MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 14 NUMBER 17 MAY 2007

REPRINT

FDA Accepts for Review Two Roche Diagnostics HPV Tests

Tests are designed to detect and genotype high-risk HPV types which, if present in persistent infections, can progress to cervical cancer

Roche Diagnostics is pleased to announce that the United States (U.S.) Food & Drug Administration has accepted for review its applications for two human papillomavirus (HPV) tests. The AMPLICOR® HPV Test is designed to enable accurate detection of 13 of the more common high-risk HPV genotypes in standard clinical samples. The LINEAR ARRAY HPV Genotyping Test is designed to identify which of the 13 high-risk HPV genotypes are present in a sample.

Studies worldwide have used the research prototype of the Roche Diagnostics LINEAR ARRAY HPV Test to better understand HPV, including a major study published in the February 28, 2007 issue of the Journal of the American Medical Association,[1] which provided the first national estimate of HPV infection prevalence in females aged 14-59 years in the U.S. The study demonstrated that the overall prevalence of HPV infection at 26.8% was higher than previous estimates. The highest prevalence of infection was observed in females aged 20 to 24 years, of whom 44.8% were infected. Prevalence of HPV types 16 and 18, which pose the greatest risk for cervical cancer, was much lower at 2.3%.

"DNA tests that are currently used in conjunction with Pap smear tests for cervical cancer screening can only tell if a woman has HPV infection, but cannot identify which type she has," said Daniel O'Day, head of Roche Molecular Diagnostics, the business area of Roche Diagnostics that developed the test. "We are pleased to be working with the FDA to bring both HPV detection and genotyping tests to the U.S. market. We believe availability of both tests could offer important, clinically relevant information to clinicians working to better identify and manage persistent, high-risk HPV infections before they progress to more serious forms of disease."

According to the U.S. Centers for Disease Control, genital infection with HPV is the most common sexually transmitted infection in the U.S. today. Over half of sexually active women and men are infected with HPV at some point in their lives. In most cases, infections with HPV are not serious. Although most cases of HPV resolve spontaneously without medical intervention, persistent infection with high-risk HPV types is associated with progression to cervical cancer and associated pre-cancerous conditions such as cervical intraepithelial neoplasia. Genotyping of high-risk HPV infections is increasingly recognized as important to management of patients.

High-risk HPV types are detected in 99% of cervical cancers and worldwide approximately 70% of cervical cancers are due to HPV types 16 and 18.[2] The American Cancer Society estimated that in 2006, over 9,700 women in the U.S. would be diagnosed with, and 3,700 women would die from, cervical cancer.

About Roche and the Roche Diagnostics Division

Roche is a leader in molecular technology and has a strong foundation in diagnostic testing using the Polymerase Chain Reaction (PCR), a DNA amplification method. Roche also has a legacy in utilizing this technology for HPV, specifically in genotyping where the genotyping assay has been used over the last ten years to help characterize the prevalence of genotypes and their association to cervical cancer.

The PCR technology which provides target amplification technology as opposed to signal technology has several advantages. One, it only requires a very small sample size as compared to the current hc2 test (250 ul compared to 4 ml). Additionally the HPV tests have been designed to include an internal control that accompanies each patient test result to verify that cellular material was present in the sample and that the specimen was extracted and amplified appropriately.

Roche intends to offer a total solution to the customer's HPV testing needs by providing both a high risk HPV screening assay and a genotyping assay. Roche expects to be the first FDA approved genotyping product on the market. Genotyping has taken on more importance clinically with publications now indicating that certain genotypes (most notably type 16 and 18) have a higher risk of developing into cervical cancer and should be followed more carefully. Type 18 patients have been known to have higher risk for adenocarcinoma and therefore should be sampled more carefully.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of drugs for cancer and transplantation and a market leader in virology. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs approximately 75,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.

Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide.

Tests under review by the FDA are not available for diagnostic use in the United States until the agency has approved the pre-market notification application for each test.

For further information, please visit our website at www.roche-diagnostics.us or www.roche.us. All trademarks used or mentioned in this release are legally protected by law.

References:

1. Journal of the American Medical Association 2007;297:813-819
2. Journal of Pathology 1999; 189:12-19 and Journal of the National Cancer Institute Monograph, 2003 (31):3-13