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New Roche Chlamydia Test Approved for Use in European Union

Test offers more reliable detection of *Chlamydia trachomatis*, the most commonly reported sexually transmitted disease in Europe.

Roche announced today that its new test for detection of *Chlamydia trachomatis* has received CE Mark certification, allowing it to be sold for clinical use in the European Union. It is designed with a dual target approach to help ensure reliability of test results even when mutations occur in the bacteria's cryptic plasmid DNA. According to Eurosurveillance, a leading independent scientific journal, *Chlamydia trachomatis* is the most commonly reported sexually transmitted disease in Europe. Although it often causes no symptoms, Chlamydia can, if left untreated, lead to complications such as pelvic inflammatory disease or infertility in women.

“Unexpected mutations in the DNA of an infectious agent such as Chlamydia can disrupt laboratory testing and, by extension, proper treatment of patients,” said Teresa L. Wright, M.D., O.B.E., Chief Medical Officer at Roche Molecular Diagnostics. “Because it is impossible to predict when these mutations will occur, we have designed this test to detect all Chlamydia strains that may cause a deletion in the cryptic plasmid, including the variant originally detected in Sweden in 2006.”

Chlamydia trachomatis is often referred to as a “silent” sexually transmitted disease because approximately three quarters of infected women have no symptoms. Once detected, *Chlamydia trachomatis* can easily be treated with antibiotics. If left untreated, health risks can include chronic pelvic pain, pelvic inflammatory disease, potentially fatal ectopic pregnancy, increased risk of HIV infection if exposed, and infertility.

The highly sensitive and reliable COBAS® TaqMan® CT Test v2.0 simultaneously detects two targets within the *C. trachomatis* cryptic plasmid and genome target DNA. In contrast to earlier generation tests, the COBAS® TaqMan® CT Test v2.0 offers real-time PCR testing on the automated COBAS® TaqMan® 48 Analyzer. This automated platform can produce up to 48 tests per run and provide results in only 2.5 hours after sample preparation. Amplification and detection in a closed system combined with Roche's proprietary AmpErase enzyme and internal controls for each test help prevent cross contamination. This enhances test results integrity and quality control in laboratories.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totaled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at www.roche.com.

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