TEST CHANGE

HPV Primary Screen by PCR With Reflex to Cytology

3016636, HPV PRMRY

Specimen Requirements:	
Patient Preparation:	
Collect:	Cervical or endocervical specimen with brush or spatula from ThinPrep kit collection kit. (ARUP supply #41785 ThinPrep (Vial and Broom) or #51369 ThinPrep (Vial, Brush, and Spatula)) available online through eSupply using ARUP Connect(TM) or~~Connector~~ contact ARUP Client Services at 800-522-2787.
Specimen Preparation:	Place collection device in corresponding ThinPrep media vial.
Transport Temperature:	Refrigerated
Unacceptable Conditions:	Bloody or dark brown specimens. Specimens in any media other than indicated above.
Remarks:	
Stability:	Ambient: 6 months; Refrigerated: 6 months; Frozen: Unacceptable
Methodology:	Qualitative Polymerase Chain Reaction (PCR)
Performed:	Tue-Sat
Reported:	1-5 days ~~Within 24 hours~~
Note:	If HPV assay is positive, then ThinPrep PAP Test (Standalone) (3018968) will be added. Additional charges apply. ~~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:	8762446; if reflexed~~,~~ add 88175 (88142 if manual);~~:~~ if reviewed by pathologist~~,~~ add 88141
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

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. Specimens positive for high-risk HPV types are reflexed to cytology. Patients positive for high-risk HPV 16 or HPV 18 should be managed according to current ASCCP guidelines (2019). ~~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.~~

Reference Interval:

Negative