IntelligentMDx Announces CE-Marking of a new high-throughput test for Group B Streptococcus intended to improve women's health and prenatal care

The Associated Press

IntelligentMDx (IMDx) announced today that it has obtained CE-marking for a new automated, high-throughput, qualitative in vitro diagnostic test designed for the rapid detection of Group B Streptococcus (GBS) for use in screening pregnant women and those in labor who may be infected with the pathogen. GBS is responsible for life-threatening bacterial infections in newborns, including sepsis, meningitis, and pneumonia. The IMDxT GBS for Abbott m2000T test utilizes real time PCR, operates on the Abbott m2000 system and addresses the needs of hospitals to rapidly screen large numbers of patients for GBS and make quick informed decisions about antibiotic treatment.

(Logo: http://photos.prnewswire.com/prnh/20120306/NE63745LOGO) The IMDx GBS for Abbott m2000 test offers robust and accurate detection of GBS from both direct swabs and enriched culture broth samples. With this test, results for up to 48 patient samples can be obtained simultaneously in approximately 5 hours or less. When compared against traditional culture methods, the IMDx GBS for Abbott m2000 test exhibits 95.5% sensitivity and 98.3% specificity with direct swabs and 100% sensitivity and 100% specificity with enriched culture broth samples.

"At IMDx we strive to develop tests that will address the specific needs of target communities," says Alice Jacobs, MD, Chairman & CEO of IMDx. "Testing for GBS is a critical step in eliminating the incidence of newborn infection. The IMDx GBS for Abbott m2000 assay is intended to improve women's health and prenatal care by providing physicians with the confidence to make intelligent treatment choices for their patients." The IMDx GBS for Abbott m2000 assay is the third CE-marked test developed under a multi-year distribution agreement between IMDx and Abbott whereby IMDx designs, develops, obtains regulatory clearances, and manufactures assays for the Abbott FDA cleared m2000 instrument.

In addition to the new GBS assay, the IMDx CE-marked test menu for use on the Abbott m2000 system includes real-time PCR assays for the detection of vancomycin-resistant enterococci (VRE) and toxigenic C.

difficile.

*The IMDx GBS for Abbott m2000 assay is CE-marked and not available for sale in the U.S. or Canada.

About IMDx Based in Cambridge, MA, IMDx (www.IntelligentMDx.com) is an

innovative company that designs, develops and manufactures molecular diagnostic products. IMDx has developed molecular solutions that are clinically impactful and competitively differentiated for a range of disease areas for current and next generation systems, including targets in infectious diseases, oncology and genetics. IMDx's expertise spans evolutionary biology, bioinformatics, microbiology, chemistry and molecular biology. These capabilities are harnessed by IMDx's proprietary bioinformatics and product development processes allowing for the rapid design and development of tests to meet clinical needs.

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