



Study Shows Use of AdvanDx's PNA FISH™ Test Was Associated With An 82% Reduction in Intensive Care Unit Mortality Rates From *Staphylococcus aureus* Bloodstream Infections.

Woburn, MA, U.S.A. – July 15, 2008 – AdvanDx today announced that a new study shows use of AdvanDx's PNA FISH™ test was associated with an 82% reduction in mortality rates from *S. aureus* bloodstream infections in the intensive care unit (ICU), a 53% reduction in overall mortality from staphylococcal bloodstream infections, and a significant reduction in antibiotic use. The study, published in the latest issue of the *Journal of Therapeutics and Clinical Risk Management*, the study was undertaken by clinicians in the Section of Infectious Diseases at Washington Hospital Center (WHC) in Washington, D.C.¹

Bloodstream infections due to *Staphylococcus* bacteria are a leading cause of hospital-acquired infection mortality. The infection is initially diagnosed when a culture of a patient's blood turns positive with Gram-positive cocci in clusters (GPCC), indicative of staphylococci. Because conventional laboratory identification methods can take 48 hours or longer, treating clinicians can't determine whether the blood culture was positive due to true infection, requiring aggressive antibiotic therapy, or due to blood culture contamination with Coagulase-Negative Staphylococci (CoNS), a group of common skin bacteria, that don't require antibiotic therapy. As a result, patients with true infections are at times undertreated whereas patients with contaminated blood cultures are often unnecessarily treated with antibiotics. PNA FISH provides rapid, molecular identification of *S. aureus* and CoNS directly from positive blood cultures in hours instead of days. The test enables laboratories to provide fast results and help clinicians guide early and effective therapy for patients with bloodstream infections.

During the WHC study period, 202 patients with positive blood cultures containing GPCC were enrolled and blindly randomized into a "Notification" group or a "Usual Care" group. For patients in the Notification group, PNA FISH results and information on the identified bacteria were reported directly to the treating clinicians whereas for patients in the Usual Care group, data were entered into the hospital's laboratory information system as usual. Medical records of enrolled patients were analyzed for demographics, comorbid conditions, location within the hospital, antimicrobial use, length of hospitalization, mortality, and other factors to understand the impact of the rapid PNA FISH results on patient care and outcomes. Significant comparison results for the two groups are listed below.

Comparison of Data for Notification of PNA FISH (NPF) group vs. Usual Care (UC) group

- Total of 202 patients enrolled in study; 101 in NPF group vs. 101 in UC group
- 61 patients with *S. aureus*; 32 in NPF group vs. 29 in UC group
- 141 patient with CoNS; 69 in NPF vs. 72 in UC group
- 44 patients in ICU vs. 158 in non-ICU
- 53% reduction in overall mortality; 8 deaths in NPF group vs. 17 deaths in UC group
- 80% reduction in mortality rate for intensive care unit (ICU) patients; 10% (2 deaths) for NPF group vs. 48% (11 deaths) for UC group
- 82% reduction in mortality rate for ICU patients with *S. aureus*; 10% for NPF group vs. 56% for UC group
- 67% reduction in median antibiotic use after notification of results; median of 1 day for NPF group vs. 3 days for UC group
- 100% reduction in median antibiotic use for CoNS patients after notification of; 0 days for NPF group vs. 2.5 days for UC group
- Trend toward \$19,441 reduction in median hospital charges; \$72,932 median charges for NPF group vs. \$92,373 for UC group

“Rapid delivery of PNA FISH data from the laboratory to treating clinicians was associated with reduced mortality in ICU patients,” said lead author Shmuel Shoham, M.D., Section of Infectious Diseases and Director of Transplant Infectious Diseases at Washington Hospital Center. “There was also a trend toward reduced length of hospitalization in non-ICU patients with *S. aureus*, and in patients with blood cultures growing CoNS regardless of location with the hospital. PNA FISH diagnostic tests provide rapid results that enable us to optimize therapy, improve patient outcomes and reduce hospital costs,” added Dr. Shoham.

“We are very excited to see the results from the Washington Hospital Center study. Not only do they show that rapid reporting of PNA FISH results can help significantly reduce unnecessary antibiotic use and improve patient care, but the rapid results also help to save lives.” said Thais T. Johansen, President and CEO of AdvanDx. “If we extrapolate the data to the rest of the United States, PNA FISH has the potential of saving close to 23,000 patient lives, reducing 514,000 days of antibiotic use and saving \$5 billion in hospital charges. In essence, implementing PNA FISH and rapidly reporting results to clinicians could be much more beneficial than the introduction of a new generation of antibiotics to treat patients with bloodstream infections.” Johansen added.

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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