



## **AdvanDx Receives FDA 510(k) Clearance for 90 Minutes Protocol for Yeast Traffic Light® PNA FISH®**

*Identification of Five Candida Species Directly from Positive Blood Cultures in 90 Minutes  
Faster Results to Help Clinicians Improve Antifungal Selection for Patients with Candidemia*

Woburn, MA, U.S.A. and Vedbaek, Denmark – July 29, 2010 – AdvanDx today announced that it has received FDA 510(k) clearance for a fast, 90 minutes protocol for its Yeast Traffic Light® 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 demonstrated excellent equivalence 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%.<sup>1</sup> While identification of the infecting *Candida* species is used to guide effective antifungal therapy, conventional laboratory methods can take up to 5 days or longer.<sup>2</sup> 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.

Yeast Traffic Light PNA FISH is the only FDA cleared method that can identify, in a single test, up to five *Candida* species directly from positive blood cultures including *C. albicans* and/or *C. parapsilosis*, *C. tropicalis*, and *C. glabrata* and/or *C. krusei*. Studies show that *Candida* species display varying resistance to commonly used antifungal agents. While *C. albicans* and *C. parapsilosis* are generally susceptible to the antifungal drug fluconazole, *C. tropicalis* may display intermediate resistance to the drug while *C. glabrata* and *C. krusei* display the highest level of fluconazole resistance.<sup>2</sup> At the same time, recent reports indicate that echinocandins may be less potent against *C. parapsilosis*.<sup>3</sup> As a result, Yeast Traffic Light PNA FISH was designed to provide identification of critical *Candida* species in hours

instead of days, enabling clinicians to optimize antifungal drug selection much earlier for patients with candidemia.

A study performed by 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* patients 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.”<sup>4</sup> With the introduction of the 90 minutes PNA FISH protocol, laboratories will now be able to further improve turn-around times for critical results and thereby help clinicians further improve care for patients with candidemia.

“The FDA clearance for Yeast Traffic Light PNA FISH completes our ambitious initiative to transition all PNA FISH tests to the shorter, 90 minute protocol in just six months” said Thais T. Johansen, President and CEO of AdvanDx. “Hospitals can now obtain accurate, actionable species identification results for the most common bloodstream pathogens in just 90 minutes, enabling clinicians to improve antimicrobial therapy, care 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.<sup>5</sup> 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)

**Yeast Traffic Light® PNA FISH® is distributed by bioMérieux, Inc. in the United States.**

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