

Women's Health **UPDATE**

FDA Approves Adjunct Screening Test With The Pap

(NAPSA)—The U.S. Food and Drug Administration (FDA) has approved a screening test to be used in conjunction with the Pap test for HPV infection in women age 30 and older. The HPV virus has been shown to be the cause of cervical cancer. The test, developed by the Digene Corporation and called DNAwithPap™ brings improved sensitivity to screening for the causes of the second leading cancer in women worldwide and has the potential to benefit over 30 million women age 30 and older who are screened in the U.S. each year.

Here are some frequently asked questions and answers about the procedure.

Q. What is DNAwithPAP?

A. It is a combination of a high risk HPV DNA Test and a Pap test for adjunct screening in women age 30 and older. Studies show the combination of the two tests is more accurate in determining the absence of disease than the Pap alone.

Q. How should DNAwithPAP be used in clinical practice?

A. DNAwithPAP is used as a primary screening test in women age 30 and older to determine the presence or absence of HPV types that can cause high-grade cervical disease and cancer. This gives clinicians the first objective measure of a woman's risk level and can better enable women to be screened in accordance with existing guidelines.

According to Digene's FDA labeling, women who are HPV negative and Pap negative should be screened in existing guidelines for low-risk women, while women who are HPV plus and Pap negative should be screened in accor-



A combination test for screening in women age 30 and older is giving women and physicians new levels of confidence in a negative screening result.

dance with existing guidelines.

Q. How does DNAwithPap determine if a woman is not at risk and how does it contribute to early detection?

A. The test will help to ensure that women age 30 and over with high-risk HPV infection will not be put into a "low-risk" screening category just because they have a normal Pap history. According to various reports, approximately half of women diagnosed with cervical cancer had a normal Pap history within the last five years.

There are over 100 types of HPV, one of the most common sexually transmitted infections. Of these, 13 key types have been shown to cause cervical cancer.

Most women with HPV will not develop cervical cancer because the infection usually regresses spontaneously. It is only persistent infection with high-risk HPV that can lead to cervical cancer. Thus, cervical cancer is an uncommon result from a common virus.