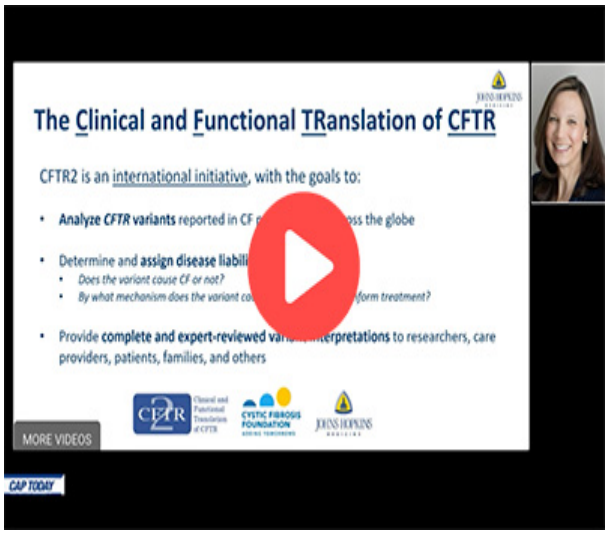
Screening Smarter: CFTR2 and Variant Interpretation-June 11, 2025

written by CAP TODAY
June 12, 2025



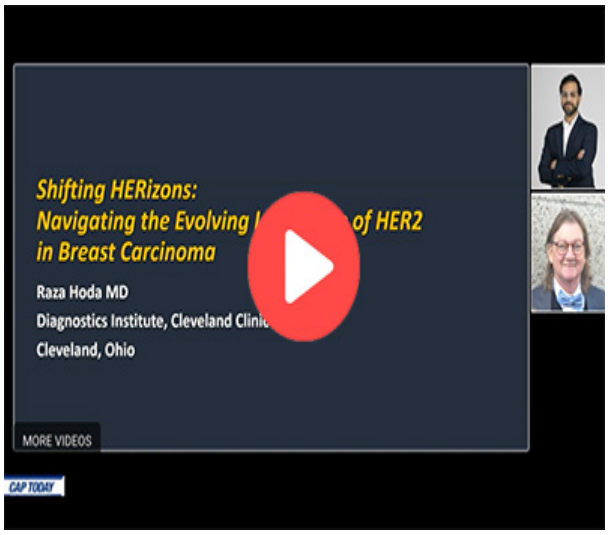
Webinar presenter **Karen Raraigh, MGC, CGCD**, Assistant Professor of Genetic Medicine at Johns Hopkins University, discusses how expanded genetic testing is playing an increasingly vital role in the management of Cystic Fibrosis (CF), helping to elevate the standard of care.

CAP TODAY
Pathology • Laboratory Medicine • Laboratory Management

©2026 CAP TODAY, all rights reserved.

Shifting HERizons: Navigating the Evolving Landscape of HER2 in Breast Carcinoma-June 10, 2025

written by CAP TODAY
June 12, 2025



Webinar presenter **Raza Hoda, MD**, Staff Pathologist, Cleveland Clinic, Assistant Professor of Pathology, Cleveland Clinic Lerner College of Medicine, discusses the importance of advancements in HER2 testing, including HER2 Ultra Low.

CAP TODAY
Pathology • Laboratory Medicine • Laboratory Management

©2026 CAP TODAY, all rights reserved.

Modern ID Diagnostics: Clinical and Financial results require robust molecular controls

written by CAP TODAY
June 12, 2025

ZeptoMetrix
an antylia scientific company

In this roundtable discussion, presenters outline key steps and considerations involved in implementing a new diagnostic assay.

CAP TODAY
Pathology • Laboratory Medicine • Laboratory Management

©2026 CAP TODAY, all rights reserved.

Qiagen launches QIAprep&amp Plasmodium kit

written by CAP TODAY
June 12, 2025

June 2025—Qiagen announced the launch of its QIAprep&amp Plasmodium kit and two companion assays to support malaria research and surveillance efforts. The solution combines sample preparation and quantitative PCR into one workflow and detects all five *Plasmodium* species in human samples. The QIAprep&amp technology detects as little as one parasite per microliter, is compatible with liquid and dried blood samples, and is suitable for use on many qPCR platforms, including the company's Rotor-Gene Q.

©2026 CAP TODAY, all rights reserved.

FDA clears Ibex Prostate Detect

written by CAP TODAY
June 12, 2025

June 2025—Ibex Medical Analytics has received FDA 510(k) clearance for Ibex Prostate Detect, an in vitro diagnostic, software only medical device that analyzes scanned histopathology whole slide images from prostate core needle biopsies prepared from H&E-stained formalin-fixed, paraffin-embedded tissue. If tissue suspicious for prostate cancer is identified, the system provides case- and slide-level alerts and includes an AI-generated heat map that identifies small and rare missed prostatic cancers.

©2026 CAP TODAY, all rights reserved.

QuidelOrtho introduces Results Manager

written by CAP TODAY
June 12, 2025

June 2025—QuidelOrtho Corp. announced the availability of the QuidelOrtho Results Manager system, an informatics solution designed to provide a seamless, user-friendly experience for community hospitals and point-of-care settings, strengthening informatics capabilities across QuidelOrtho's diagnostics portfolio. The system provides continuous tracking of instruments and assays, streamlines workflows with autoverification and simplified rule-writing tools, and integrates with multiple instruments and unlimited concurrent users.

©2026 CAP TODAY, all rights reserved.

FDA clears Beckman Coulter DxC 500i analyzer

written by CAP TODAY
June 12, 2025

June 2025—Beckman Coulter Diagnostics announced that its DxC 500i clinical analyzer received FDA 510(k) clearance. The integrated chemistry and immunoassay analyzer has a throughput of up to 800 clinical chemistry tests and 100 immunoassay tests per hour and features FlexMode operations, which prioritize immunoassay and chemistry testing according to each sample's urgency.

©2026 CAP TODAY, all rights reserved.

IDT introduces xGen hybridization, wash kit v3

written by CAP TODAY
June 12, 2025

June 2025—Integrated DNA Technologies unveiled its xGen Hybridization and Wash version 3 kit. The kit features a high-throughput workflow that eliminates heated buffers and reduces hands-on time by 20 percent. The one-hour hybridization step delivers high-quality results and enables users to get from sample to sequencer in one day. The kit supports library inputs as low as 100 ng and pairs with xGen predesigned or custom Hyb panels and xGen Blocking Oligos.

©2026 CAP TODAY, all rights reserved.

FDA clears Liaison Plex Gram-negative blood culture assay

written by CAP TODAY
June 12, 2025

June 2025—Diasorin announced it has received FDA 510(k) clearance for the Liaison Plex Gram-negative blood culture assay, the second of the company's three multiplex molecular panels for blood culture pathogen identification on the Liaison Plex. The assay is designed to identify 27 targets—19 Gram-negative bacteria and eight relevant resistance gene targets, including *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Pseudomonas aeruginosa, Acinetobacter* species, *Citrobacter* species, *Enterobacter* species, and *Proteus* species. Results are available about two hours after a Gram stain.

©2026 CAP TODAY, all rights reserved.

MMQCI releases FilmArray tropical fever quality control

written by CAP TODAY
June 12, 2025

June 2025—Maine Molecular Quality Controls announced the release of the FilmArray TF control panel, for users of the FDA-cleared BioFire FilmArray tropical fever panel. The multiplexed control is intended for use as an external positive and negative assayed quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of viral, bacterial, and parasitic pathogens. The kit includes six 200-µL positive controls and six 200-µL negative controls.

©2026 CAP TODAY, all rights reserved.