

HPVG

HPV Genotyping

GA Test Code	7575
Method	DNA Sequencing <i>Note:</i> This assay identifies the <i>specific type of HPV</i> present in the patient sample (type 6, 11, 16, 18, 45, etc.). It is normally preceded by Test #395H or Test #478 to establish the presence of HPV.
Specimens	ThinPrep: 8.0 (4.0) mL, store and ship ambient (up to 3 months). SurePath: 3.0 (2.0) mL, store and ship ambient (14 days). hc2 DNA Collection Device: Cervical brush can be stored and shipped in STM up to 2 weeks ambient, 3 weeks refrigerated, or 3 months frozen. Fresh Tissue: 3 mm ³ , refrigerated (7 days) or frozen. FFPE (Formalin-fixed, Paraffin-embedded) Tissue: submit 6 shavings in 3-micron sections, sterile container, ambient. <i>Please do not submit entire FFPE tissue block, unless you are unable to produce shavings.</i> Slides: provide tissue on 5-6 slides <i>without</i> cover slips, ambient. Anal ThinPrep: 4.0 mL (2.0 mL), store and ship ambient (up to 3 months). Anal Swab: Insert a Dacron or polyester swab 2-3 inches into anus. Rotate 360 degrees while applying firm pressure and withdrawing slowly. Place swab in viral transport medium or saline. Refrigerate (up to 7 days).
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time/temp instructions not followed.
Reference Range	Not Detected
Limit of Detection	For samples initially tested by Hybrid Capture 2, Genotyping can be performed for HPV RLU/cutoff value of 5.0 or greater.
Turnaround Time	4-9 days
CPT Code	87623, 87624

Description

This assay uses multiplex PCR to amplify the L1 gene of most known HPV types. The amplified DNA is subjected to dideoxy sequencing followed by capillary electrophoresis to determine the specific subtype of HPV (e.g. type 6, 16, 51, etc.) present in the patient sample. The human *beta-globin* gene is amplified from tissue samples (fresh and paraffin-embedded) to ensure that DNA extracted from the sample is of sufficient quantity and quality.

Clinical Utility

Of the 13 or 14 recognized high-risk types of HPV, types 16 and 18 are highly prevalent and more oncogenic than other high-risk types. Specifically, high-risk types 16 and 18 have been reported to cause 70% of cervical cancers and 90% of the head and neck cancers caused by HPV. Studies have shown that women with HPV type 16 cervical infections are at greater risk of developing CIN3+ compared to other high-risk types. Women with normal cytology that are HPV type 18 positive not only have an increased risk of CIN3+, but also adenocarcinoma. Regarding head and neck cancers, nearly 50% of all oropharyngeal cancers and up to 15% of oral cancers are attributable to HPV.

The clinical utility of HPV genotyping assays was discussed at the 2006 ASCCP Consensus Conference. Based on the data available in 2006, it was determined that in cytology negative women 30 years and older who are HPV DNA positive (for any of the 13 or 14 high-risk types of HPV detected by the FDA-approved high-risk HPV assays) molecular genotyping assays that detect HPV 16 and 18 would be clinically useful for differentiating which women should be referred for immediate colposcopy (positive for types 16 or 18), and which should be followed-up with repeat cytology and high-risk HPV testing in 12 months (negative for types 16 and 18).