Put It on the Board

June 2018—FDA clears T2Bacteria panel for detecting sepsis-causing pathogens

T2 Biosystems received market clearance from the Food and Drug Administration for the T2Bacteria panel for the direct detection of bacterial species in human whole blood specimens from patients with suspected bloodstream infections.

The T2Bacteria panel provides sensitive detection of five sepsis-causing bacterial pathogens directly from a whole blood specimen in about five hours. This was more than 2.5 days faster than blood-culture–dependent tests as demonstrated in the more than 1,400-patient pivotal trial conducted at 11 hospitals in the United States, according to the company.

The T2Bacteria panel achieved an overall average sensitivity of 90 percent and an overall average specificity of 98 percent, while demonstrating no interference from the presence of antibiotics in the bloodstream, T2 Biosystems said in a statement.

“The results from the T2Bacteria pivotal clinical trial were impressive, demonstrating excellent performance and advantages over blood culture,” said principal investigator Minh-Hong Nguyen, MD, director of the antimicrobial management program and of transplant infectious diseases at the University of Pittsburgh Medical Center.

The T2Bacteria panel, like the previously FDA-cleared T2Candida panel, runs on the company’s FDA-cleared T2Dx instrument. T2Bacteria identifies the following: *Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Staphylococcus aureus*.

Veracyte provides early access to genomic classifier for IPF diagnosis

Veracyte has launched an early access program to begin making its Envisia Genomic Classifier available to patients being evaluated for interstitial lung diseases, including idiopathic pulmonary fibrosis.

Physicians from Thomas Jefferson University, Keck Medicine of USC, Providence Sacred Heart Medical Center in Washington state, and the University of California, Los Angeles, are among the first to participate in the program and offer patients the new genomic test.

The Envisia Genomic Classifier combines RNA sequencing and machine learning to improve the ability to differentiate IPF from other interstitial lung diseases through patient samples that are obtained by transbronchial biopsy. The 190-gene test detects the genomic pattern of usual interstitial pneumonia, a hallmark of IPF, with 88 percent specificity and 70 percent sensitivity.

“Our Early Access Program, while limited to a small number of institutions, will enable us to begin providing access to the test in advance of its anticipated, nationwide commercial expansion in 2019,” Veracyte chair and CEO Bonnie Anderson said in a statement.

A study published Jan. 17 in *BMC Pulmonary Medicine* (Cosgrove GP, et al. doi:10.1186/s12890-017-0560-x) found that more than half of patients with IPF or other interstitial lung diseases were misdiagnosed at least once and that, for four in 10 ILD patients, diagnosis took more than a year. Among those patients with IPF, more than one in five reported treatment during the diagnostic process with systemic corticosteroids, a potentially harmful therapy for IPF patients.

Abbott introduces Afinion 2 analyzer for diabetes care

Abbott launched its Afinion 2 analyzer in the United States. It is a point-of-care, rapid, multi-assay platform that

streamlines and simplifies the delivery of hemoglobin A1c and albumin to creatinine ratio results.

Along with providing rapid results—three minutes for HbA1c, five minutes for ACR—the Afinion 2 platform offers all-in-one connectivity to laboratory and hospital information systems and a sleeker, quieter experience for clinicians and patients, Abbott said in a statement.

Qiagen announces partnership, exhibits new NGS panels

Qiagen has partnered with Freenome, an artificial intelligence genomics company, to speed the development and commercialization of next-generation sequencing tests. The alliance is part of internal initiatives and partnerships that Qiagen says it is creating to reach patients more quickly with NGS tests.

At the American Society of Clinical Oncology annual meeting earlier this month, Qiagen showcased its new panels for the GeneReader NGS system ahead of market launch, including the GeneRead QIAact BRCA Advanced Panel, a comprehensive assay for research in somatic and hereditary mutations, and the QIAact Myeloid DNA Panel, which supports myeloid neoplasm research, covering 25 genes and their variants including SNVs and indels. In addition, a new version of the GeneRead QIAact Actionable Insights Tumor Panel, with higher analytical sensitivity and specificity for somatic variants, will be released. The panels are available for research use only.

Myriad to acquire Counsyl

Myriad Genetics has signed a definitive agreement to acquire Counsyl, a provider of expanded carrier screening and noninvasive prenatal screening, for $375 million.

Counsyl was founded in 2007. It generated more than $134 million in revenue and performed more than 280,000 reproductive genetic tests in the 12 months preceding Myriad’s May 28 announcement of its intent to acquire Counsyl, according to Myriad’s statement.

On completion of the transaction, Counsyl will become a wholly owned subsidiary of Myriad.
“By offering Counsyl’s best-in-class reproductive testing products in conjunction with Myriad’s leading hereditary cancer tests, we are well positioned to be the premier women’s health genetic testing company,” Mark C. Capone, president and CEO of Myriad Genetics, said in the statement.