GENETIC ASSAYS
A Molecular Diagnostics Laboratory

HPVH **HPV High Risk** DNA by Hybrid Capture® 2 **(w/ ID of 16,18,45)**

GA Test Code	**395H**
Method	***FDA-approved*** Hybrid Capture® 2 (for high-risk HPV types) **Identification** performed using Real-Time Polymerase Chain Reaction (rPCR) ***Note:*** High-risk detections will automatically be tested to determine if they are types **16, 18,** or **45.** To identify a specific HPV type other than 16, 18, or 45, order Test **#7575 HPV Genotyping** (RLU/cutoff value must be at least 5.0)
Specimens	**ThinPrep**: 5.0 mL (3.0 mL), store and ship ambient (up to 3 months). **SurePath**: 3.0 mL (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. ***Note:*** *Cervical specimens must be collected prior to the application of acetic acid or iodine if colposcopic examination is being performed.*
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; cervical sample collected after application of acetic acid or iodine.
Reference Range	Not Detected High-risk type profile: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
Turnaround Time	24-48 hours
CPT Code	87624; If ***Detected***, add 87625

Description

The Hybrid Capture® 2 (hc2) HPV DNA test is an *in vitro* nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of thirteen types of human papillomavirus (HPV) DNA in cervical specimens. The hc2 HPV DNA Test can detect high and intermediate-risk HPV types 16/18/31/33/35/39/45/51/52/56/58/59/68. 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

1) To aid in the diagnosis of sexually transmitted HPV infections with high and intermediate-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68.
2) To rapidly identify and distinguish if highly oncogenic HPV high-risk types 16, 18, and 45 are present.
3) To screen patients with ASC-US (atypical squamous cells of undetermined significance) Pap smear results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.
4) In women with low-grade squamous intraepithelial lesion (LSIL) or high-grade squamous intraepithelial lesion (HSIL) Pap smear results, prior to colposcopy, an hc2 HPV DNA Test result will aid in patient management by assisting with risk assessment of women to determine absence of high-grade disease.

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