

# Human Papillomavirus (HPV) Genotyping

## FOR DETECTION OF HPV TYPE 16 AND 18 IN CLINICAL SPECIMENS

### Test Highlights

- In contrast to the high-risk HPV assay that tests for all high-risk HPV types, this test is designed to detect HPV types 16 and 18 only.
- HPV types 16 and 18 are the types most commonly found in cervical cancer.
- This test is performed on the same specimen types used for high-risk HPV testing and can aid in triage of women over age of 30 with negative Pap cytology but a positive high-risk HPV test.<sup>1,2</sup>

### Clinical Background

- HPV is the most common sexually transmitted infection in the United States.
- There are more than 100 different HPV types. Approximately 40 HPV types infect the anogenital mucosa. These types can be classified as high-risk, intermediate risk, and low-risk types, depending on propensity to cause cervical cancer.
- Infections with high-risk HPV types are also associated with cancers of the vulva, vagina, anus, penis, and oropharynx.
- Most infections are asymptomatic and resolve spontaneously.
- Among high-risk HPV types, infections with types 16 and 18 confer the highest risk for persistence and the subsequent development of cervical cancer.
- Screening with cervical cytology (Pap smear) has decreased the incidence of cervical cancer deaths in developed countries.
- Detection of high-risk HPV types in cervical specimens has also been used for screening and aiding in risk stratification and patient management.

### Epidemiology

- Cervical cancer is the second leading cause of cancer-related deaths worldwide.
- About 11,000 women are diagnosed with cervical cancer in the United States every year.

### Indication for Ordering

Current ASCCP guidelines recommend HPV genotyping for types 16 and 18 in women over the age of 30 who have negative Pap cytology but a positive high-risk HPV screening test. Presence or absence of HPV 16 or 18 can assist in further patient management decisions (e.g., immediate colposcopy versus repeat testing at a later time).<sup>1,3</sup>

### Interpretation

- The HPV genotyping test detects HPV high-risk types 16 and 18, which are strongly associated with cervical cancer and its precursor lesions.
- Results of this test should be correlated with the clinical context, including cytologic and histologic findings.

- Sensitivity may be affected by specimen integrity and/or cellularity.
- A negative test result does not exclude the possibility of HPV 16 and/or HPV 18 infection, as very low levels of infection or sampling error may cause false-negative results.
- A false-negative result may also be obtained in specimens that are contaminated with high levels of contraceptive jelly and/or antifungal creams.

### Limitations

- This test only detects DNA of HPV types 16 and 18. It does not detect DNA of the other high-risk HPV types, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, which are also associated with cervical cancer and its precursor lesions. It is NOT intended to test for high-risk HPV types and should be used only in patients who have tested positive with a test for high-risk HPV types.
- Cross-reactivity to high levels of HPV high-risk type 31 can be seen.<sup>4</sup>
- High levels of contraceptive jelly and/or anti-fungal creams may cause false-negative results.<sup>4</sup>
- HPV genotyping is not suitable for women under age 30.<sup>1</sup>
- HPV genotyping is not intended for women with abnormal cervical cytology, since results do not affect management.<sup>1</sup>
- This test is not recommended for evaluation of suspected sexual abuse.<sup>4</sup>

### Methodology

Invader method.

### Related Tests:

- Human Papillomavirus (HPV) High Risk DNA by Invader Method with Reflex to Human Papillomavirus (HPV), Genotypes 16 and 18 (2005283)
- Human Papillomavirus (HPV) DNA Probe, High Risk, Cervical Brush (Digene) (0065999)
- Human Papillomavirus (HPV) DNA Probe, High Risk, Surepath® (AutoCyte) (0060744)
- Human Papillomavirus (HPV) DNA Probe, High Risk, ThinPrep® (0060750)

## References

1. American Society for Colposcopy and Cervical Pathology (ASCCP): Consensus guidelines. <http://www.asccp.org/ConsensusGuidelines/HPVGenotypingClinicalUpdate/tabid/5963/Default.aspx> (accessed on April 25, 2011).
2. American Society for Colposcopy and Cervical Pathology. Use of HPV genotyping to manage HPV HR positive /cytology negative. Women 30 years and older. [http://www.asccp.org/Portals/9/docs/pdfs/Consensus%20Guidelines/hpv\\_genotyping\\_20090320.pdf](http://www.asccp.org/Portals/9/docs/pdfs/Consensus%20Guidelines/hpv_genotyping_20090320.pdf) (accessed on July 6, 2011).
3. Wright TC, et al. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *Am J Obstet Gynecol* 2007;197:346–55.
4. Cervista™ HPV 16/18 (package insert). Madison, WI: Third Wave Technologies, Inc.; 2009.

## Test Information

### 2005277 Human Papillomavirus (HPV), Genotypes 16 and 18

For specific collection, transport, and testing information, refer to the ARUP website at [www.aruplab.com](http://www.aruplab.com).

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at [www.arupconsult.com](http://www.arupconsult.com).

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