

Gram-negative blood culture assay to ID and treat sepsis, 10/13

AdvanDx, a provider of molecular diagnostic tests for identifying pathogens that cause critical infections in hospitalized patients, announced the commercial launch of Gram-Negative QuickFISH BC, the third FDA-cleared test in its QuickFISH blood culture pathogen identification platform.

Gram-Negative QuickFISH BC is a rapid molecular diagnostic test that identifies bloodstream infections caused by *Escherichia coli*, *Pseudomonas aeruginosa*, and *Klebsiella pneumoniae* within 20 minutes of a positive blood culture.

The new gram-negative assay expands AdvanDx's QuickFISH platform, which can now identify the pathogens responsible for 90 percent of positive blood cultures. The platform also includes two gram-positive QuickFISH tests: *Staphylococcus* QuickFISH BC, for the identification of *Staphylococcus aureus* and/or coagulase-negative staphylococci, and *Enterococcus* QuickFISH BC, for the identification of *Enterococcus faecalis* and selected other enterococci. AdvanDx anticipates regulatory clearance and commercial launch of its fourth QuickFISH assay, for the identification of *Candida* species, later this year.

AdvanDx developed the QuickFISH platform based on its clinically-proven, proprietary PNA technology. The platform enables unprecedented 20-minute species identification of bacteria directly from positive blood cultures, allowing pathogen identification to be reported at the same time as Gram stain results. This rapid identification allows health care providers to optimize antibiotic therapy.

The test requires less than five minutes of hands-on time, simplifying laboratory workflow, and uses built-in universal controls, ensuring confidence in test results. Limited instrumentation and capital investment are required, making the platform easy and inexpensive to implement.

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