

Test Name

HPV WITH REFLEX TO GENOTYPE

Synonyms

HPV w/ REFLEX

Intended Use / Indications

Detect E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The use of the test is indicated: 1. To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) to determine the need for referral to colposcopy. 2. In women 30 years and older, the Aptima HPV assay can be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV types.

If HPV E6/E7 is positive, HPV Genotype is performed. The Aptima HPV Genotype assay detects viral messenger RNA (mRNA) of HPV types 16, 18, and 45. The assay differentiates HPV 16 from HPV 18/45.

Methodology

Target amplification nucleic acid probe for mRNA

Test Code

1107

Specimen Type

ThinPrep liquid Pap specimen

Preferred Container

Entire ThinPrep vial secured tightly

Temperature/Stability

Store 2-30°C: 105 days. No more than 30 days above 8°C.

Handling

Avoid douching 48-72 hours prior to examination. Do not collect during or shortly after menstrual period. Collect cervical specimens in ThinPrep Pap Test vials containing PreservCyt Solution with broom-type or cytobrush/spatula collection devices according to the manufacturer's instructions.

Reject

Specimens >3 months old. Male patient. SurePath, other specimens.

Panel Includes

HPV mRNA E6/E7 and Reflex if positive to HPV GENOTYPES 16, 18/45

Limitations and Additional Information

Performance characteristics available upon request.

Expected TAT: 3 days

Rev. 05Nov2019