients.

And the band neutrophil counts play on

written by CAP TODAY
December 27, 2023

December 2023—The recent CAP proficiency testing questionnaire was meant to be the coup de grâce. Hematology PT participants were asked about their band neutrophil reporting practices and, given that these manually generated counts were supposedly on their way out decades ago, the authors of the survey questionnaire expected to see very little activity. The survey, they hoped, would be a way to pound the final, data-driven nail in the coffin. Or, as lead author Maria (Ria) Vergara-Lluri, MD, puts it, "We thought this had all been laid to rest 30 years ago." It wasn't. Says Dr. Vergara-Lluri: "Surprise: 86 percent of labs that participated still report bands." The results of the survey upended many of the assumptions, if not hopes, the authors might have had. Among laboratories that reported manual differentials, they found that most reported bands (4,554 of 5,268). Moreover, only 73 percent reported band reference ranges. On the morphologic challenge, bands classified as "easy" were indeed easy—participants classified them well.

Corista DP3 platform gets CE IVD mark

written by CAP TODAY
December 27, 2023

Dec. 14, 2023—Corista announced today that its DP3 platform has been certified with the CE in vitro diagnostic mark for routine diagnosis in the European Union and United Kingdom.

In fee schedule final rule, lower cuts than proposed

written by CAP TODAY
December 27, 2023

December 2023—In the 2024 Medicare physician fee schedule final rule, the Centers for Medicare and Medicaid Services reacted favorably to the CAP's advocacy to mitigate payment decreases to pathologists next year. Overall, payments to pathologists are expected to decrease by an estimated 2.7 percent.

New guidance on lab analysis in diabetes

written by CAP TODAY
December 27, 2023

December 2023—The third and latest edition of recommendations for laboratory analysis in diagnosing and managing diabetes mellitus, released this summer, provide guidance on, among other things, ketone testing, glycolysis, and point-of-care testing. The last such recommendations were published in 2011.

In ED/urgent cares, the lab tests and the POC team

written by CAP TODAY
December 27, 2023

December 2023—A point-of-care testing team from TriCore was part of standing up three dual emergency department/urgent care centers in as many years, with a fourth set to open in March 2024. “They are super busy, as was expected. There’s a great need for this type of site,” says Kathleen David, MT(ASCP).

Study of suspected transfusion reactions to begin Jan. 1

written by CAP TODAY
December 27, 2023

A new CAP Quality Practices study on rates and turnaround times for investigating and reporting suspected transfusion reactions will begin on
Jan. 1, 2024. Enrollment is open now and will continue through Feb. 5, 2024.