



## **AdvanDx Receives FDA 510(k) Clearance for *E. coli*/*P. aeruginosa* PNA FISH®**

*First Diagnostic Test for Identifying *E. coli* and *P. aeruginosa* Directly from Positive Blood Cultures*

*PNA FISH to Provide Critical Results 24-48 Hours Sooner Than Conventional Methods Helping Clinicians to Improve Care and Outcomes for 100,000 Patients with Bloodstream Infections*

Woburn, MA, U.S.A. and Vedbaek, Denmark - January 30, 2009 - AdvanDx today announced it received FDA 510(k) clearance for *E. coli*/*P. aeruginosa* PNA FISH® to identify *Escherichia coli* and/or *Pseudomonas aeruginosa* directly from positive blood cultures. *E. coli*/*P. aeruginosa* PNA FISH is the first-ever test for identifying *E. coli* and *P. aeruginosa* directly from positive blood cultures and the latest addition to AdvanDx's easy-to-use, molecular-based PNA FISH diagnostics platform. PNA FISH tests now provide rapid species identification for the vast majority of Gram-stain results in hours instead of days, enabling therapy guiding results for 95-99% of patients with positive blood cultures.

Every year, an estimated 100,000 patients develop bloodstream infections (BSI) due to Gram-negative pathogens such as *E. coli* and/or *P. aeruginosa*. Patients afflicted by these serious infections spend an average of 5-24 days in the hospital, suffer mortality rates as high as 40% and cost institutions on average \$40,000 to \$60,000 per case (1,2). These grim statistics are due in part to Gram-negative bacteria's increasing resistance to a multitude of antibiotic agents, especially in *P. aeruginosa*, creating complex therapy decisions for clinicians. Treatment challenges are further compounded by conventional laboratory testing methods for Gram-negative pathogens that take 24-48 hours to provide results, forcing clinicians to treat patients empirically which may not provide full coverage for the infecting pathogen.

Studies show that providing a 24 hour "head start" on appropriate narrow-spectrum therapy for Gram-negative bloodstream infections may improve clinical outcomes, reduce antibiotic resistance

rates and reduce the incidences of adverse events (3,4). *E. coli*/*P. aeruginosa* PNA FISH will, for the first time, enable microbiology labs to provide clinicians rapid, accurate Gram-negative pathogen identification in hours, not days.

"We are very excited to launch *E. coli*/*P. aeruginosa* PNA FISH as another critical tool to help laboratories and clinicians provide faster results and improve care for patients with life threatening infections," said Thais T. Johansen, President and CEO of AdvanDx. "Our PNA FISH diagnostic platform now provides a complete solution by enabling rapid identification results for 95 to 99% of all patients with positive blood cultures," Johansen concluded.

### **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 world's leading provider of advanced molecular diagnostic products for the prevention, diagnosis and treatment of life-threatening, bacterial 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)

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