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News

Abbott Receives FDA Clearance for Molecular Diagnostic Test for Detection of Chlamydia and Gonorrhea Infections

New Test Detects Variant Chlamydia Strain First Identified in Sweden in 2006

DES PLAINES, Ill., June 28 , 2010 — Abbott announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration to market a new, sensitive molecular diagnostic test and instrument to simultaneously detect two of the nation's most prevalent sexually transmitted diseases (STDs), gonorrhea and chlamydia, including a new variant strain of chlamydia recently discovered in Sweden.

Media:
Don Braakman
(847) 937-0080

Financial:
Tina Ventura
(847) 935-9390

Abbott received independent 510(k) clearances for both the Abbott RealTime *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) assay and the Abbott m2000 System. They are required to be used together as a system for the detection of CT/NG from multiple specimen types including urine, urethral, vaginal and endocervical swabs. Also cleared was the Abbott multi-Collect Specimen Collection Kit, a unique device for collection and room-temperature transportation of multiple samples, including urine samples and endocervical, vaginal and male urethral swab specimens, in one collection device.

"Because many people with chlamydia are co-infected with gonorrhea, it's important to test for both diseases simultaneously," said Klara Abravaya, Ph.D., senior director, research and development, Abbott Molecular. "Left untreated, chlamydia and gonorrhea can lead to pelvic inflammatory disease, urethritis and sterility."

Abbott worked in collaboration with leading international STD researchers to develop the chlamydia test, which was introduced in the European Union in 2008 to address a newly discovered variant strain of the bacteria initially identified in Sweden.

"New tests were needed to target additional parts of the chlamydia bacteria, and Abbott responded fast to our request for research test kits that would pick up the variant strain," said Torvald Ripa, M.D., Ph.D., assistant professor, Department of Clinical Microbiology and Infection Control, Hospital of Halmstad, Sweden, who discovered the new strain.

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While there have been no reports of the variant strain in the United States, chlamydia remains the nation's most frequently reported bacterial sexually transmitted disease (STD), according to the Centers for Disease Control and Prevention (CDC).

In 2008, more than 1.2 million chlamydial infections were reported to the CDC, an increase of 9 percent over the previous year. Under-reporting is substantial because many people with chlamydia are not aware of their infections and do not seek testing. By contrast, gonorrhea incidence has remained relatively stable, although the CDC has reported slight overall declines in the rate of infection in recent years.

Public health officials nationwide are particularly concerned by the even steeper increases in chlamydia in teens and young adults. For example, a recent voluntary chlamydia screening conducted at one high school in Michigan showed that 10 percent of students were infected, according to the county health department. Routine screening of high-risk populations is viewed by infectious disease experts as essential for controlling the U.S. chlamydia epidemic because the disease can be asymptomatic.

Molecular or nucleic acid amplification tests (NAAT) are currently the standard method for detecting chlamydia and gonorrhea infections, and are widely used. The advantage of NAAT over traditional culture methods is that they are generally more sensitive and specific and can identify more positive specimens.

About Abbott RealTime CT/NG

The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of CT and the genomic DNA of NG. The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.

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About Abbott Molecular

Abbott Molecular (abbottmolecular.com) is an emerging leader in molecular diagnostics – the analysis of DNA, RNA, and proteins at the molecular level. Abbott Molecular's instruments and reagents detect pathogens and subtle, but key changes in patients' genes and chromosomes, which can aid in earlier diagnoses, selection of appropriate therapies and monitoring of disease recurrence.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

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