

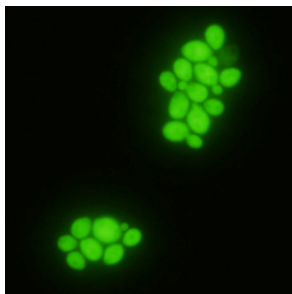


AdvanDx Receives FDA 510(k) Clearance for Yeast Traffic Light PNA FISH™

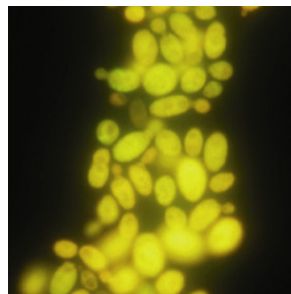
New Product Provides First Capability To Rapidly Identify Five Candida Species Directly From Positive Blood Cultures In One Test

Woburn, MA, U.S.A. – September 23, 2008– AdvanDx today announced it received FDA 510(k) clearance of the Yeast Traffic Light PNA FISH™ to identify *Candida* yeast species directly from positive blood cultures. The Yeast Traffic Light™ is the latest addition to AdvanDx's easy-to-use, molecular-based PNA FISH™ diagnostics platform that provides rapid identification of bloodstream pathogens in hours instead of days.

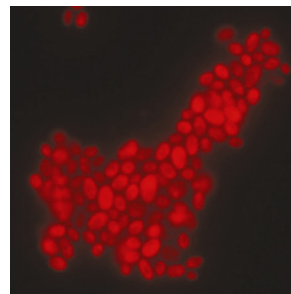
Yeast Traffic Light PNA FISH Results



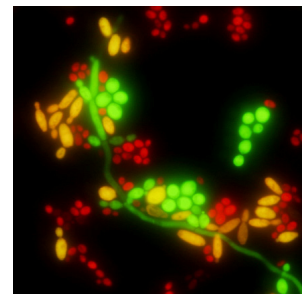
Green fluorescing cells
(*C. albicans* and/or *C. parapsilosis*)



Yellow fluorescing cells
(*C. tropicalis*)



Red fluorescing cells
(*C. glabrata* and/or *C. krusei*)



Mixed

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 methods can take up to 5 days or longer. For the first time, laboratories can identify, in a single Yeast Traffic Light 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* in hours instead of days, enabling clinicians to provide early, effective and appropriate antifungal therapy for patients afflicted with candidemia.

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.² At the same time, recent reports indicate that caspofungin, a newer and more expensive broad-spectrum antifungal drug, may be less potent against *C. parapsilosis*.³ Yeast Traffic Light was designed to identify these *Candida* species as early as possible and provide rapid and actionable results to help clinicians guide appropriate antifungal therapy.

A recent study by Della-Latta et al. presented at the 2008 ECCMID meeting in Barcelona, Spain demonstrated that rapid identification of *Candida* species using PNA FISH can significantly impact antifungal selection and care for patients with candidemia. In the study, rapid identification of *C. albicans* led to a switch to fluconazole for 70% of the patients that had been on caspofungin. At the same time, rapid identification of *C. glabrata*, a *Candida* species with high levels of resistance to fluconazole, led to an 81% switch to caspofungin for those patients that had otherwise been given fluconazole. 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.”

“The Yeast Traffic Light PNA FISH test demonstrates AdvanDx’s commitment to developing cutting-edge molecular diagnostic products that provide fast results for these serious infections,” said Thais T. Johansen, President and CEO of AdvanDx. “The test will ultimately enable clinicians to provide more appropriate care, improve antifungal selection and hopefully improve outcomes for their patients,” 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

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References:

1. Spellberg et al. Current Treatment Strategies for Disseminated Candidiasis. Clin. Infect. Dis. 42: 244-251. 2005
2. Pfaller et al. Epidemiology of invasive candidiasis: a persistent public health problem. Clin Microbiol Rev. 2007 Jan;20(1):133-63.
3. Aperis et al. Developments in the treatment of candidiasis: more choices and new challenges. Expert Opin Investig Drugs. 2006 Nov;15(11):1319-36.
4. Della-Latta et al. Impact of Rapid Identification of *C. albicans* and *C. glabrata* Directly from Blood Cultures using PNA FISH Technology on Selection of Antifungal Therapy. Poster 1382. ECCMID 2008. Barcelona, Spain.

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