



# HealthCare

Clinical Laboratories

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July 6, 2010

HCCL is pleased to announce the availability of HPV-High Risk testing and HPV Genotyping beginning July 12, 2010. LIS test builds below.

Cervista HPV HR (High-Risk), designed to detect the 14 high-risk types of human papillomavirus (HPV) known to cause cervical cancer, is the first HPV DNA test approved by the FDA in more than 10 years. Cervista HPV 16/18 is the first HPV test approved for genotyping for HPV types 16 and 18, known to be associated with approximately 70% of all cervical cancers in the United States.

HPV HR test has been approved for two uses:

- To screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.
- Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

The Cervista HPV 16/18 test has been approved for two uses:

- In women 30 years and older the test may be used adjunctively with the Cervista HPV HR test in combination with cervical cytology to assess the presence or absence of specific high-risk HPV types.
- Used adjunctively with the Cervista HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of specific high-risk HPV types. The results of this test are not intended to prevent women from proceeding to colposcopy.

It is also noted that for both the Cervista HPV HR test and the Cervista HPV 16/18 test, the test results, along with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

Over 100 HPV types have been documented in the literature, approximately 40 of which infect the anogenital area and are transmitted sexually. Anogenital HPV is associated with virtually all cancers of the cervix.<sup>1</sup> Cervical cancer has previously been shown to be highly preventable when cytological and HPV screening programs are employed to facilitate the detection and treatment of pre-cancerous lesions.

Of the sexually transmitted types of HPV, 14 oncogenic genotypes (HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), are considered high-risk (HR) HPV types due to their strong association with cervical cancers (relative to low risk HPV types, which have little or no association with cervical cancer).

The presence of high-risk HPV DNA in conjunction with an equivocal or ambiguous cytology result (ASC-US) places a woman at increased risk for having an underlying cervical intraepithelial neoplasia 2 or 3 (CIN2 or CIN3).

CIN3, while occurring in only approximately 5% of ASC-US cases, is an immediate precursor to cervical cancer and consequently its detection is very important for patient management. Therefore, the identification of those women with ASC-US cytology in conjunction with a high-risk HPV infection is a useful aid for clinicians to decide who should be monitored or treated more aggressively.

Current scientific literature suggests that persistent infection with high-risk HPV is the main risk factor for development of high-grade cervical neoplasia and cancer. Apparent persistence may represent continuous infection with a single HPV type, with multiple HPV types, or reinfection. Nonetheless, women with normal cervical cytology who are HR HPV negative appear to be at low risk for having or developing cervical precancerous lesions.

HPV types 16 and 18 are recognized as both highly oncogenic and persistent, associated with 60% and 10% of cervical cancers, respectively, while also having the lowest clearance rates in cervical screening. As a result, numerous studies report that women infected with HPV types 16 and 18 have a significantly higher risk for developing  $\geq$ CIN3 than women infected with other high-risk types.

According to the *2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests*, women with negative cervical cytology results who test positive for the presence of high-risk HPV DNA would benefit from type-specific HPV genotyping. Studies support the validity of genotyping for HPV types 16 and 18, whether it is used as a follow-up to a high-risk HPV screening test or performed concurrently.