

[FDA approves OncoReveal CDx on Illumina MiSeq Dx system](#)

written by CAP TODAY
May 15, 2024

May 2024—Pillar Biosciences announced that the FDA has approved the company's premarket approval supplement application for its OncoReveal CDx pan-cancer solid tumor in vitro diagnostic assay. The panel covers 22 clinically relevant genes in one multiplex reaction and has a fully automatable workflow with a sample-to-report time of as little as 48 hours. Up to 46 clinical samples can be batched on a single MiSeq Dx run.



©2026 CAP TODAY, all rights reserved.

[Bosch, Randox invest €150 million in Vivalytic platform](#)

written by CAP TODAY
May 15, 2024

May 2024—Bosch and Randox Laboratories have entered into a strategic partnership in which the two companies will invest around €150 million in joint research, development, and distribution for new tests for Bosch's Vivalytic platform. One goal of the partnership is to develop an in vitro diagnostic multiplex sepsis test for the Vivalytic analyzer. It will be the first test to feature Bosch's novel BioMEMS technology.



©2026 CAP TODAY, all rights reserved.

[Abbott TBI cartridge cleared for use with whole blood](#)

written by CAP TODAY
May 15, 2024

May 2024—Abbott’s i-Stat TBI cartridge has received FDA clearance for use with whole blood, allowing clinicians to help assess patients with suspected concussion at the patient’s bedside. The test measures ubiquitin C-terminal hydrolase L1 and glial fibrillary acidic protein to help evaluate patients 18 years of age and older up to 24 hours after injury. Results are available in 15 minutes on the portable i-Stat Alinity system.



©2026 CAP TODAY, all rights reserved.

[Bio-Rad expands availability of Unity Next Peer QC](#)

written by CAP TODAY
May 15, 2024

May 2024—Bio-Rad Laboratories has launched its Unity Next Peer QC data management software in Europe, the Middle East, and Africa. The software is designed to help troubleshoot quality control failures and increase confidence in patient testing results and offers on-demand access to peer reporting and quality control data. Labs new to Bio-Rad’s suite of QC data management products can get guided support and training from the company.



©2026 CAP TODAY, all rights reserved.

[Verichem updates data reduction software](#)

written by CAP TODAY
May 15, 2024

May 2024—Verichem Laboratories has upgraded its Web-based, CLIA-compliant data reduction and test reporting software. The new version allows customers to save reports on the company's server for future editing and edit previous submissions for up to three days after the initial submission. Previous submissions are autosaved so users can edit data without rekeying or reentering any other component information. The software is available to customers at no cost.



©2026 CAP TODAY, all rights reserved.

[Newcomer Supply to distribute HistoCyte cell line controls](#)

written by CAP TODAY
May 15, 2024

May 2024—Newcomer Supply announced it is distributing HistoCyte Laboratories cell line controls for research use only. HistoCyte uses proprietary methods to process cell lines into tissue-like controls. The products are standardized, developed, and manufactured to provide consistent morphology and staining results throughout the FFPE block. Cell line controls are available as either precut slides or in cell microarray blocks.



©2026 CAP TODAY, all rights reserved.

FDA clears Scopio Labs digital bone marrow aspirate application

written by CAP TODAY
May 15, 2024

May 2024—Scopio Labs announced it has been granted de novo clearance by the FDA for its Full-Field Bone Marrow Aspirate application for use on the company's X100 and X100HT platforms. The application is designed to assist users in streamlining bone marrow aspirate review and reporting. It automates the detection and visualization of hematopoietic cells in stained smears, facilitating evaluations such as bone marrow smear quality assessment, blast cell and plasma cell estimation, and calculation of the myeloid to erythroid ratio.



©2026 CAP TODAY, all rights reserved.

Sysmex now selling hemostasis products under its brand

written by CAP TODAY
May 15, 2024

May 2024—Sysmex America announced it will sell hemostasis instruments and reagents to laboratories in the United States under the company's mutual original equipment manufacturer agreement with Siemens Healthineers. The agreement allows the companies to distribute hemostasis instruments provided by Sysmex and reagents provided by Siemens under their respective brands.



©2026 CAP TODAY, all rights reserved.

FDA clears QIAstat-Dx respiratory syndromic testing panel

written by CAP TODAY
May 15, 2024

May 13, 2024—Qiagen announced that the FDA has cleared its QIAstat-Dx Respiratory Panel Plus syndromic test for clinical use.



©2026 CAP TODAY, all rights reserved.

FDA clears Halo AP Dx digital pathology platform

written by CAP TODAY
May 15, 2024

May 8, 2024—Indica Labs received FDA 510(k) clearance for its Halo AP Dx digital pathology platform for use in primary diagnosis.



©2026 CAP TODAY, all rights reserved.