AMP case report: Unique patterns of BTK resistance: two independently arising resistance clones in response to covalent BTK inhibitor therapy in CLL/SLL

written by CAP TODAY
October 15, 2025

October 2025—Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is a mature B-cell neoplasm composed of small atypical lymphoid cells that often coexpress CD5 and CD23 and are characterized by scant cytoplasm, clumped nuclear chromatin, and indistinct nucleoli. CLL/SLL can involve the peripheral blood, bone marrow, and various lymphoid tissues such as the lymph nodes, tonsils, and spleen, and it may occasionally present in extranodal locations as well.[1] Within involved lymph nodes, pale-staining proliferation centers consisting of prolymphocytes or paraimmunoblasts are a characteristic finding in CLL/SLL.

Scopio receives fourth FDA clearance

written by CAP TODAY
October 15, 2025

October 2025—Scopio Labs received FDA clearance to include decision support system features for its X100 and X100HT platforms and Peripheral Blood Smear Application. The upgraded solution provides AI-driven analysis and grading for 23 distinct RBC morphology parameters and for the presence of platelet clumps across the clinically relevant areas of the sample, from the monolayer to the feathered edge.

MeMed completes development of BV Flex test

written by CAP TODAY
October 15, 2025

October 2025—MeMed has completed its multiyear development of MeMed BV Flex, a next-generation test designed to expand the reach of MeMed BV into decentralized, CLIA-waived settings. The test enables differentiation between bacterial and viral infections in 15 minutes using capillary blood from a finger prick.

StatLab launches PiSmart S1 slide printer

written by CAP TODAY
October 15, 2025

October 2025—StatLab Medical Products has launched the PiSmart S1 single hopper slide printer. The PiSmart S1 features an intuitive touchscreen interface and a compact footprint that supports on-demand printing. Four years of service is included with the use of StatLab-validated slides, which will soon be manufactured at the company's Arlington, Tex., facility. This integrated approach—pairing printers with precision-manufactured, validated KT premium slides—creates a complete solution built for accuracy and reliability, according to a press release from StatLab.

QuidelOrtho launches certified analyzer program

written by CAP TODAY
October 15, 2025

October 2025—QuidelOrtho Corp. has launched a certified analyzer program designed to expand access to high-quality diagnostic testing in rural and community hospitals across the United States. The program is tailored for clinics, physician office labs, and small hospitals with fewer than 100 beds. Each analyzer in the program undergoes a robust, multipoint certification process at QuidelOrtho's Rochester, NY, facility. It includes more than 140 system checks, functional adjustments, hardware cleaning or replacement, and extensive performance testing. The program features certified Vitros XT 7600 and 5600 integrated systems and the Vitros 3600 immunodiagnostic system. A 12-month warranty on service and support is included.

Agilent MMR IHC panel approved as a CDx for colorectal cancer

written by CAP TODAY
October 15, 2025

October 2025—Agilent Technologies MMR IHC Panel pharmDx (Dako Omnis) has received FDA approval as a companion diagnostic test for colorectal cancer. The test aids in identifying mismatch repair deficient colorectal cancer patients who are eligible for treatment with Bristol Myers Squibb's Opdivo (nivolumab) or Opdivo in combination with Yervoy (ipilimumab). It was developed and validated to detect the loss of function of any of the four MMR proteins in formalin-fixed, paraffin-embedded colorectal cancer tissue.

OGT, Qiagen partner to offer sample-to-report workflow

written by CAP TODAY
October 15, 2025

October 2025—OGT and Qiagen Digital Insights are partnering to expand OGT's bioinformatics capabilities by integrating Qiagen's tertiary analysis solution, QCI Interpret, with OGT's SureSeq next-generation sequencing panels. QCI Interpret delivers AI-powered, expert-curated classifications along with oncologist-reviewed summaries and transparent evidence links. Through this collaboration, SureSeq NGS panel users will have access to streamlined genomic insights and efficient, scalable reporting from sample to result.

Idylla CDx MSI test gets FDA premarket approval

written by CAP TODAY
October 15, 2025

October 2025—Biocartis' Idylla CDx MSI test, developed in partnership with Bristol Myers Squibb, has received FDA premarket approval. The test aids in identifying eligible microsatellite instability-high colorectal cancer patients who may benefit from treatment with Opdivo (nivolumab) alone or in combination with Yervoy (ipilimumab), as established in the CheckMate 8HW trial.

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

written by CAP TODAY
October 15, 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.

Randox expands its operations in West Virginia

written by CAP TODAY
October 15, 2025

October 2025—Randox Laboratories plans to expand its facility in Jefferson County, W. Va., from a 48-person sales and distribution operation to a full-scale production laboratory. The company says the expansion will further increase its annual production of 4.1 billion tests and significantly enhance its capacity to serve customers worldwide, from hospitals, laboratories, and coroners' offices to food safety testing facilities. The project will create opportunities for local suppliers and service providers. Once complete, the upgraded facility in Kearneysville will produce next-generation diagnostic products and

equipment.