FDA clears iCubate platform, 11/17

November 2017—Molecular diagnostic device company iCubate has earned FDA clearance for its iCubate platform, the iC-System, and its first clinical assay, the iC-GPC Assay, used for the rapid detection of pathogenic bacteria associated with bloodstream infection.

The iC-GPC Assay is a multiplexed, in vitro diagnostic test for the identification of five of the most common Gram-positive organisms associated with Gram-positive bacteremia, including *Staphylococcus aureus*. The assay also identifies three clinically relevant antibiotic resistance markers specific to methicillin-resistant *Staphylococcus* and vancomycin-resistant *Enterococcus*.

The system's core technology uses amplicon-rescued multiplex PCR, which detects multiple pathogens simultaneously. The iCubate platform and assay provide results up to 48 hours faster than conventional methods, according to the company.

***iCubate**, 855-256-3330*