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Roche Introduces New Health Canada Approved Automated Clinical Laboratory System for Testing of Human Papillomavirus, Chlamydia and *N. gonorrhoeae*

New cobas® 4800 System designed to increase laboratory efficiency and medical value

Roche Diagnostics Canada (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of a new Health Canada approved clinical laboratory system designed to increase laboratory testing efficiency and to accommodate current and long-term molecular diagnostic needs. The **cobas® 4800 System** combines *in vitro* diagnostic tests for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and human papillomavirus (HPV) testing with fully-automated sample preparation and real-time polymerase chain reaction (PCR) technology. Designed to greatly improve laboratory workflow and provide useful information that physicians can immediately act upon, the new **cobas® 4800 System** is now available in Canada.

“With the introduction of the **cobas® 4800 System** in Canada, clinical laboratories now have access to Roche technology that is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information with increased testing throughput,” said Christopher Parker, President and General Manager of Roche Diagnostics in Canada.

Roche designed the **cobas® 4800 System** to meet the needs of a majority of clinical laboratories. The system combines state-of-the-art sample preparation with Roche’s proprietary real-time PCR technology for the amplification and detection of genetic material (deoxyribonucleic acid or DNA) associated with HPV, CT or NG infections. The intuitive, easy-to-use software integrates sample preparation, amplification and detection, and results management.

The HPV test is designed to detect the 14 HPV high-risk genotypes widely accepted to cause cervical cancer. In addition to identifying these 14 HPV genotypes as a group, the **cobas® 4800 HPV test** enables simultaneous and individual identification of the two genotypes (HPV 16 and 18) that put women at highest risk for cervical cancer. Roche’s CT and NG tests detect bacterial DNA associated with chlamydia and gonorrhea infections and are designed to minimize the potential effect that bacterial DNA sequence variations could have on the ability to detect an infection.

Roche launched the **cobas® 4800 System** in countries that accept the CE-Mark in December 2009. The **cobas® 4800 System** is not available in the U.

About Human Papillomavirus and Cervical Cancer

Persistent infection with human papillomavirus is the principal cause of cervical cancer in women, with HPV implicated in greater than 99% of cervical cancers worldwide. Of the more than 118 different types of HPV, 14 types are currently considered high-risk for the development of cervical cancer and its precursor lesions (types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). Of these 14 genotypes, HPV types 16 and 18 have been identified as the highest risk genotypes. Nucleic acid (DNA) testing is a sensitive and non-invasive method for determining the presence of a cervical HPV infection.

About *Chlamydia trachomatis*

Chlamydia trachomatis is the most frequently reported bacterial sexually transmitted disease (STD) in many countries in Europe, according to the European Centre for Disease Prevention and Control (ECDC), and the second most leading cause of sexually transmitted diseases worldwide. Since approximately half of CT infections are asymptomatic, many cases go undetected and untreated. The consequences of an untreated chlamydial infection can be severe, leading to urethritis, conjunctivitis or infertility, among other conditions. With robust internal controls and by simultaneously amplifying and detecting two different bacterial genome and plasmid regions, Roche's cobas® 4800 CT test is designed to detect all known variants associated with clinical *Chlamydia trachomatis* infections, including the Swedish mutant strain.

About *Neisseria gonorrhoeae*

Gonorrhea is a sexually transmitted disease caused by the bacteria *Neisseria gonorrhoeae*. In 2006, a total of 358,366 cases of NG infection were reported to the U.S. Centers for Disease Control (CDC), and it is estimated that more than 700,000 persons acquire new infections each year. NG infections in men can lead to urethritis or epididymitis, and in women can lead to endocervical infection or pelvic inflammatory disease, among other conditions. Roche's cobas® 4800 NG test is designed to simultaneously amplify and detect two areas of a new DNA target region specific for *Neisseria gonorrhoeae*. Dual PCR products allow the test to detect a wider variety of NG variants without sacrificing sensitivity, while at the same time improving specificity.

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 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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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