

HPV Testing

Creighton Medical Laboratories is pleased to begin offering in house, high risk Human Papillomavirus (HPV) testing using molecular signal amplification methodology (Invader). These tests were previously sent out to our reference laboratory.

Patients with a cytologic diagnosis of ASCUS (atypical squamous cells of undetermined significance) and a positive High-Risk HPV test have a risk for high-grade cervical dysplasia and carcinoma similar to that of women with a cytologic diagnosis of LSIL (low-grade squamous intraepithelial lesion). Women with a cytologic diagnosis of ASCUS and a negative High-Risk HPV test have a low risk of high grade dysplasia and carcinoma, and are generally followed in the same way patients with a "non-neoplastic" cytologic diagnosis. Women aged 30 years and older who have both negative cervical cytology and negative High-Risk HPV DNA test are at low risk for developing high-grade dysplasia or carcinoma during the next 3-5 years. The FDA has approved the combination of cervical cytology and HPV testing for primary screening for cervical cancer for women aged 30 years and older. All SurePath cervicovaginal cytology samples with ASCUS, AGUS or ASCUS-H diagnosis, not recently tested for HPV, will have reflex HPV test unless specifically requested otherwise by the clinicians. A negative High-Risk HPV DNA study by itself does not rule out current or future cervical dysplasia or carcinoma. These results should always be correlated with the other patient findings, including cytology, histology, and clinical features.

Third Wave Technology's Invader assay is used to look for 13 High-Risk HPV strains using 3 probe tools based on genetic phylogeny clustering: HPV A5/A6 oligo mix (HPV types 51 & 56), HPV A7 oligo mix (HPV types 18, 39, 45, 59, 68), and HPV A9 oligo mix (HPV types 16, 31, 33, 35, 52, 58). The assay determines the presence of any of these high risk HPV strains but does not determine the specific strain present nor does it assay for the low risk strains whose clinical significance is uncertain. Reports in the literature and CML's internal validation assays indicate that the Invader assay has better selectivity for high risk genotypes as compared to the traditional hybrid capture-2 assay. In addition, the Invader assay contains an internal control to confirm specimen quality which the hybrid capture-2 assay lacks.

Effective Date: January 15, 2007

Specimen Requirements: Cervical sample collected in Sure Path collection media

Test Order: HPV

CPT Code: 87621

Availability: Results available within 5 working days of specimen receipt

Please forward this to appropriate staff members within your facility. If you have any questions, please contact CML at (402) 280-4382 or email us at cml@creighton.edu. Visit our website <http://www.cml.md/testing/> for additional information.

Creighton Medical Laboratories is proud to be your partner in providing effective and timely health care.



Creighton Medical Laboratories

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