

Tribun Health enters pharmaceutical market

written by CAP TODAY

June 19, 2022

June 2022—Tribun Health announced its expansion into the pharmaceutical market with the appointment of Loic Dartois as vice president of pharma. Dartois joined Tribun Health in March and is developing commercial offerings for the pharma industry. “Digital pathology data combined with best-in-class AI models has the power to improve treatments’ responses to a better targeted population,” Dartois said in a press release. “Thanks to its growing footprint in health care institutions in Europe and North America, Tribun Health is best positioned to support the pharmaceutical industry in its precision medicine transformation using an industry-leading digital pathology platform and deploying a thought leadership AI team.”



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Bio-Rad introduces anti-cemiplimab antibodies

written by CAP TODAY

June 19, 2022

June 2022—Bio-Rad Laboratories introduced a range of antibodies specific to cemiplimab (Libtayo) that inhibit the binding of the drug to its target, human programmed death receptor-1. The ready-made antibodies are suitable for developing selective and sensitive assays for the bioanalysis and drug monitoring of cemiplimab.



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[Siemens gets breakthrough device designation for sNfL assay](#)

written by CAP TODAY
June 19, 2022

June 2022—Siemens Healthineers announced the FDA has granted breakthrough device designation for the Advia Centaur serum neurofilament light chain (sNfL) assay, developed in collaboration with Novartis Pharma. The assay quantitatively measures NfL in human serum and plasma and is intended to be used in conjunction with clinical, imaging, and laboratory findings as an aid in identifying adult patients with relapsing multiple sclerosis who are at lower risk, versus higher risk, of multiple sclerosis disease activity.



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[ZeptoMetrix NATtrol SARS-CoV-2 omicron control](#)

written by CAP TODAY
June 19, 2022

June 2022—ZeptoMetrix announced the release of its NATtrol SARS-CoV-2 Omicron External Run Control, for research use only, to evaluate the performance of nucleic acid tests for determining the presence of SARS-CoV-2 omicron variant RNA. The control is formulated with purified, intact organisms and is for use with a real-time PCR thermal cycler. The product is available in six 0.5-mL vials and is refrigerator stable at 2° to 8°C.



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[Versant Dx announces strategy to accelerate use of digital pathology](#)

written by CAP TODAY
June 19, 2022

June 2022—Versant Diagnostics has announced a strategy in which the company will focus on anatomic pathology, precision medicine, and the digital transformation of the industry. The company said it is positioning itself to become the nation's largest independent physician services company through the acquisition of independent pathology practices, and it will provide capital for practices to convert to digital pathology while maintaining physician leadership.



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[CE-marked Nova Max Pro creatinine/eGFR meter launched in EU](#)

written by CAP TODAY
June 19, 2022

June 2022—Nova Biomedical launched the CE-marked Nova Max Pro creatinine/eGFR meter system in the EU market. Nova Max Pro is designed to improve kidney care through kidney function screening and early detection of kidney disease in point-of-care settings outside the hospital. The meter and creatinine biosensor measure blood creatinine and calculate estimated glomerular filtration rate from a 1.2- μ L capillary fingerstick blood sample in 30 seconds. The measuring technology is based on the Nova StatSensor Creatinine technology.



[PreciseDx AI-enabled digital pathology detects Parkinson's disease](#)

written by CAP TODAY
June 19, 2022

June 2022—PreciseDx announced its AI-enabled digital pathology technology can accurately diagnose Parkinson's disease in patients prior to severe onset of symptoms.



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[Seegene RV assay gets CE-IVD mark, Australian TGA approval](#)

written by CAP TODAY
June 19, 2022

June 2022—Seegene announced that its Allplex RV Master Assay has achieved CE-IVD marking and received approval from Australia's Therapeutic Goods Administration.



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FDA clears Scopio Labs digital cell morphology platform

written by CAP TODAY
June 19, 2022

June 17, 2022—Scopio Labs received FDA 510(k) clearance for its X100HT hematology digital cell morphology platform with peripheral blood smear review.



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Breast cancer breakthrough sparks HER2 quest

written by CAP TODAY
June 19, 2022

June 2022—The latest advance in breast cancer treatment is a big one—the promising antibody drug conjugate fam-trastuzumab deruxtecan-nxki, or T-DXd (Enhertu). The drug was granted breakthrough therapy designation this spring for patients with HER2-low metastatic breast cancer, and the drug and trial on which the decision was based were the focus of the plenary session at the ASCO annual meeting in early June. “This drug in particular is a variant of a drug we are all very familiar with—Herceptin, or trastuzumab,” says David Rimm, MD, PhD, the Anthony N. Brady professor of pathology, professor of medicine (oncology), director of the translational pathology and Yale pathology tissue services, and director of the physician scientist training program in pathology, Department of Pathology, Yale University School of Medicine. Also familiar: the IHC test to determine eligibility for the drug, a companion diagnostic developed decades ago. But that’s where easy familiarity ends.



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