



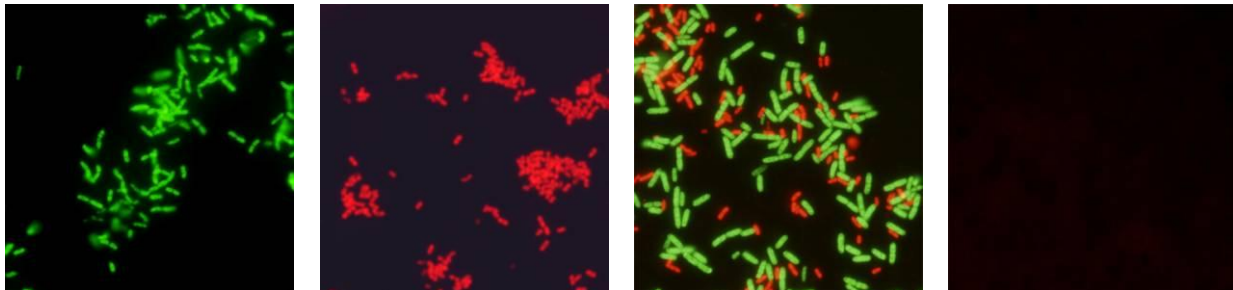
AdvanDx Receives FDA 510(k) Clearance for EK/*P. aeruginosa* PNA FISH®

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

PNA FISH Provides Critical Results 24-48 Hours Sooner Than Conventional Methods to Help Clinicians Improve Care and Outcomes for 100,000 Patients with Gram-Negative Bloodstream Infections

Woburn, MA, U.S.A. and Vedbaek, Denmark – May 5, 2009 – AdvanDx today announced it received FDA 510(k) clearance for EK/*P. aeruginosa* PNA FISH® to identify *Escherichia coli* and/or *K. pneumoniae* as well as *Pseudomonas aeruginosa* directly from positive blood cultures. EK/*P. aeruginosa* PNA FISH is the first-ever test capable of identifying *E. coli* and/or *K. pneumoniae* 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, therapy-guiding results for 95-99% of patients with bloodstream infections and positive blood cultures.

EK/*P. aeruginosa* PNA FISH Results



Green fluorescing cells
(*E. coli* and/or *K. pneumoniae*)

Red fluorescing cells
(*P. aeruginosa*)

Mixed

Negative

Every year, an estimated 100,000 patients develop bloodstream infections (BSI) due to Gram-negative pathogens mainly *E. coli*, *K. pneumoniae* and *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* and increasingly in *K. pneumoniae*, creating complex therapy decisions for clinicians. Treatment challenges are further compounded by conventional laboratory testing methods that take 24-48 hours or longer to identify the causative pathogen forcing clinicians to treat patients empirically. This empirical

antibiotic coverage can lead to both unnecessary treatment with broad-spectrum antibiotics as well as inadequate treatment if highly virulent and resistant pathogens are not suspected and covered for.

Studies show that providing a 24 hours “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). EK/*P. aeruginosa* PNA FISH will enable microbiology labs to provide clinicians rapid, accurate Gram-negative pathogen identification results in hours, instead of days.

“We are very excited to launch EK/*P. aeruginosa* PNA FISH and provide another critical tool to help laboratories and clinicians provide faster results and improve care for patients with these 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 bloodstream infections,” 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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