HOTLINE: Effective November 15, 2021

New Test **2011940** **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep** **TP HPV1618**

Methodology: Qualitative Polymerase Chain Reaction
Performed: Tuesday-Saturday
Reported: 1-5 days

Specimen Required: Collect: Cervical specimen with brush or spatula from ThinPrep kit and place in PreservCyt Media.
Specimen Preparation: Mix well. Transfer 3 mL to an ARUP Standard Transport Tube. (Min 1.5 mL). If test is being used for primary screening, submit specimen aliquot and retain the original specimen at the client site.
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: 6 months; Refrigerated: 6 months; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data:
This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) 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.

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

CPT Code(s): 87624

New York DOH Approved.

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