## Variant Strain of Chlamydia May Go Undetected

## Ability of the BD ProbeTec(TM) ET System to Detect Variant Chlamydia Trachomatis is Confirmed

BALTIMORE, April 26 /PRNewswire-FirstCall/ -- Amid reports of a variant strain of Chlamydia trachomatis (vCT) that is not detected by certain molecular tests, BD Diagnostics, a segment of BD (NYSE: BDX), announced today that testing performed using the BD ProbeTec(TM) Chlamydia trachomatis (CT) amplified DNA assay confirms the product's ability to detect this organism analytically.

Recent reports in Eurosurveillance attribute decreases of 25 percent in infection incidence in Sweden due to the inability of certain molecular diagnostic tests to detect the vCT. The vCT infection has also recently been reported in Denmark and Oslo, Norway. BD conducted analytical studies to validate that the BD ProbeTec CT assay successfully detects vCT with equivalent analytical sensitivity levels to other known circulating CT strains.

"We rely on our testing methods to be highly accurate," said Henrik Westh, MD, DMSc., Associate Clinical Research Professor, Hvidovre Hospital, Copenhagen, Denmark. "The potential inability to detect the vCT is a significant concern to us as the vCT endemic is only a few miles from us and a single case has just been identified in Copenhagen. Our laboratory testing of the vCT using the BD ProbeTec System revealed that the vCT was as easily detected as the 'wildtype' CT." "Wildtype" is the term for the common circulating strain of an organism.

## About Chlamydia trachomatis

Chlamydia trachomatis is a sexually transmitted organism, infecting more than 3 million people annually in the United States at a cost of more than \$2.0 billion per year. Most young women who become infected never experience symptoms that would prompt them to see a doctor. Left untreated, up to 40 percent of infected women develop pelvic inflammatory disease, and of these cases, 17 percent become infertile, 17 percent develop chronic pain, and 9 percent have a potentially life-threatening tubal pregnancy. Molecular testing has become the standard of care in diagnosing chlamydial infection due to the high sensitivity of the tests for detecting the organism. For the past decade, laboratories in Sweden have used nucleic acid amplification tests (NAAT) to diagnose C. trachomatis infections. These NAAT tests use the cryptic plasmid (a non-chromosomal genetic element found in most C. trachomatis strains) as the target area.

"Sexually transmitted infections often have no symptoms and therefore frequently go unrecognized and undiagnosed," said Lynn Barclay, Chief Executive Officer of American Social Health Association. "Undetected and untreated infections not only lead to further transmission, but can have serious health consequences and medical costs. Infections that are detected are easily treated, which makes the identification through testing so important."

Analytical Evaluation of BD ProbeTec Chlamydia trachomatis Assay

Early in 2007, BD Diagnostics obtained the vCT strain for analytical testing and sequencing of the cryptic plasmid. The analytical studies found that 100 percent of the assay replicates yielded positive results, with no false positives. Importantly, the sequencing data confirmed the vCT mutations reside completely outside the region targeted by the BD ProbeTec System. BD will report complete test results at the Clinical Virology Symposium in April, 2007.

## About BD

BD, a leading global medical technology company that manufactures and sells medical devices, instrument systems and reagents, is dedicated to improving people's health throughout the world. BD is focused on improving drug therapy, enhancing the quality and speed of diagnosing infectious diseases, and advancing research and discovery of new drugs and vaccines. The Company's capabilities are instrumental in combating many of the world's most pressing diseases. Founded in 1897 and headquartered in Franklin Lakes, New Jersey, BD employs approximately 27,000 people in approximately 50 countries throughout the world. The Company serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public. For more information, please visit <a href="http://www.bd.com">http://www.bd.com</a>.

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