# Media Release



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# Roche submits application for clearance of Chlamydia and Gonorrhoeae test

Test detects and expands menu on the recently approved cobas 4800 instrument

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has filed for FDA clearance of its Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) tests.

When cleared this standardized and fully automated test will help physicians detect and subsequently treat patients with the disease. Clinical trial data will be presented at the 21st European Congress of Clinical Microbiology and Infectious Diseases (ECCMID, May 7-13, Milan, Italy) demonstrating the effectiveness of the assay using multiple sample types. The test is suitable for use in a broad range of settings and laboratories. Roche was the first company to offer a Polymerase Chain Reaction (PCR) based CT/NG test. This latest offering builds on that legacy while introducing novel features that meet customer needs.

"We are pleased to submit for review this innovative test that will address a key medical need," said Paul Brown, Ph.D., Head of Roche Molecular Diagnostics. "With this test Roche will expand the menu on the recently approved cobas 4800 platform currently in use in the US for HPV testing and so continue to improve the workflow for laboratories."

## **About Chlamydia**

Chlamydia is the most common bacterial Sexually Transmitted Disease (STD) with the highest prevalence among youth. Routine screening for chlamydial infection in young women has been demonstrated to reduce infection rates and the long-term consequences of untreated disease, as well as lowering the cost of this STD to society. The Center for Disease Control recommends annual Chlamydia trachomatis screening for all sexually active females under 25 years old and additional testing for pregnant women and those with risk factors.

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### About cobas 4800 CT/NG test

The test runs on the fully automated cobas 4800 platform which was recently introduced in the US concurrent with the approval of Roche's HPV test.

The cobas CT/NG test is a qualitative in-vitro test for the detection of CT/NG in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection CT/NG in a single analysis. The test, CE marked in 2009, is currently available in numerous countries around the world.

The cobas 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information.

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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