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Roche receives FDA clearance for test to screen and diagnose chlamydia and gonorrhea infection in symptomatic and asymptomatic patients

New cobas CT/NG test expands cobas 4800 system menu beyond clinically proven HPV test to further enhance laboratory efficiency, automation capabilities

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has provided 510(k) clearance to the cobas[®]CT/NG Test for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections in both symptomatic and asymptomatic patients from male urine and self-collected vaginal swabs. A polymerase chain reaction (PCR)-based multiplex dual probe assay, the test for chlamydia and gonorrhea offers excellent sensitivity and high specificity and runs on the automated cobas 4800 System, complementing the cobas HPV (Human Papillomavirus) Test that received FDA approval in April.

“This new test will give labs in the U.S. an efficient solution for offering clinicians chlamydia and gonorrhea screening using the preferred specimen types,” said Paul Brown, head of Roche Molecular Diagnostics. “Since it received CE mark in 2009, the test has been very well received by labs outside the U.S. and we are pleased to be able to offer it to the U.S. market.”

Male urine and self-collected vaginal swabs are the preferred specimen types for CT and NG testing, according to the summary report from the U.S. Association of Public Health Laboratories and Centers for Disease Control and Prevention.¹ The use of these specimen types is considered a progressive option for CT/NG screening, as they show high sensitivity yet are less invasive and less painful to collect than urethral or endocervical samples and thus may help promote screening compliance. The registrational trial for the cobas CT/NG test also confirmed that self-collected vaginal specimens and male urine specimens provide increased sensitivity and specificity when compared with alternative specimen types across patient populations with both low and high disease prevalence.

“This test will contribute to lowering the burden of disease by providing accurate results from

easy to obtain samples – self collected vaginal swabs from women and first catch urine from males. Allowing patients to be active participants in maintaining their health will encourage screening and facilitate clinic flow,” said Dr. Barbara Van der Pol, assistant professor of epidemiology at the Indiana University School of Public Health.

The introduction of the new test expands the menu for the cobas 4800 System and enables laboratories to combine the cobas CT/NG Test and the cobas HPV Test onto a single platform. In addition to the current assays that focus on women’s health, Roche is developing tests for the cobas 4800 System menu in the areas of microbiology and oncology.

About the cobas 4800 System and the cobas HPV Test

The cobas 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information. The system offers true walk-away automation and can run up to 282 tests in less than 12 hours, providing rapid analysis of screening tests to meet the needs of the majority of clinical labs.

The cobas HPV Test is the only clinically validated, FDA-approved and CE-marked assay that simultaneously provides pooled results on high-risk genotypes and individual results on the highest-risk genotypes, HPV 16 and HPV 18. Knowing a woman’s status with high-risk HPV genotypes is important as it can provide predictive information about her risk for cervical pre-cancer or cancer.²

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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¹Association of Public Health Laboratories per the Expert Consultation Meeting Summary Report. Produced in cooperation with the Centers for Disease Control and Prevention titled: “Laboratory Diagnostic Testing for Chlamydia trachomatis and Neisseria gonorrhoeae”, dated January 13-15, 2009, Atlanta, GA.

² Bosch FX, de Sanjose S. Chapter 1: human papillomavirus and cervical cancer – burden and assessment of causality. *J Natl Cancer Inst Monogr.* 2003; 31:3-13.