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XPERT GBS—RAPID ON-SITE MOLECULAR TEST REVOLUTIONIZES GROUP B STREPTOCOCCUS TESTING

Cepheid (Sunnyvale, CA), a broad based molecular diagnostics company, recently received 510(k) clearance from the U.S Food and Drug Administration to market its **Xpert GBS™ test for Group B Streptococcus (GBS)**. Xpert GBS is the only *in vitro* diagnostic test to fully meet CDC criteria for rapid intrapartum GBS testing (*1*). Now fast and accurate intrapartum or antepartum GBS results can be available in less than 75 minutes, delivered with 91.9 percent sensitivity and 95.6 percent specificity for intrapartum testing. This revolutionary *in vitro* diagnostic test is the first and only molecular test designed for use in the clinical lab and near patient by non-laboratory professionals, such as labor and delivery nurses when needed—24 hours a day, 365 days a year. In addition to providing faster diagnosis, the use of Xpert GBS may help reduce unnecessary antibiotic treatment of women not colonized with the GBS bacteria.

The current standard of care for preventing neonatal GBS disease calls for the use of culture in screening expectant mothers at 35-37 weeks of gestation (*1*). Although adequate for obtaining antepartum GBS results, this is an unacceptable solution for providing timely results for intrapartum patients whose GBS status is unknown when they present in the hospital to deliver. Current rapid GBS testing methods provide an underwhelming sensitivity level of less than 65 percent. The Xpert GBS test yields highly sensitive results from a swab in about an hour where standard culture-based testing may take several days. GBS is easily treated and neonatal transmission can be prevented if antibiotics are administered to the expectant mother prior to delivery.

Jeanne Jordan, PhD, Associate Professor of Pathology, University of Pittsburgh, Magee Women's Hospital (Pittsburgh, PA), states that "Approximately 10 to 15 percent of patients come into labor and delivery without knowing their GBS status. Being able to have a test that can be used 24/7 in a timely manner to give you an answer within a two-hour time frame allows a physician to have very useful information to make the decision whether he or she is going to continue a patient on antibiotics, or initiate antibiotics." By identifying mothers colonized with GBS, the test will allow for more properly directed antibiotic prophylaxis and, as stated by Dr. Jordan, "you will not be providing antibiotics unnecessarily, which can contribute to the

development of antibiotic resistant bacterial strains."

According to the U.S. Centers for Disease Control, GBS is the most common cause of life-threatening infections in newborns and is the leading infectious cause of neonatal morbidity and mortality. GBS affects about 1 in every 2,000 babies born in the United States. Between 10 and 30 percent of pregnant women carry the GBS bacterium in the vagina or rectal area and transmission occurs from these GBS colonized women to their babies during childbirth (*1*, *2*, *3*, *4*,). Left untreated, GBS can cause the development of sepsis, pneumonia, and meningitis—leading to sight or hearing loss, mental retardation or death. GBS-related sepsis and meningitis in newborns results in a 4 percent fatality rate of those infected. Treatment of infected mothers and infants costs the healthcare system approximately $300 million each year. GBS infections are more common than other illnesses for which pregnant women are screened, such as rubella, Down's Syndrome and spinal bifida; yet, GBS remains generally unknown to the public.

The Xpert GBS test is a qualitative *in vitro* diagnostic test designed to detect GBS DNA from vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with flourogenic detection of the amplified DNA.. The Xpert GBS test, performed on Cepheid's GeneXpert System®, delivers unparalleled ease-of-use. Users simply perform four easy steps and the GeneXpert System does the rest. Cepheid's Xpert GBS assay empowers clinicians to make appropriate patient management decisions at a critical time such as during labor and delivery. The Xpert GBS Assay includes unique internal controls to help insure quality of results.

Rodney K. Edwards, MD, Assistant Professor, Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, University of Florida College of Medicine (Gainesville, FL), had this to say about the Xpert GBS test: "This test can be done as a bedside test for patients in labor and we can find out rapidly what a patient's colonization status is *at that time*. This is important because there is cross-over between colonization earlier in pregnancy and colonization at the time of delivery, as some patients change status. By using this test, we would be able to target intrapartum antibiotic prophylaxis ONLY for women who are truly are at risk of their baby developing an infection with that organism."

The performance characteristics of the Xpert GBS Assay were determined in both laboratory and near patient settings from testing done on specimens from 791 maternity patients. All subjects had culturing done and most also had a 2nd GBS Nucleic Acid Amplification Test (NAAT) performed. The 2nd NAAT targets a sequence in the *cfb* gene and was previously FDA-cleared. As compared to culture, the Xpert GBS test demonstrated a sensitivity of 91.9% and specificity of 95.6% for intrapartum specimens and a sensitivity of 85.3% and specificity of 98.1% for antepartum specimens. The 2nd previously cleared GBS NAAT test demonstrated a sensitivity of 81.4% and specificity of 95.6% for intrapartum specimens and a sensitivity of 74.5% and specificity of 97.0% for antepartum specimens.

For more information concerning Cepheid or the Xpert GBS, please call 1-888-336-2743 or visit the company's website at www.cepheid.com/gbs.

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