GENETIC ASSAYS
A Molecular Diagnostics Laboratory

HPV — HPV DNA by PCR (w/ ID of 16, 18, 45)

GA Test Code	**478**
Method	**HPV DNA Detection** by conventional PCR **ID of 16, 18, & 45** by Real-Time Polymerase Chain Reaction (rPCR) ***Note:*** Detection and ID performed simultaneously. To identify a specific HPV type other than 16, 18, or 45, order reflex to Test **#7575 HPV Genotyping.**
Specimens	**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. *Please do not submit entire FFPE tissue block, unless you are unable to produce shavings.* **Slides:** provide tissue on 5-6 slides *without* cover slips, ambient. ***Note:*** Submitting fewer than the recommended number of shavings or slides is acceptable if adequate tissue/cellular material is present. **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 and/or temperature instructions not followed.
Reference Range	Not Detected
Turnaround Time	48-72 hours
CPT Code	87623, 87624; If ***Detected***, add 87625

Description

This assay uses conventional multiplex PCR to amplify the L1 gene of most known HPV types. HPV DNA is detected by agarose gel electrophoresis. Additionally, Real-Time PCR is utilized to specifically identify and distinguish if highly oncogenic HPV high-risk types 16, 18, and 45 are present.

Clinical Utility

Recent evidence has shown that HPV plays a role in the development of head and neck cancers. In fact, nearly 50% of all oropharyngeal cancers and up to 15% of oral cancers are attributable to HPV. In contrast to cervical infections with HPV where multiple HPV types have been detected simultaneously, most oral and oropharyngeal infections involve a single type of HPV. The causal relationship between oncogenic HPV and malignancy indicates the importance of being able to rapidly detect specific HPV types (e.g. 16, 18, 45) when it is suspected that a lesion may harbor an HPV infection. This would aid in the assessment of precancerous lesions and impact on the decision to allow the lesion to resolve on its own or treat the lesion before it progressed to a more severe form of disease. Additionally, low risk types of HPV impact negatively on quality of life, indicating the importance of identifying HPV types involved in the development of warts. Using our assays to distinguish between common types of HPV responsible for cancers as well as those involved in the development of warts helps facilitate the understanding of HPV epidemiology and pathology.

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D'Souza G, Kreimer AR, Viscidi R, Pawlita M, Fakhry C, Koch WM, Westra WH, Gillison ML: Case-control study of human papillomavirus and oropharyngeal cancer. *N Engl J Med* 2007, 356:1944-56.
X, Diaz M, de Sanjose S, et al. Worldwide human papillomavirus etiology of cervical adenocarcinoma and its cofactors: implications for screening and prevention. *J Nat'l Cancer Inst* 2006; 98:303-15.

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