

New FDA-approved Cervista™ HPV DNA High-Risk Screen and 16/18 Genotype Tests for the Diagnosis and Management of HPV Infection

Quick Facts

- ▶ High-Risk HPV DNA screening is recommended in conjunction with cervical cytology for women age 30 years and over.²
- ▶ The 2006 Consensus Guidelines included a recommendation for women 30 years and older with negative cytology and positive HPV DNA tests to have HPV genotyping performed for types 16 and 18. Women positive for type 16 or 18 should be referred for immediate colposcopy and those negative for either high-risk type may be followed up with repeat cytology and high-risk HPV testing in 12 months.
- ▶ The new High-Risk HPV screening assay cross reacts with fewer low-risk types than the previous assay.

For more information, please contact your local marketing representative.

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CLINICAL APPLICATION

The Cervista™ HPV HR Test

- Identifies 14 high-risk types of HPV: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 (including the 13 types detected by the Hybrid Capture 2 HPV DNA Assay).
- FDA-approved for screening patients with ASC-US cervical cytology results to determine the need for referral colposcopy.
- FDA-approved for adjunctive use 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 Genotype Test

- Detects and distinguishes high-risk HPV types 16 and 18.
 - FDA-approved for adjunctive use with the Cervista™ HPV HR test in combination with cervical cytology in women 30 years and older to assess the presence or absence of high-risk types 16 and/or 18.
 - FDA-approved for adjunctive use with the Cervista™ HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of high-risk types 16 and/or 18.
- The results of this test are not intended to prevent women from proceeding to colposcopy.***

CLINICAL BACKGROUND

The presence of certain HPV types in the female genital tract is associated with a number of diseases, including condyloma, Bowenoid papulosis, cervical, vaginal, and vulvar intraepithelial neoplasia and carcinoma. It is generally accepted that these viruses are predominantly sexually transmitted and that high-risk HPV types are a major recognized risk factor for development of cervical cancer. Infection of the cervix with high-risk HPV types can be associated with cytological and histological changes that are detected by Pap screening, colposcopy, or biopsy.

- Human papillomavirus (HPV) infections are extremely common in sexually active women and most are transient and benign. Some HPV-infected women, however, do not spontaneously clear the infection and will progress to develop persistent infection.
- High-grade lesions caused by persistent infection of high-risk types of HPV may progress to cervical carcinoma if the precursors are not detected through screening and subsequently treated.
- High-risk types of HPV DNA can be detected in more than 95% of squamous cell carcinomas of the cervix.
- High-Risk HPV screening, in conjunction with cervical cytology testing, attains very high negative-predictive values.

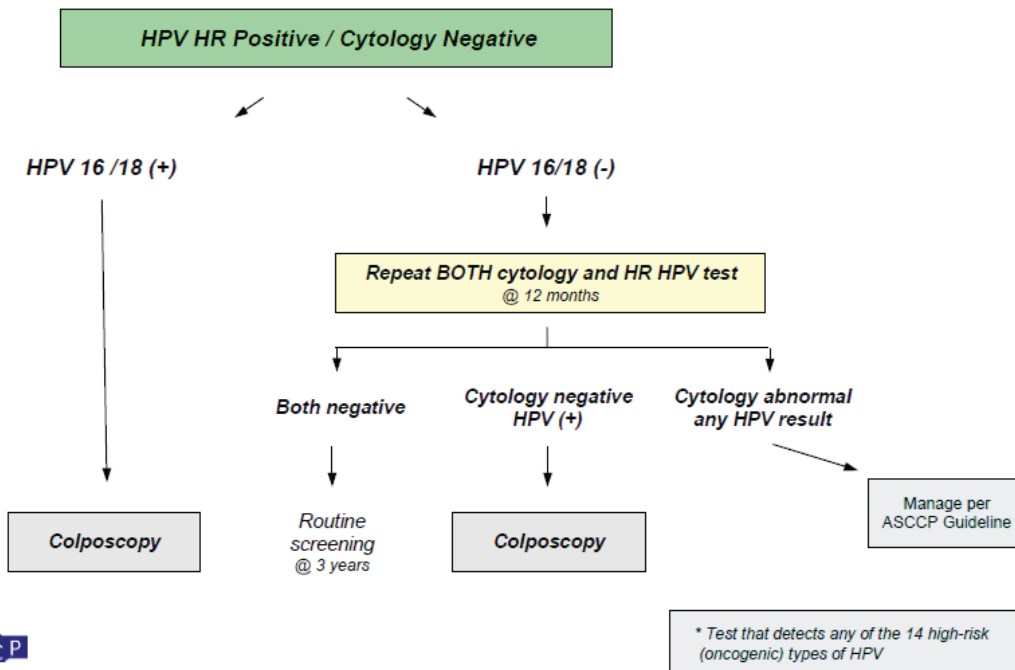


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CLINICAL MANAGEMENT

2009 ASCCP Recommendations For Use of HPV Genotyping to Manage HPV HR Positive / Cytology Negative Women 30 Years and Older



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SELECTED REFERENCES

1. Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D; 2006 ASCCP-sponsored Consensus Conference. 2006 Consensus guidelines for the management of women with abnormal cervical screening tests. *J Low Genit Tract Dis.* 2007;11:201-222
2. Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D; 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 Consensus guidelines for the management of women with abnormal cervical screening tests. *Am J Obstet Gynecol.* 2007;197:346-355

TEST INFORMATION

Human Papillomavirus DNA Probe High Risk	
METHOD	Invader
ORDER CODE	HPVDG
CPT CODE	87621
SPECIMEN REQUIREMENTS	ThinPrep or SurePath pap test solution
COMMENTS	Unacceptable conditions: samples in EIA transport media, wooden swabs, male samples, cervical biopsies, specimens collected in Digene cervical sampler
RANGES	Negative for High Risk Human Papillomavirus

Human Papillomavirus 16/18 Genotype	
METHOD	Invader
ORDER CODE	HPVGNT
CPT CODE	83891, 83896 x 10, 83903, 83892 x 4, 83912
SPECIMEN REQUIREMENTS	ThinPrep or SurePath pap test solution
COMMENTS	Unacceptable conditions: samples in EIA transport media, wooden swabs, male samples, cervical biopsies, specimens collected in Digene cervical sampler
RANGES	Type 16 not detected; Type 18 not detected

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