FDA clears two ePlex blood culture identification panels

Dec. 28, 2018—GenMark Diagnostics has received FDA 510(k) market clearance for its ePlex Blood Culture Identification Fungal Pathogen Panel. This panel, together with the ePlex Blood Culture Identification Gram-Positive Panel, which received FDA clearance Dec. 20, and Gram-Negative Panel were developed for the diagnosis and disease management of bloodstream infections that can lead to sepsis.

“Receiving FDA clearance for two of our three ePlex BCID panels is an exciting way to end the year,” Hany Massarany, president and chief executive officer of GenMark, said in a press release. “Our third panel is currently under review by FDA and we continue to expect its clearance in the early part of next year. We expect BCID to be a key contributor to our 2019 performance, driving both ePlex placements and assay sales.”