Copan announces leadership transition in medical and scientific affairs

written by CAP TODAY
September 16, 2025

September 2025—Copan Diagnostics has appointed Hema Kapoor, MD, D(ABMM), as director of medical and scientific affairs for the Americas, succeeding Susan Sharp, PhD, D(ABMM), who will retire this month following more than three decades of distinguished service to clinical microbiology. Dr. Sharp joined Copan in 2018, after a career spanning more than 30 years as a clinical microbiologist, educator, and industry leader. She previously served as chief of microbiology at Kaiser Permanente and held leadership roles at the American Society for Microbiology, including chair of the committee on laboratory practices and past president. A diplomate of the American Board of Medical Microbiology and fellow of the American Academy of Microbiology, Dr. Sharp has been recognized with ASM's highest clinical honor, the BioMérieux Sonnenwirth Award, and the ABMM Professional Recognition Award. At Copan, her leadership has been defined by keen insight and a steadfast advocacy for advancing microbiology.

Cepheid gets Health Canada license for Xpert HIV-1 Viral Load XC

written by CAP TODAY
September 16, 2025

September 2025—Cepheid has received a medical device license from Health Canada for its Xpert HIV-1 Viral Load XC, a next-generation extended-coverage test intended to aid in assessing HIV viral load levels. The test is designed for use on the company's GeneXpert systems.

Roche receives CE mark for Elecsys pTau181

written by CAP TODAY
September 16, 2025

September 2025—Roche has received the CE mark for its Elecsys pTau181 test to measure phosphorylated tau 181 protein, an indicator of amyloid pathology. The test, developed in collaboration with Eli Lilly, can be used by clinicians in conjunction with other clinical information to rule out Alzheimer's disease as the cause of cognitive decline.
The CE mark for the test was based on data from a prospective, multicenter study that included 787 patients in the United States, Europe, and Australia. The study showed the test was able to rule out Alzheimer's disease with a high negative predictive value of 93.8 percent, based on a 22.5 percent prevalence of amyloid positivity according to PET scans, and with 83.6 percent sensitivity.

Illumina launches TruSight Oncology 500 v2 research assay

written by CAP TODAY
September 16, 2025

September 2025—Illumina has launched TruSight Oncology 500 version 2, the next generation of the company's flagship pancancer next-generation sequencing assay that enables in-house comprehensive genomic profiling from formalin-fixed, paraffin-embedded tissue for oncology research. A key enhancement of the new assay is fully integrated homologous recombination deficiency analysis included for every sample, powered by a gold-standard genomic instability scoring algorithm licensed from Myriad Genetics. Other updates include more sensitive variant calling and improved coverage of difficult genomic regions. The new kit has 50 percent less packaging and 70 percent fewer tubes.

ArteraAI Prostate gets breakthrough device designation

written by CAP TODAY
September 16, 2025

September 2025—The FDA has granted breakthrough device designation to Artera's ArteraAI Prostate, an AI precision medicine tool intended to assist clinicians with risk-based decisions for patients with localized prostate cancer. ArteraAI Prostate analyzes digital pathology images of a patient's prostate cancer biopsy slide to prognosticate long-term outcomes, such as 10-year risk of distant metastasis and prostate-cancer specific mortality, to help clinicians determine the most appropriate treatment option.

Qiagen, Incyte to develop CDx for patients with myeloproliferative neoplasms

written by CAP TODAY
September 16, 2025

September 2025—Qiagen is collaborating with Incyte to develop a novel diagnostic panel to support Incyte's portfolio of investigational therapies, including Incyte's monoclonal antibody INCA033989, for patients with myeloproliferative neoplasms. Under the terms of the master collaboration agreement, Qiagen will develop a multimodal panel using next-generation sequencing technology for detecting clinically relevant gene alterations in hematological malignancies. The panel will be validated using the

Illumina NextSeq 550Dx.

New England Biolabs launches NEBNext library prep kit

written by CAP TODAY
September 16, 2025

September 2025—New England Biolabs launched the NEBNext Low-bias Small RNA library prep kit, designed to minimize biased representation of small RNA species in sequencing data. A novel splint adaptor increases the diversity of interactions, facilitating ligation and increasing sensitivity, with a streamlined, simplified protocol. As a result, researchers can analyze all RNA species present in biologically relevant samples. Standard and 2'-O-methylated samples can also be processed using the same protocol, with multiplexing enabled through up to 480 compatible unique dual index primer pairs (available separately). Total workflow time is approximately 3.5 hours and the shelf life is 18 months.

SehaMed, New Day Dx to launch ColoHealth in the Middle East

written by CAP TODAY
September 16, 2025

September 2025—SehaMed Global (Bristol, England) announced a strategic distribution agreement with New Day Diagnostics of Knoxville, Tenn., to bring ColoHealth, an FDA-approved blood test for the early detection of colorectal cancer, to patients in Saudi Arabia, the United Arab Emirates, and other countries in the Middle East. Under the terms of the agreement, SehaMed will leverage its network of distributors across the Gulf Cooperation Council to introduce ColoHealth.

Randox unveils Evidence RABTA

written by CAP TODAY
September 16, 2025

August 2025—Randox has launched the Evidence RABTA (random access biochip technology analyzer), capable of processing up to 60 samples per hour and delivering up to 2,640 test results per hour. The analyzer offers seamless random access capabilities, allows users to assign samples as priority, and uses single-use tips for aspiration and dispensing. The time to first result is 36 minutes, with up to 44 results per sample. Walkaway time is up to 2.5 hours.

Vizgen, Hamamatsu partner to streamline spatial biology workflows

written by CAP TODAY
September 16, 2025

August 2025—Vizgen and Hamamatsu Photonics have entered a strategic partnership that integrates Hamamatsu's MoxiePlex multiplex immunofluorescence imaging system with Vizgen's reagent and assay portfolio. The companies plan to combine their expertise through validated InSituPlex panels, coupled with MoxiePlex, as an integrated multiplexed proteomic biomarker offering capable of multisite deployments for translational and clinical research applications.