Media Release

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Roche receives FDA clearance to use additional specimen types for chlamydia and gonorrhea test

Expanded application for real-time PCR-based test provides laboratories with comprehensive CT/NG test on fully automated cobas® 4800 System

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the use of four additional specimen types with the **cobas**® CT/NG v2.0 Test to help physicians diagnose Chlamydia trachomatis (CT) and Neisseria Gonorrhoeae (NG) infections in symptomatic and asymptomatic patients. In addition to self-collected vaginal swabs (collected in a clinical setting) and male urine specimens, the test may now be used with endocervical and clinician-collected vaginal specimens, female urine specimens collected in **cobas**® PCR media, and cervical specimens collected in PreservCyt® solution.

The clinical performance of the **cobas**® CT/NG v2.0 Test using the additional specimen types was validated in the VENUS Studies, which included 6,004 patients (5,266 females and 738 males), representing over 26,000 specimens collected in two clinical studies.

"International efforts directed at reducing the CT/NG burden through more timely and accurate detection of CT/NG will be accelerated by diagnostic testing which allows for identification of both symptomatic and asymptomatic patients," said Dr. Jane Gibson, Ph.D. Professor of Pathology, University of Central Florida Health Sciences Campus. "The **cobas**® CT/NG v2.0 Test has demonstrated consistent, dependable performance using a broad spectrum of approved sample types, which provides laboratories with a highly efficient tool for use in both routine screening and diagnostic patient testing."

"With the addition of these specimen types, the **cobas**® CT/NG v2.0 Test now provides U.S. labs with a comprehensive offering for chlamydia and gonorrhea testing," said Paul Brown, head of Roche Molecular Diagnostics. "This will enable more labs running the **cobas**® 4800

System to combine CT/NG and HPV testing onto a single automated platform and further optimize their workflow."

The test is performed on the **cobas**® 4800 System, which is currently the only FDA-approved system to offer primary vial loading for both CT/NG and HPV testing. The streamlined workflow can help labs reduce costs, improve turnaround time and free staff to spend time on other critical tasks.

About the cobas® CT/NG v2.0 Test

The **cobas**® CT/NG v2.0 Test is a qualitative in-vitro test for the detection of CT/NG DNA in patient specimens. It utilizes amplification of target DNA by Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of CT/NG in a single analysis.

About the cobas® 4800 System

The **cobas**® 4800 System offers true walk-away automation of nucleic acid purification, PCR set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The system also runs the **cobas**® HPV Test, the **cobas**® BRAF V600 Mutation Test and the **cobas**® EGFR Mutation Test.

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 financial burden on the healthcare system. The Centers for Disease Control and Prevention (CDC) 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.

About Gonorrhea

Gonorrhea is the second most commonly reported bacterial STD in the United States. Infections in males are generally symptomatic, motivating infected patients to seek evaluation by a clinician for identification and treatment before the onset of serious complications. Gonococcal infections in women are often asymptomatic and may not be immediately recognized, which can progress to Pelvic Inflammatory Disease, tubal scarring, infertility and ectopic pregnancy. Screening of sexually active women under the age of 25 and those at high risk for infection is the focus of successful detection programs in the United States.

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, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner 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 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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