



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

C. albicans and *C. glabrata* Identification in 90 Minutes Direct from Positive Blood Cultures

Faster Results to Help Clinicians Improve Antifungal Selection and Reduce Antifungal Costs for Patients with Candida Bloodstream Infections

Woburn, MA, U.S.A. and Vedbaek, Denmark – March 31, 2010 – AdvanDx today announced that it has received FDA 510(k) clearance for a fast, 90 minutes protocol for its *C. albicans* PNA FISH® and *C. albicans/C. glabrata* 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% agreement between the 90 minutes protocol, the original PNA FISH protocol and conventional identification methods, ensuring the faster protocol maintains the very high sensitivity and specificity required versus slower, conventional methods.

Candidemia, a bloodstream infection caused by *Candida* species, is one of the most serious hospital acquired infections, afflicting over 24,000 patients in the U.S. every year. Immunocompromised transplantation, oncology and AIDS patients are especially at risk for contracting the infection with mortality rates as high as 50%.¹ While identification of the infecting *Candida* species is used to guide effective antifungal therapy, conventional laboratory identification methods can take up to 5 days or longer.² Therefore, patients are often treated empirically either with fluconazole, a relatively inexpensive, generic antifungal agent, or with an echinocandin, a new class of antifungal drugs that have broad activity against *Candida* species but are also substantially more expensive. As a result, patients often receive inappropriate, inadequate or sometimes unnecessarily broad therapy.

PNA FISH is the only FDA cleared method that provides rapid, molecular identification of *Candida* species direct from positive blood cultures. Results are available in hours instead of days, and enable clinicians to optimize antifungal drug selection much earlier for patients with candidemia. A study performed at the University of Maryland Medical Center demonstrated that PNA FISH improved time to species identification by 35 to 52 hours. The faster results enabled clinicians to provide optimal antifungal therapy earlier and helped reduce antifungal costs by \$1,800 per patient, all without adversely affecting patient outcomes.³ In a separate study, Della-Latta et al. at Columbia University Medical Center demonstrated that rapid PNA FISH results led to an early switch to caspofungin, an

echinocandin, for 81% of patients with *C. glabrata* infections treated empirically with fluconazole. The rapid results also led to an early switch to fluconazole for 70% of patients with *C. albicans* infections treated empirically with caspofungin. Based on the study results, the authors concluded that the PNA FISH test “can impact the appropriate selection of the most effective antifungal therapy, thereby making it a clinically relevant diagnostic assay.”⁴

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 antifungal selection, care, and outcomes for patients with candidemia.

“The FDA clearances for both *C. albicans* PNA FISH and *C. albicans/C. glabrata* PNA FISH marks a major milestone for AdvanDx as it completes our transition to the 90 minute protocol for PNA FISH tests covering all four Gram-stain classes” said Thais T. Johansen, President and CEO of AdvanDx.

“Hospitals can now provide accurate, actionable species identification results for the majority of critical bloodstream pathogens in just 90 minutes, enabling clinicians to improve antimicrobial therapy and outcomes for their patients,” 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

***C. albicans* PNA FISH[®] and *C. albicans/C. glabrata* PNA FISH[®] are distributed by bioMérieux, Inc. in the United States.**

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