

[Abbott gets expanded approval for HPV assay](#)

written by CAP TODAY
November 13, 2025

November 2025—FDA approves Abbott’s Alinity m HR HPV assay for self-collected vaginal samples in clinical settings.



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[CytoCell KMT2A FISH probe kit granted de novo classification](#)

written by CAP TODAY
November 13, 2025

November 2025—FDA granted de novo classification for OGT’s CytoCell KMT2A Breakapart FISH Probe Kit PDx as a companion diagnostic for Syndax’s menin inhibitor, Revuforj.



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[Tosoh gets clearance for next-gen GR01 HbA1c](#)

[analyzer](#)

written by CAP TODAY
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November 2025—Tosoh Bioscience received FDA clearance for its HLC 723-GR01 analyzer, which uses proprietary technology to deliver A1c results in 50 seconds and detect common hemoglobin variants.



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[Quest launches advanced PGx test service](#)

written by CAP TODAY
November 13, 2025

November 2025—Quest Diagnostics launched a pharmacogenomic laboratory test service to help providers understand a patient’s genetic response to drug therapies.



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[Quickvue Influenza + SARS test available for professional use](#)

written by CAP TODAY
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November 2025—QuidelOrtho's Quickvue Influenza + SARS test, a CLIA-waived immunoassay, is now available for professional use.



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[Data presented at ACEP25 show the utility of MeMed BV](#)

written by CAP TODAY
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November 2025—Presentations at the American College of Emergency Physicians Scientific Assembly 2025 highlighted MeMed BV's effectiveness in distinguishing between bacterial and viral infections.



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[OGT launches SureSeq Myeloid MRD Plus NGS panel](#)

written by CAP TODAY
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Nov. 11, 2025—OGT launched the SureSeq Myeloid MRD Plus NGS panel, to detect ultra-low frequency variants in key measurable residual disease-associated biomarkers in acute myeloid leukemia.

[AI starting points and stepping stones](#)

written by CAP TODAY
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Laboratories considering AI-driven workflows should first identify the specific problem they aim to solve and assess if simpler coding solutions are sufficient. While out-of-the-box AI solutions from vendors offer a lower barrier to entry, laboratories must ensure these solutions align with their workflows and validate them in their own environments.

[New toxicology testing guidance to come](#)

written by CAP TODAY
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Two new ADLM documents provide guidance on toxicology testing for emergency departments, replacing a 2003 guideline. The documents address test menus, turnaround times, and the importance of educating ED staff on assay limitations.

