

FDA approves T-Cell Select to automate TB testing

written by CAP TODAY
September 22, 2022

Sept. 22, 2022—Oxford Immunotec, a division of PerkinElmer, announced FDA approval of its T-Cell Select reagent kit for automating the company's T-SPOT.TB test workflow for in vitro diagnostic use by certified laboratories.



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Digital Pathology Connections debuts at PathVisions 2022

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Digital Pathology Connections, a worldwide community for professionals interested in the digital future of the anatomic pathology laboratory, debuted at the Pathology Visions 2022 conference, held in Las Vegas, Oct. 16-18. Digital Pathology Connections (DPC) is a virtual community providing educational content and enabling discussions on trending topics in pathology.



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FDA clears Roche Cobas Pure for low- to mid-vol labs

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Sept. 19, 2022—Roche received FDA 510(k) clearance for the Cobas Pure, a compact and modular solution that combines clinical chemistry, immunoassay, and ion-selective electrode diagnostic testing on a single platform with a footprint of about 21 square feet.



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Roche receives EUA for Cobas SARS-CoV-2 Duo

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September 2022—Roche announced that the FDA issued emergency use authorization for the Cobas SARS-CoV-2 Duo for use on the fully automated Cobas 6800/8800 systems. The real-time RT-PCR assay is for the in vitro qualitative and quantitative detection of SARS-CoV-2 RNA in nasal and nasopharyngeal swab specimens. The assay also performs quantitation of SARS-CoV-2 RNA levels in the collected specimen; however, only the qualitative result of the assay is intended for use as an aid in diagnosing SARS-CoV-2 infection in patients suspected of COVID-19 by their health care provider.



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Bio-Rad launches RNA library prep kit

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September 2022—Bio-Rad Laboratories has launched its SEQuoia Express Stranded RNA Library Prep Kit. The three-tube kit uses a novel reverse transcriptase with ligation-free adapter addition chemistry to yield a reproducible, quantitative RNA sequencing library in three hours. The kit enables users to construct robust libraries that capture mRNA and long noncoding RNA (>200 bp) transcripts for differential gene expression analysis and novel transcript discovery.



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BD, Accelerate announce collaboration for antimicrobial ID Dx

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September 2022—BD and Accelerate Diagnostics announced a worldwide commercial collaboration agreement in which BD will offer Accelerate's rapid testing solution for antibiotic resistance and susceptibility. Under the agreement, BD will market and sell the Accelerate Pheno system and Accelerate Arc module and associated test kits through its worldwide sales network in territories where products have regulatory approval or registration.



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[Verichem clinical reference materials for microprotein, CO₂ testing](#)

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September 2022—Liquid-stable and ready-to-use clinical reference materials for microprotein testing are available from Verichem Laboratories. The products are intended for the calibration and calibration verification of clinical systems testing for total protein and albumin in urine and cerebrospinal fluid samples and incorporate human protein components for optimum reactivity.



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[Hamilton, Bionano announce UHMW DNA extraction solution](#)

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September 2022—Hamilton and Bionano Genomics announced the development of the Long String Vantage for isolating ultra high molecular weight DNA for use in optical genome mapping. The Bionano Prep SP Blood and Cell Culture DNA Isolation Kit runs on the Long String Vantage and can obtain up to 12 UHMW DNA samples in less than four hours.



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BD COVID-19, flu A/B, RSV test gets CE mark

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September 2022—BD announced that the BD Max Respiratory Viral Panel, a molecular diagnostic combination test for SARS-CoV-2, influenza A and B, and respiratory syncytial virus, has been CE marked to the IVD directive 98/79/EC. The test uses a single nasal swab or a single nasopharyngeal swab sample to determine if a patient has COVID-19, flu, or RSV.



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Study shows Abbott's TBI test could predict outcomes from brain injury

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September 2022—Abbott announced that a study published in *Lancet Neurology* demonstrates the ability of two blood-based biomarkers to predict how a person will recover from traumatic brain injury (TBI) (Korley FK, et al. *Lancet Neurol.* 2022;21[9]:803–813).



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