

[Put It on the Board](#)

written by CAP TODAY
August 16, 2022

August 2022—The FDA has granted breakthrough device designation to Roche’s Elecsys Amyloid Plasma Panel for detection of early Alzheimer’s disease. It detects and measures AD biomarkers in blood plasma to indicate the need for further confirmatory testing.



©2026 CAP TODAY, all rights reserved.

[Roche Ventana MMR RxDx gets expanded approval](#)

written by CAP TODAY
August 16, 2022

Aug. 15, 2022—Roche announced that the FDA has approved a label expansion for the Ventana MMR RxDx panel, an immunohistochemistry companion diagnostic test to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair (dMMR) and who may be eligible for Keytruda (pembrolizumab).



©2026 CAP TODAY, all rights reserved.

[Enhertu approved for patients with HER2-low metastatic breast cancer](#)

written by CAP TODAY
August 16, 2022

August 8, 2022—AstraZeneca and Daiichi Sankyo's Enhertu (trastuzumab deruxtecan) has been approved in the U.S. for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy.



©2026 CAP TODAY, all rights reserved.

[FDA clears BioMérieux Nephrocheck test on Vidas platform](#)

written by CAP TODAY
August 16, 2022

July 29, 2022—The FDA has cleared the BioMérieux Vidas Nephrocheck assay, for use to detect kidney stress in patients at risk of acute kidney injury.



©2026 CAP TODAY, all rights reserved.

[CellaVision launches Diff-Line for low-vol hematology labs](#)

written by CAP TODAY
August 16, 2022

July 27, 2022—CellaVision announced today at the AACC meeting the launch of its Diff-Line by CellaVision, a workflow solution for low-volume hematology laboratories.



©2026 CAP TODAY, all rights reserved.

[Roche amyloid plasma panel designated a breakthrough device](#)

written by CAP TODAY
August 16, 2022

July 20, 2022—Roche announced yesterday that the FDA has granted breakthrough device designation to the Elecsys Amyloid Plasma Panel.



©2026 CAP TODAY, all rights reserved.

[EKF to distribute FDA-cleared Lucica glycated albumin test](#)

written by CAP TODAY
August 16, 2022

July 2022—EKF Diagnostics announced the availability of the FDA-cleared Lucica Glycated Albumin-L test kit, manufactured by Asahi Kasei Pharma Corp. and sold exclusively in the United States by EKF. Lucica Glycated Albumin-L is a specific, quantitative test for glycated albumin for the intermediate-term monitoring of glycemic control in patients with diabetes.



©2026 CAP TODAY, all rights reserved.

[BioMérieux Chikungunya dx tests get CE mark](#)

written by CAP TODAY
August 16, 2022

July 2022—BioMérieux announced the CE marking of its Vidas Anti-Chikungunya IgM and Anti-Chikungunya IgG tests to diagnose Chikungunya virus infection. The tests can detect infection during the acute phase and into the chronic phase and run on the company's Vidas immunoassay instruments.



©2026 CAP TODAY, all rights reserved.

[Seegene develops assay to detect monkeypox virus](#)

written by CAP TODAY
August 16, 2022

July 2022—Seegene has developed a PCR test to detect monkeypox virus. The Novaplex MPXV assay, for research use only, was developed using the company's AI-based automated test development system and can identify positive cases of the monkeypox virus in 90 minutes.



©2026 CAP TODAY, all rights reserved.

[Sarstedt launches web shop](#)

written by CAP TODAY
August 16, 2022

July 2022—Sarstedt has launched a web shop for direct online ordering of its labware consumables, specimen collection devices, and small instruments. The shop is available to customers in the United States and can be accessed via the company website at www.sarstedt.com or directly at www.shop.sarstedt.us.



©2026 CAP TODAY, all rights reserved.