

[Study highlights benefits of T2MR technology](#)

written by CAP TODAY

June 21, 2021

June 2021—T2 Biosystems announced that *Expert Review of Medical Devices* published meta-analysis findings confirming that using the company's magnetic resonance (T2MR) technology for identification of bloodstream infections provides faster time to detection, faster transition to targeted microbial therapy, faster de-escalation of empirical therapy, and shorter intensive care unit and hospital stay, and with comparable mortality rate versus the current blood culture standard (Giannella M, et al. Online ahead of print April 16, 2021. doi:10.1080/17434440.2021.1919508). Study authors systematically searched Medline, Embase, and Cochrane Central Register of Controlled Trials for randomized trials or observational controlled studies of patients with suspected bloodstream infections receiving a diagnosis with T2MR or blood culture, ultimately including 14 studies.



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[LGC SeraCare releases two blood TMB reference standards](#)

written by CAP TODAY

June 21, 2021

June 21, 2021—LGC SeraCare released two new blood tumor mutational burden reference standards, Seraseq Blood TMB Score 7 and Seraseq Blood TMB Score 26.



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[Roche test gets EUA for symptomatic, asymptomatic people](#)

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June 18, 2021—Roche announced that the FDA granted emergency use authorization for the Cobas SARS-CoV-2 Nucleic acid test for use on the Cobas Liat System.



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[FDA approves avapritinib for advanced systemic mastocytosis](#)

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June 17, 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.



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Higher stakes in systemic mastocytosis

written by CAP TODAY
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June 2021—Mastocytosis is not for quitters. Not at any point, from considering the possible diagnosis, to doing a complement of stains, to looking for mutations beyond *KIT* D816V, to being curious about the presence of mast cells even after making a diagnosis of another myeloid disease. Patients have already learned this grueling lesson. They can easily spend years seeking answers before their disease is properly identified. Pathologists can speed up that process—and the time to do so is now, says Tracy George, MD, chief medical officer and incoming president of ARUP Laboratories, and medical director of hematopathology. Notes Dr. George: “There’s some exciting stuff going on with systemic mastocytosis.” New targeted *KIT* inhibitors appear to be quite effective, including at least one agent for advanced systemic mastocytosis that has been submitted to the Food and Drug Administration. “We anticipate there’s going to be approval by the FDA this summer,” says Dr. George, who’s been involved in the clinical trials for avapritinib (Blueprint Medicines).



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1- or 2-step: Outcomes studied in GDM screening

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June 2021—If screening for gestational diabetes mellitus were a dance competition, it might have a contest between quickstep and paso doble as its signature event. That tournament could pit the one-step testing protocol (twice as likely to diagnose GDM) against the two-step testing protocol (significantly easier for pregnant women to adhere to).



[Puzzling out platelet function disorders](#)

written by CAP TODAY

June 21, 2021

June 2021—In an AACC virtual session last December, Catherine P. M. Hayward, MD, PhD, of McMaster University, set out the stepwise approach to testing for platelet function disorders, explained the methods used to assess platelet aggregation response, and reported what most clinical labs do.



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[Virtual, blended inspections a sign of the times](#)

written by CAP TODAY

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June 2021—As COVID-19 restrictions halted traditional laboratory inspections, virtual and blended inspections became the stand-ins, and early adopters say there's much to like and hold on to post-pandemic.



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pTX and pNX should not be used in tumor staging

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June 2021—For the June 2021 release of updates for the CAP cancer protocols and the corresponding electronic cancer checklists used by electronic health record vendors, pTX and pNX will no longer be selectable options for use by pathologists when assigning pathologic staging based on definitive surgical resection (pTNM). This change is coming after extensive discussions with the American Joint Committee on Cancer (AJCC) and with its unanimous endorsement. Why are we making this change?



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Compass group roundtable: ‘Gaps loom large’: labor shortage hitting hard

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June 2021—A brief update on SARS-CoV-2 variant testing and then a look at the latest on the laboratory labor struggle. That’s what Compass Group members provided when they spoke May 4 in another of their monthly calls led by CAP TODAY publisher Bob McGonnagle. “We’ve accepted that if we’re going to solve the [labor] issue,” said Sam Terese of Alverno Laboratories, “we’ll have to create the workforce. They’re not coming to us in any other way.” With McGonnagle and Terese were Bob Stallone and James Crawford, MD, PhD, Northwell; Sterling Bennett, MD, MS, Intermountain; John Waugh, MS, MT(ASCP), Henry Ford; Peter Dysert, MD, Baylor Scott & White; Steven Carroll, MD, PhD, Medical University of South Carolina; Stan Schofield, MaineHealth; Gregory Sossaman, MD, Ochsner; Clark Day, Indiana University; Diana Kremitske, MS, MHA, MT(ASCP), Geisinger; Julie Hess, AdventHealth; Terrence Dolan, MD, Regional Medical Laboratory; and Dan Ingemansen, Sanford. The Compass Group is an organization of not-for-profit IDN system lab leaders who collaborate to identify and share best practices and strategies. Here is what they said.



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