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

written by CAP TODAY
October 14, 2025

October 2025—Bio-Rad Laboratories has launched its Unity Next Peer QC data management software throughout the Asia-Pacific region. The software is designed to help troubleshoot quality control errors and increase confidence in patient testing results. It offers on-demand access to peer reporting and quality control data and provides data visualization and report generation for compliance management. Labs new to Bio-Rad's suite of QC data management products can get guided support and training from the company.

Roche mass spec test categorized as moderate complexity

written by CAP TODAY
October 14, 2025

October 2025—The Food and Drug Administration has categorized Roche's Ionify 25-Hydroxy Vitamin D total assay as moderate complexity under the Clinical Laboratory Improvement Amendments of 1988. Roche reported that this is the first time a mass-spectrometry-based test has achieved this designation.

Magnified Learning offers consulting, educational services

written by CAP TODAY
October 14, 2025

October 2025—Magnified Learning offers consulting services across the spectrum of health care operations, including supply chain management, revenue cycle optimization, operational excellence, and organizational change management. The company's approach leverages next-generation Lean Six Sigma, clinical integration strategies, and advanced technology platforms to create a sustainable alignment between operational performance and financial outcomes. Magnified Learning also offers online certification programs that feature sophisticated online learning management systems with self-paced curricula, comprehensive content previews, and embedded assessment tools compatible across all major operating systems. Each certification includes continuous learning pathways and recertification opportunities.

Haystack MRD ctDNA test gets breakthrough device designation

written by CAP TODAY
October 14, 2025

October 2025—The Food and Drug Administration has granted breakthrough device designation for Quest Diagnostic's Haystack MRD circulating tumor DNA test. The test is used for identifying minimal residual disease in patients with stage two colorectal cancer following curative-intent surgical treatment who may benefit from adjuvant therapy in accordance with therapeutic product labeling.

FDA clears assay to detect CTX-M enzymes

written by CAP TODAY
October 14, 2025

October 2025—The FDA has cleared Hardy Diagnostics' 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. These enzymes confer resistance to many beta-lactam antibiotics, making infections more difficult to treat. The test delivers results in 15 minutes.

Eppendorf introduces next-generation mechanical pipettes

written by CAP TODAY
October 14, 2025

October 2025—Eppendorf has launched the Eppendorf Research 3 Neo mechanical pipette. Users can choose between two volume settings and speeds. The pipette can be adjusted for different liquid types, tip geometries, and reverse pipetting and a volume lock feature prevents unintentional volume changes. The use of ColorTag marking rings provides color-coded identification.

From the President’s Desk

written by CAP TODAY
October 14, 2025

October 2025—For my inaugural column in CAP TODAY, I’d like to begin by saying thank you. Thank you, CAP members, for the honor of allowing me to serve as your president. Thanks to my mentors, peers, and colleagues for helping me along this path. And my deepest gratitude to my wife, Jenny, and my daughter, Jasmine, for the extraordinary journey that began in China and led to my own American dream in the U.S. and to Louisiana, where I practice.

Clinical pathology selected abstracts

written by CAP TODAY
October 14, 2025

October 2025—Whole genome sequencing is being evaluated in newborn screening to increase the diagnosis and treatment of rare clinical conditions. Such screening raises ethical questions about which results to report and the impact of those results on parents and their children. It is important to focus on societal norms when designing whole genome sequencing–newborn screening (WGS-NBS) to make sure people accept the testing and minimize patient harm. Although parents value the fact that WGS-NBS can lead to early diagnosis and treatment of various conditions, they recognize that results may cause psychological distress, eliminate children’s autonomy, raise data-storage and privacy concerns, and lead to uncertainty regarding adult-onset medical conditions. The public, in general, supports WGS-NBS for clinically actionable childhood-onset conditions, with the caveats that health professionals are

trained to interpret such results and genetic counseling is available.

Anatomic pathology selected abstracts

written by CAP TODAY
October 14, 2025

October 2025—Crystal-storing histiocytosis is a rare disorder in which crystals accumulate in the cytoplasm of histiocytes. It is usually associated with a lymphoplasmacytic neoplasm. Cutaneous crystal-storing histiocytosis (CSH) is extraordinarily rare and limited to case reports in the literature. The authors reported on two cases of CSH with cutaneous involvement. Case one was a 65-year-old male with a four-month history of a pruritic eruption that started as a solitary pink to skin-colored indurated plaque on the anterior neck before progressing to involve the whole neck, chest wall, and face.

Molecular pathology selected abstracts

written by CAP TODAY
October 14, 2025

October 2025—GATA2 deficiency is a rare inherited condition that disrupts the normal development of blood and immune cells. People born with this genetic disorder may experience low blood counts, frequent infections, or such problems as lymphedema and hearing loss. The most serious long-term risk is development of myelodysplastic syndrome (MDS), a bone marrow disorder that can progress to leukemia. The authors conducted a large study in which they followed 218 people with confirmed

GATA2 mutations to understand when and how MDS develops. In this cohort, symptoms of GATA2 deficiency were present in 205 of the participants, of whom 187 (91.2 percent) had MDS.