

NEW TEST

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HPV Primary Screen by PCR With Reflex to Cytology

3016636, HPV PRMRY

Specimen Requirements:

Patient Preparation:

Collect: Cervical or endocervical specimen with SurePath collection kit. Cervical or endocervical specimen with brush or spatula from ThinPrep 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 contact ARUP Client Services at 800-522-2787.

Specimen Preparation: Place collection device in corresponding SurePath or ThinPrep media vial.

Transport Temperature: Refrigerated

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

Remarks:

Stability: SurePath - Ambient: 1 month; Refrigerated: 6 months; Frozen: Unacceptable ThinPrep - Ambient: 6 months; Refrigerated: 6 months; Frozen: Unacceptable

Methodology: Qualitative Polymerase Chain Reaction (PCR)

Performed: Tue-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 88142; if reviewed by pathologist add 88141

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

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.

Reference Interval:

Negative

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