

[Paige Lymph Node gets FDA breakthrough device designation](#)

written by CAP TODAY
November 7, 2023

Nov. 7, 2023—Paige announced that the FDA has granted breakthrough device designation for Paige Lymph Node, an AI application used to detect breast cancer metastases in lymph node tissue.



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[Roche gets FDA approval for HPV test on Cobas 5800 system](#)

written by CAP TODAY
November 7, 2023

Nov. 6, 2023—Roche announced that the FDA has approved the Cobas HPV test for use on its next-generation Cobas 5800 molecular instrument.



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FDA approves Abbott HPV test to run on Alinity m

written by CAP TODAY
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Nov. 3, 2023—Abbott has received FDA approval for its molecular human papillomavirus screening test to run on its Alinity m system.



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Bio-Rad cardiac control compatible with Beckman analyzers

written by CAP TODAY
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Nov. 2, 2023—Bio-Rad Laboratories has announced the expanded compatibility of its cardiac control, Cardiac Advance, to include Beckman Coulter instruments.



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Feasibility study results evaluating Mainz advanced adenoma biomarkers

written by CAP TODAY
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October 2023—Mainz Biomed announced results of an independent feasibility study conducted in collaboration with members of the National Cancer Institute’s Early Detection Research Network to evaluate the company’s portfolio of five mRNA biomarkers, which it acquired from Université de Sherbrooke, Quebec.



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Digital path’s star rises from the mists

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October 2023—In living up to its promise as a new technology that will revolutionize clinical care through greater ease, speed, and accuracy of diagnosis, digital pathology has been sluggish. While many analysts, starting at least two decades ago, forecasted that digital pathology would elbow aside glass slides for good, that milestone is still far out of reach. As health economist and chief executive officer of the New York City-based digital pathology company Paige, Andy Moye, PhD, puts it bluntly: “In probably 90 to 95 percent of the cases in the U.S., a pathologist still makes the diagnosis of cancer the way they did it back in 1910: by looking at a glass slide under a microscope.” Mark Lloyd, PhD, vice president of pathology for Fujifilm, says he wouldn’t be surprised to hear that perhaps only five percent to 10 percent of hospitals have moved beyond using only glass slides to offer pathologists digital pathology capability. In fact, Dr. Lloyd thinks those percentages are overstated. What is the market share for the clinical use of digital pathology?



[Looking ahead to respiratory virus season](#)

written by CAP TODAY

November 7, 2023

October 2023—With respiratory virus season near, those with a close eye on it in August gave the lay of the land for test algorithms, technologies, and forecasts, even as SARS-CoV-2 and RSV cases were rising in parts of the country.



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[Soon to be required: current susceptibility testing breakpoints](#)

written by CAP TODAY

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October 2023—A CAP accreditation program requirement that microbiology laboratories use current antimicrobial susceptibility testing breakpoints, which was added to the checklist in 2021, will go into effect Jan. 1, 2024.



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[Inside lab's experience with assays for Alzheimer's](#)

written by CAP TODAY
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October 2023—Orders for cerebrospinal fluid testing for Alzheimer's disease have grown at Mayo Clinic since spring 2020, when testing was first offered. When aducanumab was approved in May 2021, test orders jumped.



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[Fast or comprehensive? Lab offers both for NSCLC](#)

written by CAP TODAY
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October 2023—For molecular testing in oncology, the choice is often fast or slow. PCR-based platforms are rapid, and comprehensive genomic profiling by next-generation sequencing is slower, and each has its pros and cons.



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