Roche Introduces New Automated Clinical Laboratory System for CE-Marked Testing of Human Papillomavirus, Chlamydia and N. gonorrhoeae

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

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of a new clinical laboratory system designed to increase laboratory testing efficiency and to accommodate current and long-term molecular diagnostic needs. The cobas 4800 System combines CE-marked 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.

The tests are designed to detect the 14 HPV high-risk genotypes widely accepted to cause cervical cancer and bacterial DNA associated with chlamydia and gonorrhea infections. By identifying 14 HPV genotypes, the cobas 4800 HPV test enables immediate identification of the two genotypes (HPV 16 and 18) that put women at highest risk for cervical cancer. 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 countries that accept CE-Mark.

“The introduction of our new cobas 4800 System delivers on Roche's commitment to provide advanced laboratory diagnostics equipment with clinically relevant tests that are designed to provide actionable results for clinicians,” said Daniel O’Day, head of Roche Molecular Diagnostics. “This new system also sets the stage for the delivery of additional diagnostic tests in both microbiology and oncology.”

The cobas 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information with increased testing throughput. With a throughput of up to 288 HPV tests or 384 CT and NG tests in eight hours, the cobas 4800 System is designed 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.

**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 and Neisseria gonorrhoeae**
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 STDs 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.
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 vastly 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
personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80’000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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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Roche Group Media Relations
Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Daniel Piller (Head)
- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Nina Schwab-Hautzinger