



AdvanDx News

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AdvanDx Receives FDA 510(k) Clearance for 90 Minutes PNA FISH® Protocol for Identifying Enterococcal Bloodstream Pathogens

*Pathogen Identification Results in 90 Minutes Direct from Positive Blood Cultures
Faster Results to Help Clinicians Improve Antibiotic Selection and Outcomes for Critical Infections
First of 8 PNA FISH Tests to Transition to Faster, 90 Minutes Protocol*

Woburn, MA, U.S.A. and Vedbaek, Denmark - October 27, 2009 - AdvanDx today announced that it has received FDA 510(k) clearance for a fast, 90 minutes protocol for its *E. faecalis*/OE PNA FISH® test. The faster protocol reduces the PNA FISH turn-around time from the original 2.5 hours to 90 minutes by reducing PNA probe hybridization from 90 minutes to 30 minutes. Clinical validation studies performed at hospitals in the United States and Europe demonstrated 100% equivalence between the 90 minutes protocol and the original PNA FISH protocol, ensuring the faster protocol maintains the very high sensitivity and specificity required versus slower, conventional methods.

Enterococcus species cause a significant percentage of bloodstream infections (BSI) as they are the fourth most common cause of hospital-acquired bacteremia within the US and the fifth most common in Europe.(1) While infections with *E. faecalis* are generally susceptible to ampicillin and rarely resistant to vancomycin, infections with *E. faecium* and other enterococci (OE) are frequently resistant to both ampicillin and vancomycin (VRE - vancomycin-resistant enterococci). Since conventional identification methods can take 3 days or longer, up to 80% of VRE bacteremia receive inappropriate antibiotic therapy, leading to higher mortality and significant additional hospital costs.(2,3,4)

Since 2003, *E. faecalis*/OE PNA FISH has been a vital test providing species identification in hours, instead of days, allowing labs to quickly report results to physicians and pharmacists to help ensure optimal therapy for Enterococcal bloodstream infections. A recently published clinical study from the University of Maryland Medical Center demonstrated that the use of *E. faecalis*/OE PNA FISH reduced time to laboratory results by 2.6 days, reduced time to appropriate therapy for *E. faecium* by 1.8 days and most importantly, reduced 30 day mortality rates by 42% for patients with *E. faecium* bacteremia.(5)

With the introduction of the 90 minutes PNA FISH protocol, laboratories will be able to further improve workflow flexibility and results reporting turn-around times. By providing even faster results, laboratories will help clinicians further improve antibiotic selection, care, and outcomes for patients with Enterococcal bloodstream infections.

"We are very excited to launch the 90 minutes *E. faecalis*/OE PNA FISH protocol in the United States," said Thais T. Johansen, President and CEO of AdvanDx. "The faster protocol marks another milestone toward AdvanDx's goal of providing a fast, easy-to-use and broad molecular diagnostic platform for early identification of bloodstream pathogens. With results in 90 minutes, hospitals will be able to provide critical results as early as possible, enabling clinicians to improve care and outcomes for patients with life-threatening infections," Johansen concluded.

[Click here for E. faecalis/OE PNA FISH® Package Insert \(KT003\)](#)

About Bloodstream Infections

Every year, 350,000 patients contract bloodstream infections, causing over 90,000 unnecessary deaths and significant costs to the healthcare system. The infection is detected when a culture of the patient's blood (i.e. a blood culture) turns positive with bacteria and yeast. Rapid and accurate identification of the specific infecting pathogen is crucial to ensure early and appropriate therapy and save patient lives.

About PNA FISH®

PNA FISH is an easy-to-use and highly sensitive and specific fluorescence *in situ* hybridization (FISH) assay that uses PNA (peptide nucleic acid) probes to target species specific ribosomal RNA (rRNA) in live bacteria and yeast. The unique properties of the non-charged, peptide backbone of PNA probes enable the use of FISH assays in exceedingly complex sample matrixes, such as blood and blood cultures, and this in turn facilitates the development of very simple, yet very accurate tests that don't require the extensive sample preparation necessary for other nucleic acid technologies.

PNA FISH tests enable microbiology labs to provide rapid and accurate identification of bloodstream pathogens directly from positive blood cultures in hours instead of days. Clinical studies show that rapid identification of bloodstream pathogens using PNA FISH tests leads to more appropriate patient therapy that saves lives and reduces unnecessary antibiotic use, patient length of stay and hospital costs.

About AdvanDx

AdvanDx is the leading provider of advanced molecular diagnostic products for the diagnosis and treatment of life-threatening, bloodstream infections. AdvanDx's easy-to-use products provide fast and accurate results that enable dramatic improvements in patient care and help to save lives and reduce hospital costs.

AdvanDx's products employ standard laboratory techniques and equipment to reduce startup, implementation, technician and maintenance time, while providing fast results without sacrificing accuracy. Major medical centers, reference labs, government institutions and community hospitals throughout the United States, Europe and Asia rely on AdvanDx products as integral parts of their medical care.

For more information visit www.AdvanDx.com.

***E. faecalis*/OE PNA FISH® is distributed by bioMérieux, Inc. in the United States.**

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