HPV 16 18/45 genotype assay, 1/14

January 2014—The FDA has approved Hologic's Aptima HPV 16 18/45 genotype assay for use on its fully automated Panther system. The Aptima HPV 16 18/45 genotype assay is performed using Hologic's ThinPrep liquid cytology specimen and is intended to test specimens from women with Aptima HPV assay-positive results. The addition of HPV genotype 45 is designed to help identify more women at risk for adenocarcinoma, with minimal impact to colposcopy rates.

The FDA has approved the test for two uses. In patients 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results and who have Aptima HPV assay-positive results, and in patients 30 years and older with Aptima HPV assay-positive results, the Aptima HPV 16 18/45 genotype assay can be used to assess the presence or absence of high-risk HPV genotypes 16, 18, and/or 45. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

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