Q&A column

written by CAP TODAY
August 18, 2025

August 2025
Q. We manage multispecialty laboratories in multiple hospital locations. Most of the laboratories function on the traditional model of compartmentalized specialty-based testing units that offer routine and specialized services with their own dedicated space, equipment, and personnel. There is a future plan to establish an offsite centralized referral lab, but to improve operational efficiency and cost savings sooner, management is considering consolidating testing services at each location. What factors should be considered while planning the consolidation, keeping in mind the plan to establish a centralized reference lab? Should the testing services that will eventually be performed in the reference lab be excluded from the current consolidation plan? And how should we manage operations during the transition phase, i.e. once consolidation is completed but prior to the reference lab implementation? Read answer.

Q. We have been discussing supervisory review of test results that are manually entered into our laboratory information system (i.e. a test result not sent via interface from an analyzer or autoverified). Examples are a urine hCG performed on a kit cassette or a manual differential performed on a CBC, entered directly into the LIS by the performing technologist. Do manual test results require supervisory review, or is it only higher-complexity tests (like the differential) performed by a medical laboratory technologist that require such review? If review is required, who can review and what is the recommended time frame? Read answer.

External controls critical to crucial assays

written by CAP TODAY
August 18, 2025

August 2025—This is the second of a new feature in CAP TODAY: a one-on-one virtual roundtable in which CAP TODAY publisher Bob McGonnagle speaks with one vendor and one laboratory expert to spotlight a company and a customer for their laboratory solutions and work. ZeptoMetrix is the sponsor of the following roundtable, which took place May 14.

Put It on the Board

written by CAP TODAY
August 18, 2025

August 2025—In a position statement released in July, the CAP urged policymakers to consider scientific and logistical evidence and to protect the integrity and safety of the national blood supply. The statement was issued in response to legislation proposed in several states that would require blood product labeling based on donor vaccination status or mandate hospitals and blood collectors to honor requests for directed and autologous donations. Misinformation surrounding COVID-19 and mRNA vaccines has led to a growing number of patient requests for blood transfusions exclusively from unvaccinated donors.

QuidelOrtho launches certified analyzer program

written by CAP TODAY
August 18, 2025

Aug. 15, 2025—QuidelOrtho Corp. has launched a certified analyzer program designed to expand access to high-quality diagnostic testing in rural and community hospitals across the United States.

Bio-Rad launches Unity Next Peer QC in Asia-Pacific region

written by CAP TODAY
August 18, 2025

Aug. 14, 2025—Bio-Rad Laboratories has launched its Unity Next Peer QC data management software throughout the Asia-Pacific region.

Pathology Visions 2025

written by CAP TODAY
August 18, 2025

Aug. 13, 2025—Pathology Visions 2025 (PathVisions25) is the premier annual meeting of the Digital Pathology Association (DPA), bringing together over 850 global health care professionals and industry innovators.

FDA clears assay to detect CTX-M enzymes

written by CAP TODAY
August 18, 2025

Aug. 12, 2025—Hardy Diagnostics announced FDA clearance of the NG-Test CTX-M Multi, an in vitro diagnostic immunoassay for the qualitative detection of CTX-M enzymes (groups 1, 2, 8, 9, and 25) from pure colonies of Enterobacterales suspected of extended-spectrum beta-lactamase production.

Thermo Fisher nabs FDA approval for NSCLC CDx

written by CAP TODAY
August 18, 2025

Aug. 11, 2025—Thermo Fisher Scientific has received FDA approval for its Oncomine Dx Target test as a companion diagnostic to identify patients who may be candidates for zongertinib (Hernexeos, Boehringer Ingelheim), a tyrosine kinase inhibitor.

Award-winning Histology Slide Printer

written by CAP TODAY
August 18, 2025

Epredia's SlideMate Laser provides high-resolution, 600-dpi laser printing on microscope slides. Laser technology, along with specialty slides, create indelible markings that can enhance traceability throughout the life of the slide. Learn More.

Evident to acquire Pramana

written by CAP TODAY
August 18, 2025

Aug. 8, 2025—Evident announced a definitive agreement to acquire Pramana.