



Women's Health

HPV Testing and Genotyping



Test Codes

HPV: HPV HR

HPV Genotyping: HPVVG

Specimen Requirement

HPV Test: 4mL ThinPrep® Pap solution; 2mL SurePath™ Test Pack solution; or 5mm⁵ biopsy in Digene tube (freeze immediately); cervical or vaginal swab

HPV Genotyping: 2mL ThinPrep or SurePath liquid cytology solution

Storage and Handling

Ship specimen at ambient except biopsy ship on dry ice.

Specimen Stability

ThinPrep, SurePath solutions: 18-25°C for 21 days

Cervical or vaginal swab: 18-25°C for 14 days

Biopsy stable frozen at -20°C indefinitely

CPT Codes

HPV Test: 87621

HPV Genotyping: 83891, 83892 x 4, 83896 x 6, 83903 x 2, 83908 x 2, 83912

Turnaround Time

HPV Test: 3 days

HPV Genotyping: 7-10 days

Identification of High-Risk HPV Types and Cervical Cancer

Cervical cancer is the second most common cancer in women worldwide, and 95 percent of all cervical carcinomas are caused by specific types of HPV.

Despite the existence of more than 100 HPV types, only about 15 have been established as oncogenic or “high risk.” The Digene Hybrid Capture 2 assay is used in clinical practice for the triage of women with equivocal cytology results (ASC-US) and in conjunction with a Pap test for general screening of all women 30 years of age and older.

While the clinical utility of high-risk HPV screening is well established, several recent studies have also highlighted the clinical utility of HPV genotyping. In particular is the observation that HPV types 16 and 18, which collectively cause approximately 70 percent of cervical cancers worldwide, are also associated with increased cumulative incidence rates for CIN3+ / cervical cancer when compared to other high-risk HPV types.

HPV16 / 18 Genotyping

To identify the presence of HPV 16 / 18 in a high-risk patient, MPLN offers HPV genotyping (INVADER® technology). This test may provide increased clinical utility for early detection of women at greatest risk for the development of CIN3+ / cervical cancer.

Clinical Advantages

HPV genotyping would allow the clinician to:

- Focus attention on women with HPV type 16 or 18 at greatest risk of cervical cancer⁴
- Permit less aggressive management of women without type 16 or 18 HPV infections⁴
- Cytology negative HPV HR positive women 30 years of age and older are generally retested after 6-12 months. By testing for HPV 16/18, a positive result would allow the women to be referred to colposcopy sooner and for more aggressive monitoring of the disease process¹



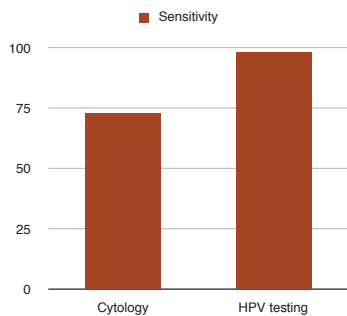
Guidelines

Standard of care now includes high-risk HPV DNA testing in combination with cytology for primary cervical cancer screening³.

Current guidelines recommend HPV testing as the preferred method of follow-up evaluation for women age 20-30 with ASC-US cytology.

- If testing is high-risk HPV negative, a repeat Pap is recommended in 12 months.
- If testing is high-risk HPV positive, colposcopy is recommended.

Screening with the HPV test in conjunction with a Pap smear is now also recommended for women age 30 and over.



The current clinical update from the ASCCP on HPV Genotyping recommends testing on women 30 years and older who are cytology negative and HPV HR positive. Detection of HPV 16/18 is clinically useful in determining referral to colposcopy, whereas a negative result could be followed up with repeat cytology and HPV high-risk testing in 12 months.

StrataFLEX™

The high-risk HPV test and HPV genotyping are components of StrataFLEX™, MPLN's innovative health management strategy that provides patient-specific reflex testing options to meet diagnostic challenges in a timely, cost effective manner.

For more information about StrataFLEX, HPV testing and genotyping, contact your local account representative or a client service specialist at 800.932.2943.

About MPLN

Pursuing excellence in laboratory medicine since 1989, MPLN offers integrated testing and professional diagnostic consultations to meet health management challenges for physicians and their patients.

Headquartered in Maryville, Tennessee, MPLN is a fully-licensed laboratory certified by the Clinical Laboratory Improvement Amendment, accredited by the College of American Pathologists, and licensed in the states of Tennessee, New York, Florida and Maryland.

References

1. ASCCP Clinical Update HPV Genotyping (2009).
2. ASCCP: Use of HPV Genotyping to Manage HPV HR Positive/Cytology Negative Women 30 Years and Older Algorithm (2009).
3. Wright TC et al. (2007). 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *Am. J. Obstet. Gynecol.* 197:346-355.
4. Khan MJ et al. (2005). The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice. *JNCI* 97:1072-1079.
5. Munoz et al. (2003). Epidemiologic classification of human papillomavirus types associated with cervical cancer. *N Engl J Med* 348:518.
6. Sherman et al. (2003). Determinants of Human Papillomavirus load among women with histological cervical intraepithelial neoplasia 3: Dominant impact of surrounding low-grade lesions. *Cancer Epidemiol Biomarkers Prev* 12:1038.
7. Schlecht NF et al. (2001). Persistent human papillomavirus infection as a predictor of cervical intraepithelial neoplasia. *JAMA* 286:3106-3114.

Trademarks:

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