HOTLINE: Effective September 8, 2020

New Test **3003005** **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep** **HPVNAA**

Methodology: Qualitative Nucleic Acid Amplification
Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Patient Prep: Females should avoid high concentrations of antifungal cream or contraceptive jelly, and should not douche prior to time of collection.
Collect: Cervical specimen with the ThinPrep Pap Test Collection kit
Storage/Transport Temperature: Refrigerated
Remarks: Specimen source required.
Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data:
This test detects high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and differentiates HPV 16 and 18 associated with cervical cancer and its precursor lesions. 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, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.
Note:

CPT Code(s): 87624

New York DOH Approved.

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