T2Bacteria pivotal trial publication

June 6, 2019—<u>T2 Biosystems</u> (Lexington, Mass.) announced that a study demonstrating the advantages of its T2Bacteria Panel and how it can aid in diagnosing blood stream infections was published in the *Annals of Internal Medicine* (Nguyen MH, et al. Epub ahead of print May 14, 2019. doi:10.7326/M18-2772). The panel identifies five ESKAPE bacteria—*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Escherichia coli*—in three to five hours.

The multicenter study enrolled and collected blood specimens from 1,427 patients who had a blood culture ordered as part of the standard of care. In the pivotal trial, the T2Bacteria Panel identified pathogens in 3.6 to 7.7 hours, whereas blood cultures took between 32 and 111 hours. In 78 percent of probable or possible blood stream infections, patients had negative blood cultures and positive T2Bacteria results despite treatment with active antibiotics. Twenty-four hours after blood draw, 20 percent of patients with positive blood cultures and positive T2Bacteria results were still not receiving effective therapy. The T2Bacteria Panel had a 99.7 percent negative predictive value, an overall sensitivity of 90 percent per patient and per assay, and an overall specificity of 90 percent per patient and 98 percent per assay.

The panel runs on the the company's T2Dx Instrument.