Tumor marker testing in body fluids calls for caution

written by CAP TODAY
June 19, 2025

June 2025—With few FDA-cleared or -approved methods for tumor marker testing in body fluids, it is the laboratory that's responsible for the tests. "A specimen arrives at your door, and you have to figure out what, if anything, you're going to do," said Jonathan Genzen, MD, PhD, MBA.

A pathologist's reflections after visiting a zipper factory

written by CAP TODAY
June 19, 2025

June 2025—Some years back, I flew south from New England, where I work as an academic cytopathologist, to North Carolina. My destination was an academic medical center where I was to give a talk on fine-needle aspiration biopsies. On my drive from the airport, I detoured to a small city that housed a company that manufactures zippers. There, on the factory floor, I watched newly made zippers exiting from rows of heavy steel machines. I asked myself: How is that like what we do as pathologists?

No MI? What Atellica hs-cTnI says about future risk

written by CAP TODAY
June 19, 2025

June 2025—Patients who present to the ED with an elevated cardiac troponin above the 99th percentile and suspected acute coronary syndrome but in whom myocardial infarction is not diagnosed are at risk for future cardiac events. But how much risk? Last fall, the Food and Drug Administration cleared Siemens Healthineers' Atellica IM High-Sensitivity Troponin I assay for prognostic risk stratification, an expanded intended use claim. Now, with this newly cleared use, "novel information is created from traditional indications," said Christopher deFilippi, MD, who was recently director of the Biocore research laboratory and vice chair of academic affairs, Inova Schar Heart and Vascular in Fairfax, Va., and is now, since June 1, at the University of Maryland.

Shorts on Standards: Regenstrief Institute and SNOMED International release 1st version of LOINC ontology

written by CAP TODAY
June 19, 2025

June 2025—Laboratories are subject to rigorous federal regulations such as continuous quality control, proficiency testing, and laboratory inspections to ensure high-quality test performance. However, few government mandates exist for the standardization of laboratory data. As a result, different laboratories have various local codes, names, reference ranges for normal and abnormal values, and formats of results and associated units for laboratory tests that might otherwise be similar or identical. While the lack of standardization is unlikely to impact the daily operations of individual laboratories, it does pose a significant barrier when results are compared or aggregated across institutions. It also poses challenges for secondary uses such as public health surveillance, outcomes analysis, research, and artificial intelligence/machine learning development.

Beyond intended use: PSA, hCG as tumor markers

written by CAP TODAY
June 19, 2025

June 2025—At Corewell Health William Beaumont University Hospital in Royal Oak, Mich., the PSA test volume for men ages 40 to 49 is significant—about 150 samples per month, or 10 percent of the laboratory's total PSA testing volume. But with no PSA assay approved for men under age 50, the laboratory set out to validate its Abbott Architect assay for this age group as a laboratory-developed test. Qian (Katie) Sun, PhD, D(ABCC), technical director of automated chemistry and urinalysis, explained how it was done in an ADLM session last year on designing validation protocols for off-label use of tumor markers in diverse patient populations. She also spoke about the use of hCG immunoassays as a tumor marker in gestational trophoblastic disease and select germ cell tumors.

Focus on instruments: scalability, timelines, and IT

written by CAP TODAY
June 19, 2025

June 2025—Chemistry and immunoassay analyzers—the customer input that shapes their development and the laboratory acquisition process and timeline. That and more, including the IT obstacles and

solutions, were the focus of a roundtable, led by CAP TODAY publisher Bob McGonnagle. He spoke with Moira Larsen, MD, MBA, of MedStar Health; Joe Baker of Baylor Scott & White; and representatives of Beckman Coulter, Roche, and Siemens Healthineers. Read about their April 15 online conversation.

BioMérieux acquires Day Zero Diagnostics

written by CAP TODAY
June 19, 2025

June 18, 2025—BioMérieux will acquire Day Zero Diagnostics, an infectious disease diagnostics company, with the aim of enhancing BioMérieux's capabilities in next-generation sequencing and rapid diagnostics.

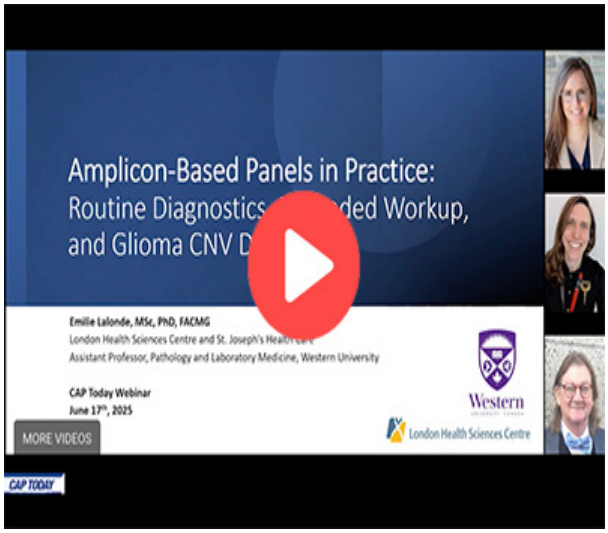
From the President's Desk

written by CAP TODAY
June 19, 2025

June 2025—June marks the American Medical Association's annual meeting of its House of Delegates, and I'd like to use this month's column to focus on why it's so important for pathologists to work closely with the AMA. The short answer is this: We need to be at the table in the greater house of medicine. But isn't it enough to be part of the CAP? After all, we are pathologists, and the CAP is far more focused on issues specific to our practice and our patients. And the CAP is constantly advocating for us at the federal and state levels of government, as well as with private payers.

Amplicon-based NGS panels in clinical practice: From broad oncology applications to advancing breast cancer care-June 17, 2025

written by CAP TODAY
June 19, 2025



Webinar presenters **Emilie Lalonde, PhD, FACMG,** Molecular Geneticist and Cytogeneticist, Molecular Diagnostics Division, PaLM, London Health Sciences Centre and St. Joseph's Health Care, Assistant Professor, Pathology and Laboratory Medicine, Western University, and **Cheryl A. Mather, MD** Medical Director, Molecular Pathology (North Sector), Alberta Precision Laboratories, Assistant Clinical Professor, Department of Laboratory Medicine & Pathology, University of Alberta, discuss how amplicon-based NGS panels meet biomarker testing guidelines in practice including routine diagnostics, expanded workup, and copy number variation (CNV) detection.

Clinical pathology selected abstracts

written by CAP TODAY
June 19, 2025

June 2025—Semaglutide is a long-acting glucagon-like peptide-1 receptor agonist medication that has FDA approval for treating diabetes and obesity and that has shown exceptional efficacy. A rapid increase in use of this drug has been accompanied by reports of reduced alcohol use and cravings during semaglutide treatment. Alcohol use is a leading modifiable cause of morbidity and mortality and accounts for four to five percent of disease burden and 2.6 million deaths per year globally. Alcohol is also associated with increased risk of common diseases, including cardiovascular and liver disease and cancers. It is estimated that approximately 29 and 11 percent of U.S. adults meet lifetime and past-year criteria for alcohol use disorder (AUD), respectively.