

# Put It on the Board

## FDA clears SeptiCytel Rapid

January 2022—The Food and Drug Administration granted 510(k) clearance for SeptiCytel Rapid, which runs on Biocartis' molecular diagnostics Idylla platform. It's a fully automated, rapid host-response test that distinguishes sepsis from infection-negative systemic inflammation in patients suspected of sepsis.

FDA clearance was based on data from retrospective and prospective studies validating the clinical accuracy of SeptiCytel Rapid. The retrospective clinical study consisted of eight sites in the United States and Europe from the MARS clinical trial (NCT01905033) and VENUS clinical trial (NCT02127502). The prospective study, NEPTUNE, evaluated real-time performance of the test in a clinical setting at Emory University, Rush University, and the University of Southern California. In retrospective and prospective studies, the sepsis status of patients was determined by a three-member panel of expert physicians.

Immunexpress of Seattle will commercialize the test to ensure availability across the U.S. this year.

## Roche releases newest AI-based digital pathology algorithms

Roche announced on Dec. 7 its research-use-only launch of three new automated digital pathology algorithms: uPath Ki-67 (30-9), uPath ER (SP1), and uPath PR (1E2) image analysis for breast cancer.

The algorithms are ready-to-use, Roche says, and integrated within its uPath enterprise software and Navify Digital Pathology, the cloud version of uPath.

## Olympus announces 1st results of AI-based tool for gastric cancer

The results of Olympus' ongoing joint research program to create an AI-based pathology diagnostic tool were announced at the Japan Society of Digital Pathology Study annual meeting in November 2021. The diagnostic tool achieved 100 percent sensitivity and 50 percent or more specificity for all gastric biopsy pathology specimens analyzed, according to an Olympus press release.

Olympus, through its Office of Innovation, began a collaboration with the Kure Medical Center and Chugoku Cancer Center in Japan in 2017 to develop an AI-based pathology diagnostic tool. In the initial testing phase, the AI was trained using 368 gastric biopsy pathology slide images.

The second phase of research began in 2020, when the diagnostic tool was expanded to six hospitals in Japan, with the aim of verifying the tool's versatility and improving its accuracy, Olympus says. The goal of this program, it says, is to deliver AI pathology diagnosis software that can assist pathologists by 2023.

The AI-based pathology tool uses a convolutional neural network optimized to analyze pathology images. This technology enables the tool to identify adenocarcinoma versus nonadenocarcinoma tissue in an image. Once the AI was trained, it was tested using 1,200 pathology whole slide images from the six hospitals. The AI classified each image as adenocarcinoma or nonadenocarcinoma and achieved 100 percent sensitivity and 50 percent or higher specificity for slides from all six hospitals.

## Quidel to acquire Ortho

Quidel and Ortho Clinical Diagnostics Holdings entered into a definitive agreement in which Quidel will acquire Ortho for \$24.68 per share of common stock using a combination of cash and newly issued shares in the combined company. The transaction is expected to close during the first half of fiscal year 2022.

Among the benefits, the companies say, is a more diverse product pipeline and enhanced R&D capabilities. The transaction is expected to accelerate an innovative pipeline.

## **CMS updates payment rates for '22**

The Protecting Medicare and American Farmers from Sequester Cuts Act, which Congress passed Dec. 9, 2021, increased payments on the Medicare physician fee schedule in 2022 by three percent. The Centers for Medicare and Medicaid Services followed by implementing the provisions in the law and increased the conversion factor used to calculate fee schedule rates, from \$33.5983 to \$34.6062. The CAP's 2022 Medicare physician fee schedule impact table showing these changes is at <https://j.mp/3Jmioht>.

The CMS had published on Nov. 2 last year its final 2022 Medicare physician fee schedule, which included an overall cut of about four percent.