FDA clears T2Bacteria Panel

May 30, 2018—The FDA cleared T2 Biosystems' T2Bacteria Panel for the direct detection of bacterial species in human whole blood specimens from patients with suspected bloodstream infections. The T2Bacteria Panel provides detection of five common sepsis-causing bacterial pathogens directly from a whole blood specimen in approximately five hours. "This was more than 2.5 days faster than blood-culture-dependent tests," T2 Biosystems said in a press release, as demonstrated in the 1,427 patient trial conducted at 11 hospitals in the U.S. (Nguyen MH, et al. Oral presentation O1092 at: 28th European Congress of Clinical Microbiology and Infectious Diseases; April 21–24, 2018; Madrid). The 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.

"The results from the T2Bacteria pivotal clinical trial were impressive, demonstrating excellent performance and advantages over blood culture," Minh-Hong Nguyen, MD, director of the antimicrobial management program and of transplant infectious diseases, University of Pittsburgh Medical Center, said in the press release. "T2Bacteria's detection of bloodstream infections and fast species identification at high sensitivity will expedite life-saving interventions such as the targeting of therapy within hours of blood draw."

The panel runs on the company's T2Dx instrument.

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