

NEW TEST – Available Now

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Human Papillomavirus (HPV) Genotypes 16 and 18/45, by Transcription-Mediated Amplification (TMA), ThinPrep

3016944, HPVGENO

Specimen Requirements:

Patient Preparation: Patient should avoid high concentrations of antifungal cream or contraceptive jelly, and should not douche prior to time of collection.

Collect: Cervical, anal, or vaginal specimen with brush or spatula from ThinPrep kit and place in PreservCyt Media

Specimen Preparation: Transport original ThinPrep or briefly vortex and transfer 1 mL to an Aptima Specimen Transfer Tube (ARUP supply #42711). Available online through eSupply using ARUP Connect (TM) or contact ARUP Client Services at 800-522-2787. To reduce the potential for contamination, ThinPrep specimens should be poured off, using sterile technique, into the Aptima Specimen Transfer Tube prior to cytology testing.

Transport Temperature: Refrigerated

Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.

Remarks: Specimen source required.

Stability: Ambient: 1 month; Refrigerated: 105 days; Frozen: Unacceptable

Methodology: Qualitative Nucleic Acid Amplification (NAA)

Performed: Wed, Sat

Reported: 1-5 days

Note: For cervical sources, a negative high-risk HPV result does not exclude the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

CPT Codes: 87625

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

This test detects E6/E7 viral messenger RNA of the high-risk HPV types 16, 18, and 45 only. It is intended for use in women 21 years and older with ASC-US cervical cytology results and in women 30 years and older as a follow-up to a positive high-risk HPV screen. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. This test is not intended for use as a stand-alone test.

HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

Reference Interval:

Negative

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.