Newsbytes

written by CAP TODAY
September 15, 2021

September 2021—When Stephen Hewitt, MD, PhD, went down the COVID-19 rabbit hole in early 2020, little did he know about the long-term value of a comprehensive COVID-19 digital pathology repository—and how such a project would come to fill his days and, occasionally, nights.

Put It on the Board

written by CAP TODAY
September 15, 2021

September 2021—Testing for chronic kidney disease in adults with hypertension and/or diabetes is low in routine clinical care, despite guideline recommendations, write the authors of a study published in *Diabetes Care* (Alfego D, et al. 2021;44[9]:2025–2032).

PreciseMDX introduces digital health platform

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Aug. 31, 2021—PreciseMDX introduced a cloud-based solution that enables labs to set up scalable, personalized, digital experiences.

Visby gets FDA clearance, CLIA waiver for POC STI test

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Aug. 30, 2021—Visby Medical announced it has received FDA 510(k) clearance and was granted a CLIA waiver to market its single-use PCR diagnostic test for the multiplexed detection of sexually transmitted

infections caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* using a self-collected vaginal swab.

FDA approves Oncomine Dx Target test as a CDx for Tibsovo

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Aug. 27, 2021—The FDA has granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target test as a companion diagnostic to identify patients with isocitrate dehydrogenase-1 mutated cholangiocarcinoma who may be candidates for Tibsovo (ivosidenib tablets).

BD launches high-throughput molecular dx platform in the U.S.

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Aug. 26, 2021—BD has launched its FDA-approved BD COR PX/GX system, a fully automated, high-throughput diagnostic platform that integrates robotics and sample management software algorithms to automate the complete molecular laboratory workflow from sample processing to diagnostic test result.

FDA grants marketing authorization to Siemens ELF test

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Aug. 25, 2021—Siemens Healthineers announced that its Enhanced Liver Fibrosis test was granted marketing authorization under the de novo review pathway.

Hardy Diagnostics releases group A strep agar

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Aug. 24, 2021—Hardy Diagnostics has released its HardyChrom Group A Strep agar, a chromogenic medium recommended for the selective cultivation and differentiation of group A streptococcus from clinical specimens.

Euroimmun launches SARS-CoV-2 NeutraLISA assay

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August 2021—Euroimmun launched its SARS-CoV-2 NeutraLISA assay, a surrogate neutralization test intended for the detection of neutralizing antibodies against SARS-CoV-2.

Cobas SARS-CoV-2 Test authorized for asymptomatic people

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August 2021—Roche's Cobas SARS-CoV-2 has received FDA emergency use authorization for testing individuals without symptoms or reasons to suspect COVID-19. This authorization supports the guidance update from the CDC to expand SARS-CoV-2 testing to include people without symptoms and applies to pooled samples containing up to and including six individual samples. Asymptomatic testing with the Cobas SARS-CoV-2 test is also available in countries accepting the CE mark.