

[FDA clears Rheonix Encompass MDx for STIs](#)

written by CAP TODAY
April 18, 2022

April 2022—Rheonix announced that the FDA has granted 510(k) clearance for its automated Encompass MDx Workstation along with its STI TriPlex assay and Male Urine Collection Kit for the detection of sexually transmitted infections. The molecular testing device is a closed system that is automated from sample loading to result reporting, provides direct tube sampling, and contains all the reagents needed.



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[Qiagen expands QIAstat-Dx syndromic testing menu](#)

written by CAP TODAY
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April 2022—Qiagen announced test enhancements to its QIAstat-Dx, a fully integrated molecular diagnostic testing solution with one-step sample processing that provides results in about one hour. The company is awaiting U.S. regulatory approval of a gastrointestinal panel designed to detect 22 common viral, bacterial, and parasitic pathogens that can cause potentially life-threatening infections. Qiagen has also registered for CE marking a meningitis/encephalitis panel designed to analyze 15 pathogens simultaneously and help distinguish between meningitis and encephalitis.



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Roche launches Cobas Pulse system

written by CAP TODAY

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April 2022—Roche announced the launch of the Cobas Pulse system, the company's newest generation of connected POC solutions for professional blood glucose management, in select countries accepting the CE mark.



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Verichem clinical reference materials for lithium

written by CAP TODAY

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April 2022—Verichem Laboratories offers two multilevel, protein-based test kits of clinical reference materials for the calibration or calibration verification of lithium assays. Intended for use with direct and indirect ion-selective electrodes, colorimetric assays, and flame photometers, the Electrolyte Standard Kit and Serum ISE Standard Kit contain NIST-verified gravimetric concentrations for lithium. The liquid-stable, ready-to-use materials can also be used for quality control monitoring, method evaluations, post-maintenance testing, and routine troubleshooting.



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[Tribun Health gets KLAS award for digital pathology](#)

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April 2022—Tribun Health announced it won a 2022 “Best in KLAS” award for digital pathology in Europe. The Best in KLAS report from KLAS Research recognizes software and services companies that excel in helping health care professionals improve patient care.



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[Opdivo + chemo approved as neoadjuvant treatment for NSCLC](#)

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April 2022—The FDA has approved Bristol Myers Squibb’s Opdivo (nivolumab) in combination with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer in the neoadjuvant setting. The treatment is approved regardless of PD-L1 status and is based on the CheckMate -816 trial, the first positive phase three trial of an immunotherapy-based combination used before surgery for resectable NSCLC.



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[Alcor, Water Street partner to accelerate expansion](#)

written by CAP TODAY
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April 2022—Alcor Scientific is partnering with Chicago-based health care investor Water Street Healthcare Partners. Water Street will invest in Alcor’s research and development initiatives, product portfolio, and international expansion. Alcor has appointed Jim Post as chief executive officer to lead its next phase of innovation and growth.



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[Roche launches Avenio Edge System](#)

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April 2022—Roche launched its Avenio Edge System, an all-in-one preanalytical platform that is designed to minimize manual touchpoints and includes ready-to-load reagents, validated protocols, onboard capabilities, and intuitive software to manage next-generation sequencing sample workflows.



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[Beckman Coulter Life Sciences, AmoyDx ink agreement](#)

written by CAP TODAY
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April 2022—Beckman Coulter Life Sciences has entered into an agreement with AmoyDx to develop applications on the Biomek NGenius liquid handling system. The Biomek NGenius system is scheduled to launch in the second quarter of this year; it is not intended or validated for use in diagnosis of disease or other conditions.



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[Pathology hospitalists in place at UMich](#)

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April 2022—Asked why he robs only trains, Richard Farnsworth’s Gentleman Bandit in *The Grey Fox* answers with a truth universally acknowledged: “A professional always specializes.” In line with that conviction, there’s little debate on the value of specialization in medicine—or, as it has evolved more recently, the extraordinary value of subspecialization in anatomic pathology. Many consider subspecialist signout to be the gold standard of review and diagnosis in pathology. Because they are dealing with a small number of pathologies, “the care that subspecialists can provide is phenomenal,” says L. Priya Kunju, MD, director of surgical pathology at University of Michigan Health. But in hospital practice at academic institutions like the University of Michigan, when it comes to time-sensitive frozen sections, subspecialization can have a downside. The need to return a diagnosis of a frozen section within 20 minutes while a surgery is in progress may require that an array of different subspecialists be close at hand, near the operating room.



