Approval of first HPV test for use with SurePath preservative fluid

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(HealthDay)—The U.S. Food and Drug Administration has approved

Roche's cobas HPV Test as the first diagnostic to be used with cervical cells obtained for a Pap test and collected in SurePath Preservative Fluid.

"Health care providers have been using samples stored in the SurePath Preservative Fluid with human papillomavirus (HPV) tests for some time now, but there have been concerns about false negative results," Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health, said in a news release. "Now health care providers have access to an FDA-approved test and the information they need to use it properly to ensure the most accurate results for their patients."

The agency notes that the test is approved for use in screening women age 30 and older for HPV in order to determine whether additional care is needed. It is also approved for use in women age 21 and older with borderline cellular cytology in order to determine whether additional follow-up and diagnostic procedures are needed. The test is not approved as a first-line primary HPV screening test, and the agency states that health care professionals should use the results in combination with other information, such as patient screening history and risk factors.

The approval is based on a clinical study of 952 eligible women 21 years and older with abnormal Pap test results. The FDA said that the Roche cobas HPV Test with SurePath Preservative Fluid demonstrated similar clinical performance when compared to a previously approved cervical sample type.

The Roche cobas HPV Test is manufactured by Roche Molecular Systems. SurePath Preservative Fluid is manufactured by Becton Dickinson and Company.

More information: More Information