



AdvanDx Receives FDA 510(k) Clearance for GBS PNA FISH® for Rapid Detection of Group B Strep from Lim Broths

Test results to establish Group B Strep colonization of pregnant women and help clinicians guide antibiotic therapy to prevent infections in newborns

GBS PNA FISH shown to detect up to 42% more positive results than conventional culture methods (1)

Woburn, MA, U.S.A. and Vedbaek, Denmark – May 15, 2009 – AdvanDx today announced it received FDA 510(k) clearance for GBS PNA FISH® for detection of *Streptococcus agalactiae*, aka Group B Strep, from turbid Lim Broths inoculated with vaginal and rectal swabs obtained from pregnant women between 35 and 37 weeks gestation. The 90 minute molecular diagnostic test enables rapid and highly sensitive detection of Group B Strep from Lim Broths to help detect colonization in pregnant women.

According to the US Centers for Disease Control and Prevention (CDC), Group B Strep is the most common cause of neonatal morbidity and mortality. Approximately 1 in 4 pregnant women are colonized with Group B Strep and can transmit the bacterium to the newborn during delivery. To prevent the transmission and subsequent infection, women are routinely screened for colonization between 35 and 37 weeks gestation, and if positive, receive antibiotics at the start of labor to eradicate the bacteria. Accurate detection of Group B Strep colonization is therefore crucial to prevent as many infections as possible. (2)

During the routine laboratory testing process, vaginal and rectal swabs from pregnant women are inoculated into selective enrichment broth, e.g. Lim Broth, and incubate overnight to stimulate the growth of Group B Strep bacteria. A sample is subsequently taken for further culture workup and identification using conventional, phenotypic methods. This process can take anywhere from 3 to 4 days, and while Lim Broth is highly sensitive and selective for Group B Strep, the subsequent workup and phenotypic identification can be time consuming and may miss some true positive samples. (3)

GBS PNA FISH combines the high sensitivity of Lim Broth with the speed, accuracy and ease-of-use of the PNA FISH molecular diagnostic platform to provide accurate Group B Strep detection fit for the routine laboratory workflow. In a recent clinical study, GBS PNA FISH was shown to detect up to 42% more Group B Strep positives than conventional culture methods. The authors of the study also found that the test produced results 2 to 3 days faster and concluded that “use of the PNA FISH assay for the

detection of GBS from Lim broth culture showed an increased sensitivity, required decreased specimen handling, and had a shorter turnaround time than culture.” (1)

“GBS PNA FISH brings another exciting application to the PNA FISH platform and is another critical tool for improving infection prevention and patient management,” said Thais T. Johansen, President and CEO of AdvanDx. “The test will enable labs to provide fast and sensitive detection of Group B Strep that in turn may help clinicians provide better preventative care for more pregnant women and their newborns,” Johansen added.

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 pathogen identification in hours instead of days. Clinical studies show that the significantly faster results help clinicians provide more appropriate patient therapy that saves lives, reduces unnecessary antibiotic use, reduces patient length of stay and reduces overall 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. Montague NS, Cleary TJ, Martinez OV, Procop GW. Detection of group B streptococci in Lim broth by use of group B streptococcus peptide nucleic acid fluorescent in situ hybridization and selective and nonselective agars. [J Clin Microbiol. 2008 Oct;46\(10\):3470-2.](#)
2. US Centers for Disease Control and Prevention. Preventing Group B Strep. <http://www.cdc.gov/groupBstrep/>
3. Davies HD, Miller MA, Faro S, Gregson D, Kehl SC, Jordan JA. Multicenter study of a rapid molecular-based assay for the diagnosis of group B Streptococcus colonization in pregnant women. [Clin Infect Dis. 2004 Oct 15;39\(8\):1129-35.](#)

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