



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

*Pathogen Identification Results in 90 Minutes Direct from Positive Blood Cultures*

*Faster Results to Help Clinicians Improve Antibiotic Selection and Outcomes for Patients with True Staphylococcal Infections while Avoiding Unnecessary Therapy due to Blood Culture Contamination*

Woburn, MA, U.S.A. and Vedbaek, Denmark – December 10, 2009 – AdvanDx today announced that it has received FDA 510(k) clearance for a fast, 90 minutes protocol for its *S. aureus* PNA FISH® and *S. aureus*/CNS PNA FISH® tests. 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 demonstrated excellent 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.

*Staphylococcus* species are both the most frequent causes of bloodstream infections (BSI) and blood culture contamination. True infections caused by *Staphylococcus aureus* present considerable clinical challenges associated with increased mortality rates, prolonged hospital stays and add significant extra hospital costs.<sup>1</sup> In the United States alone, 300,000 hospitalized patients contract a *S. aureus* infection leading to more than 12,000 deaths, 2.7 million excess LOS days and close to \$9.5 billion in excess hospital charges.<sup>2</sup> Blood culture contamination with Coagulase-Negative Staphylococci (CNS) on the other hand, account for up to 30% of all positive blood cultures and often result in a false diagnosis of a true staphylococcal bloodstream infection that leads to unnecessary coverage with broad-spectrum antibiotics, extra length of stay and unnecessary extra costs. As conventional identification methods can take several days to differentiate between true infection and contamination, clinicians must rely on empiric therapy which may result in either unnecessary or inadequate treatment.

Since 2003, the use of PNA FISH for rapid identification of staphylococcal bloodstream pathogens has drastically improved therapy decisions and outcomes for patients with bloodstream infections by providing results in hours, instead of days to help physicians and pharmacists optimize antibiotic therapy earlier. A clinical study performed at the Washington Hospital Center (Washington, D.C.) demonstrated that rapid identification and notification of PNA FISH results reduced ICU and overall mortality rates by 82% and 53% respectively, while reducing antibiotic use for patients with CNS positive blood cultures. In a separate study performed at the University of Maryland Medical Center (Baltimore,

MD) rapid PNA FISH results, helped reduce unnecessary vancomycin use by 4.5 doses, length of stay by 2 days and hospital costs by \$4,005 for patients with CNS contaminated blood cultures.<sup>1,3</sup>

With the introduction of the 90 minutes PNA FISH protocol, laboratories will be able to further improve turn-around times for critical results and thereby help clinicians further improve antibiotic selection, care, and outcomes for patients with staphylococcal bloodstream infections.

“We are extremely pleased with the latest FDA clearances for the faster PNA FISH protocols for *S. aureus* and Coagulase-Negative Staph” said Thais T. Johansen, President and CEO of AdvanDx. “Staphylococci present significant challenges for managing patient care and controlling hospital costs. With fast PNA FISH results, hospitals have a tool to help both improve patient care and reduce unnecessary costs,” Johansen concluded.

### **About Bloodstream Infections**

Every year, close to 875,000 patients in the United States contract bloodstream infections, leading to over 150,000 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 or 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](http://www.AdvanDx.com)

***S. aureus* PNA FISH<sup>®</sup> and *S. aureus*/CNS PNA FISH<sup>®</sup> are distributed by bioMérieux, Inc. in the United States.**

**CONTACTS:**

Joen T. Johansen  
Director of Marketing  
AdvanDx  
+1-339-227-4052  
[jjt@advandx.com](mailto:jjt@advandx.com)

References

1. Ly et al. Ther Clin Risk Manag. 2008 Jun;4(3):637-40.
2. Noskin et al. Arch Intern Med. 2005 Aug 8-22;165(15):1756-61.
3. J Antimicrob Chemother. 2006 Jul;58(1):154-8.

PN1715A