Quantitative antibiotic susceptibility testing, 5/17

May 2017—Accelerate Diagnostics announced that the FDA has granted the de novo request to market the Accelerate Pheno system and Accelerate PhenoTest BC kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples. The blood culture kit is indicated for susceptibility testing of specific pathogenic bacteria commonly associated with bacteremia and produces results up to 40 hours faster than conventional methods, according to the company.

The kit is a multiplexed in vitro diagnostic test that uses qualitative nucleic acid fluorescence in situ hybridization identification and quantitative antimicrobial susceptibility testing methods intended for use with the Accelerate Pheno system. The kit can simultaneously detect and identify multiple microbial targets followed by susceptibility testing of the appropriate detected bacterial organisms using morphokinetic cellular analysis of individual microbial cells and colonies under the challenge of antibiotics.

The Accelerate clinical study included more than 39,000 tests conducted on 1,850 samples across 13 trial sites and exceeded the requirements of the FDA for identification and antimicrobial susceptibility testing. The study showed overall sensitivity of 97.4 percent and specificity of 99.3 percent for identification. For susceptibility, overall essential and categorical agreement versus standard broth microdilution was 96.3 percent and 96.4 percent, respectively.

The kit includes 140 assays for both identification and susceptibility testing, of which 116 were submitted to the FDA.

***Accelerate Diagnostics**, 520-365-3100*