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

Pathogen Identification Results in 90 Minutes Direct from Positive Blood Cultures
Faster Results to Help Clinicians Improve Pseudomonal vs. Non-Pseudomonal Antibiotic Selection for Patients with Critical Infections

Woburn, MA, U.S.A. and Vedbaek, Denmark - December 22, 2009 - AdvanDx today announced that it has received FDA 510(k) clearance for a fast, 90 minutes protocol for its *E. coli*/*P. aeruginosa* PNA FISH® and EK/*P. aeruginosa* 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 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.

"Gram-negative bloodstream infections can be very difficult to treat, especially due to the highly variable antimicrobial resistance patterns associated with different species. The ability of the PNA FISH assay to identify *Pseudomonas aeruginosa* in contrast to *Escherichia coli* and *Klebsiella pneumoniae* directly from a positive blood culture within 90 minutes, can lead to the initiation of pathogen-specific empiric antimicrobial regimens. This assay can have a real-time, positive impact on patient therapy and management." said Dr. Phyllis Della-Latta, Professor of Clinical Pathology in Medicine and Director of Clinical Microbiology Service at Columbia University Medical Center, NewYork-Presbyterian Hospital (New York, NY).

Every year, an estimated 100,000 patients develop bloodstream infections (BSI) due to Gram-negative pathogens such as *E. coli*, *K. pneumoniae* and *P. aeruginosa*. Gram-negative bloodstream infections are associated with mortality rates as high as 40% and can be difficult to treat due to increasing resistance to antimicrobial agents, especially for P. aeruginosa.(1) Treatment challenges are further compounded by conventional laboratory testing methods that take 24 to 48 hours or longer to identify the causative pathogen, forcing clinicians to treat patients empirically with antibiotics that may or may not cover for *P. aeruginosa*.

As the first FDA cleared rapid, molecular tests for Gram-negative bloodstream infections, *E. coli*/*P. aeruginosa* PNA FISH and EK/*P. aeruginosa* PNA FISH are vital new tools that enable microbiology labs to provide Gram-negative species identification in hours, instead of days to help physicians and pharmacists optimize antibiotic therapy earlier. Clinical studies have shown that delays in appropriate therapy for *P. aeruginosa* are associated with increased mortality rates of up to 72%. Given that up to 30% of patients with *P. aeruginosa* receive inappropriate coverage, early administration of effective pseudomonal therapy is crucial to improving patient outcomes.(2,3) At the same time, unnecessarily broad-coverage for less resistant and less virulent pathogens should be avoided in order to prevent the development and spread of antibiotic resistant pathogens.

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 pseudomonal vs. non-pseudomonal antibiotic selection for patients with Gram-negative bloodstream infections.

"We are very excited to continue the speedy transition of our PNA FISH tests to the 90 minutes protocol in the United States," said Thais T. Johansen, President and CEO of AdvanDx. "The FDA clearances for both the *E. coli*/*P. aeruginosa* PNA FISH and EK/*P. aeruginosa* PNA FISH tests brings AdvanDx a step closer to providing accurate and actionable results in just 90 minutes for the most critical bloodstream pathogens," 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

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