

[FDA clears respiratory viral panel for BD Max](#)

written by CAP TODAY
October 3, 2023

September 2023—BD announced FDA 510(k) clearance for its BD Respiratory Viral Panel for the BD Max system. It is a single molecular diagnostic combination test that uses a single nasal or nasopharyngeal swab sample to determine if a patient has SARS-CoV-2, influenza A, influenza B, or respiratory syncytial virus. Results are available in about two hours.



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[FDA clears Thermo Fisher assays for preeclampsia](#)

written by CAP TODAY
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September 2023—Thermo Fisher Scientific announced FDA clearance of its Brahms PlGF plus Kryptor and Brahms sFlt-1 Kryptor novel biomarkers for the risk assessment and clinical management of preeclampsia. The assays received FDA breakthrough designation in May.



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[FDA clears Thermo Fisher chromogranin A assay](#)

written by CAP TODAY
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Sept. 28, 2023—Thermo Fisher Scientific announced FDA clearance of its Thermo Scientific Brahms CgA II Kryptor, an automated immunofluorescent assay for the quantitative determination of the concentration of chromogranin A in human serum.



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[Pillar Biosciences launches OncoReveal Core LBx NGS kit](#)

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Sept. 27, 2023—Pillar Biosciences announced the global launch of OncoReveal Core LBx, a research use only, liquid biopsy-based next-generation sequencing kit for pan-cancer tumor profiling.



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FDA clears Streck quality controls for bloodstream infections

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Sept. 26, 2023—Streck announced that its MDx-Chex for BC-GP and MDx-Chex for BC-GN quality controls, designed to verify the performance of the Luminex Verigene Blood Culture Gram-Positive (BC-GP) and Gram-Negative (BC-GN) tests for blood stream infection and sepsis, have been granted FDA clearance for use in diagnostic procedures.



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BioMérieux submits 510(k), CLIA-waiver application for R/ST panel

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Sept. 25, 2023—BioMérieux has submitted the BioFire SpotFire Respiratory/Sore Throat (R/ST) panel to the FDA for a dual 510(k) clearance and CLIA waiver.



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[QuidelOrtho gets CLIA waiver for Sofia 2 SARS Antigen+ FIA](#)

written by CAP TODAY
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Sept. 22, 2023—QuidelOrtho has been granted a CLIA waiver from the FDA for its Sofia 2 SARS Antigen+ FIA.



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[Evident announces alliance to automate digital pathology workflows](#)

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Sept. 19, 2023—Evident announced an alliance with Corista, Sakura Finetek, and Visiopharm to deliver an automated, end-to-end workflow solution for pathology in the United States.



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Tests for paraneoplastic syndromes in neurology

written by CAP TODAY
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September 2023—Laboratory testing for paraneoplastic neurologic syndromes is neither commonplace nor cheap. It also comes with its own enigmatical math, as Michael Levy, MD, PhD, recently experienced. As the director of the Neuroimmunology Clinic and Research Laboratory in Massachusetts General Hospital's Department of Neurology, Dr. Levy keeps an eye on PNS laboratory testing (which is performed at Mayo Clinic) at his institution.



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Many knots to untangle in lab test names

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September 2023—Ambiguities, inconsistencies, omissions, and other defects in the naming of laboratory tests can send test orders and results interpretation awry, particularly with some of the most common tests. Even among clinicians and laboratorians working at the same hospital for years, smooth sailing is not guaranteed. The authors of a study published in *Archives of Pathology & Laboratory Medicine* hope to change that. Their aim is to alert patient-facing providers and laboratories to the risks that ambiguous or nonstandardized laboratory test naming poses and to provide practical rules for minimizing those risks.



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