



FDA News

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FDA Approves Expanded Use of HPV Test

The Food and Drug Administration (FDA) today approved expanded use of a laboratory test to detect the presence in women of human papillomavirus (HPV), one of the most common sexually transmitted infections.

There are more than 100 types of HPVs. The test, the HC2 High-Risk HPV DNA Test, manufactured by Digene Corp., of Gaithersburg, Md., can identify 13 of the high-risk types associated with the development of cervical cancer. The HPV DNA test does not test for cancer, but for the HPV viruses that can cause cell changes in the cervix. If left untreated, these changes can eventually lead to cancer in some women.

FDA initially approved the HPV DNA test in March 2000 for testing women who had abnormal Pap test results to determine whether they needed to be referred for further examination. The new indication allows the test to be used for screening, in conjunction with the Pap test, of women over age 30 for HPV infection. It should be used along with the Pap test, a complete medical history and an evaluation of other risk factors to help physicians determine what kind of follow-up is necessary.

“Knowing whether or not a woman is infected with high-risk HPV is added information that will help physicians detect and treat early cell changes that might eventually lead to cervical cancer,” said FDA Commissioner Mark B. McClellan, M.D., Ph.D. “FDA is committed to bringing safe and effective new technologies to the market quickly.”

Up to 20 percent of the sexually active U.S. population is believed to be infected with HPV at any one time. Most women who become infected with HPV are able to eradicate the virus and suffer no apparent long-term consequences to their health. But a few women develop a persistent infection that can eventually lead to pre-cancerous changes in the cervix.

The HPV DNA test, like the Pap test, is performed by collecting cells from the cervix and then sending them to a laboratory for analysis. The test detects high-risk types of HPV in cell DNA even before there are any conclusive visible changes to the cervical cells.

Women who have normal Pap test results and no HPV infection are at very low risk (0.2%) for developing cervical cancer. Women who have an abnormal Pap test and a positive HPV test are at higher risk (6%-7% or greater) of developing cervical cancer if not treated.

FDA approved the expanded use of the test based on published literature describing studies of a cross section of women with normal and abnormal Pap test results who tested positive or negative for high-risk types of HPV. FDA also took into account additional input from professional societies, FDA advisory panel members and other interested parties in arriving at a decision.

The HPV DNA test is not intended to substitute for regular Pap screening. Nor is it intended to screen women under 30 who have normal Pap tests. Although the rate of HPV infection in this group is high, most infections are short-lived and not associated with cervical cancer.

Some 50 million women get Pap tests annually in the United States. According to the American Cancer Society, in 2003, 12,200 women will be diagnosed with cervical cancer and 4,100 will die from the disease. With proper screening, cervical cancer is avoidable and, if caught early, curable.

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