Diagnostics for detecting candida species, 12/14

December 2014—T2 Biosystems received FDA market authorization for its T2Candida Panel and T2Dx Instrument for the direct detection of candida species in human whole blood specimens from patients with symptoms of, or medical conditions predisposing patients to, invasive fungal infections.

T2Candida and T2Dx provide sensitive detection of specific sepsis-causing pathogens directly from a whole blood specimen in approximately four hours. In the pivotal trial, T2Candida and T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. The mean time to a positive result for T2Candida was 4.4 hours versus 129 hours for blood culture and species identification; the mean time for a negative result for T2Candida was 4.2 hours, compared with 120 hours for blood culture. T2Candida and T2Dx were reviewed under the FDA de novo classification process for devices with low to moderate risk that are first of a kind, according to a company statement.

T2Candida and T2Dx are powered by T2MR, a proprietary magnetic-resonance-based diagnostic technology.

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