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

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DES PLAINES, Ill., June 28 /PRNewswire-FirstCall/ -- Abbott (NYSE: ABT [1]) 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.

Abbott received independent 510(k) clearances for both the Abbott RealTi*me* *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) assay and the Abbott *m*2000 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 *m*ulti-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 '/>"/>

SOURCE [2]

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