



HPV

HPV (High-risk) DNA by Hybrid Capture® 2

GA Test Code	395H
Method	FDA-approved Hybrid Capture® 2 (for High-risk HPV types) Note: To identify the specific HPV Type, order reflex to Test #7575 HPV Genotyping (must have HPV RLU/cutoff value of 5.0 or greater)
Specimens	ThinPrep: 4.0 mL (2.0 mL), store and ship ambient (up to 3 months). SurePath: 1.0 mL (0.5 mL), store and ship ambient (28 days). hc2 DNA Collection Device: Cervical brush can be stored and shipped in STM up to 2 weeks ambient, and an additional week if refrigerated. After that, specimens can be frozen up to 3 months prior to testing. Note: Cervical specimens must be collected prior to the application of acetic acid or iodine if colposcopic examination is being performed. Biopsy: fresh tissue (preferred), 3 mm ³ , refrigerated (7 days) or frozen; for formalin-fixed, paraffin-embedded blocks, six 3-micron sections preferred, ambient; for needle biopsy, 2.0 mL (1.0 mL), refrigerated or frozen.
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	87621

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, but cannot determine the specific HPV type 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 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.
- 3) 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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Nobbenhuis MAE, Walboomers JMM, Helmerhorst TJM, et al: Relation of human papillomavirus status to cervical lesions and consequences for cervical-cancer screening: a prospective study. *Lancet* 1999; 354:20-25.

Manos MM, Kinney WK, Hurley LB, et al: Identifying women with cervical neoplasia: using human papillomavirus DNA testing for equivocal Papanicolaou results. *JAMA* 1999; 281:1605-1610.

Clavel C, Masure M, Bory J-P, et al: Hybrid Capture II based human papillomavirus detection, a sensitive test to detect in routine high-grade cervical lesions: a preliminary study on 1518 women. *Br. J. Cancer* 1999; 80:1306-1311.

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