MEDCO FORUM®
PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

Medco Forum Presents:

cobas® HPV Test Provides Detailed Genotyping Results Needed To Stratify Patients By Risk

ATHENA Study Validated cobas® HPV Test For Cervical Cancer Screening

One in 10 women who are positive for the highest-risk genotypes, HPV-16 and HPV-18, have high-grade cervical disease that is missed by cytology.

The cobas® HPV Test (Roche Molecular Systems, Inc.) is the only clinically validated, FDA-approved assay that simultaneously provides a pooled result on high-risk genotypes and individual results on HPV-16 and HPV-18.

Among the 14 HR-HPV genotypes, HPV-16 and HPV-18 confer the greatest risk for cervical intraepithelial neoplasia grade 2 (CIN 2) or worse. The addition of high-risk HPV testing to Pap cytology can increase the sensitivity of ≥CIN 2 detection. Because the cobas HPV Test is performed with the same sample taken during a routine pap, patients can avoid multiple office visits for repeat collection.

Dr. Jeffrey M. Litt, M.D., an OB/GYN with Partners in Women's Health practice in Jupiter, Florida, states: "The cobas HPV Test is a real-time PCR (polymerase chain reaction) test that delivers three results in one. Up until the introduction of the cobas HPV Test, we have only been able to test for the 14 high-risk genotypes in one pooled result, then when the pooled result was positive, had to order a second test for HPV-16 and HPV-18 as a reflex test. If we are now able to identify the two most virulent of the high-risk strains up front, we can then manage abnormal pap smears a little better in addition to having important risk information about women with normal pap smears, but HPV positive results. With the cobas HPV Test, we are able to know the patient's HPV-16 and HPV-18 results separately from the other 12 high-risk strains, which are less virulent."

The ATHENA HPV Study

The ATHENA (Addressing THE Need for Advanced HPV Diagnostics) HPV study, which evaluated the clinical usefulness of the cobas HPV Test, involved a total of 46,877 women ≥21 years of age who underwent routine cytological cervical cancer screening and were enrolled at 61 clinical performance sites in 23 different states during 2008 and 2009. In the ATHENA study, approximately 1 in 10 women ≥30 years of age who had a normal Pap result, but who tested positive for HPV-16 and/or HPV-18, actually had cervical pre-cancer. The data from ATHENA show that a woman aged ≥30 years with negative for intraepithelial lesions or malignancy (NILM) cytology who tests positive for HPV-16 has a 13.6 percent risk of having a biopsy-confirmed CIN 2 or greater lesion.

New recommendations for cervical cancer screening were released in March 2012 by a multidisciplinary partnership among the American Cancer Society/ American Society for Colposcopy and Cervical Pathology/ American Society for Clinical Pathology (ACS/ASCCP/ ASCP). Now for women age 30 to 65 years, screening with cytology and high-risk HPV testing ("co-testing") every 5 years is preferred, or cytology alone every 3 years (acceptable).

For more information about the cobas HPV Test, please see us at the ACOG conference, Booth #729, or visit our website at www.HPV16and18.com.