NEW TEST – Available Now

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Human Papillomavirus (HPV) High Risk Screen by Transcription-Mediated Amplification (TMA), with Reflex to Genotypes 16 and 18/45, ThinPrep

3016945, HPV REFLEX

Specimen Requirements:	
Patient Preparation:	Patients 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:	Sun-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:	87624; if reflexed, add 87625
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

This test detects E6/E7 viral messenger RNA of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. This test does not discriminate between the 14 high-risk HPV types. 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. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types.

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

If Human Papillomavirus (HPV), High Risk is positive, then HPV genotypes 16, 18/45 will be added. Additional charges apply.

Reference Interval:

Negative

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