

Laboratory Bulletin

Important News from DCL Medical Laboratories



May 2009

FDA Approved HPV 16/18 Genotyping now performed in-house at DCL

DCL is pleased to announce that we are now able to offer an FDA-approved HPV 16 and 18 Genotyping assay as an in-house test. HPV 16/18 Genotyping can provide valuable assistance to physicians when determining the next steps for patients who test HPV HR positive and Pap negative.

This Laboratory Bulletin contains important information about HPV 16/18 Genotyping and how to request this testing from DCL Medical Laboratories. If you have any questions, please contact DCL Client Services at (317) 874-1334 or toll free at (866) 874-1334.

HPV 16 and 18 Genotyping

Human papilloma virus (HPV) is one of the most common sexually transmitted infectious pathogens. There are over 50 HPV genotypes that are known to infect the genital tract. Of these, only a small number of subtypes have been clinically linked to a causative source of cervical cancer, conventionally recognized as "high-risk." Of the 14 recognized high-risk types of HPV, types 16 and 18 are highly prevalent and are more oncogenic than other high risk types.

Several studies have demonstrated that cytology negative women that are positive for HPV 16 or 18 are at greater risk of having or developing CIN3+ than women with LSIL cytology. In addition, the presence of high-risk HPV DNA in conjunction with an equivocal or ambiguous cytology result (ASC-US) is consistent with increased risk for having an underlying cervical intraepithelial neoplasia of grade 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, determination of HPV status is a useful adjunct in the clinical management of patients with ASC-US cytology and assists in risk assessment for monitoring or more aggressive treatment regimens.

Based on studies reported in 2006, it was determined that in cytology negative women, 30 years of age and older, who are HPV high-risk positive, further clarification of HPV 16/18 genotype status would be clinically useful for triage of patients between recommendation for colposcopy and those who could be followed-up with repeat cytology and high-risk HPV testing in 12 months.

HPV 16 and 18 Genotyping	
Collection Container:	ThinPrep vial
Storage/Stability:	30 days room temperature
Turnaround Time:	1 - 3 days
Preferred amount:	4.0 mL
Minimum amount:	2.0 mL
Centrifuge required?:	No
Fasting required?:	No
Method:	Invader® chemistry
Reference Range:	Not detected
Special Instructions:	HPV 16/18 genotyping may be requested through two methods: 1. An automatic reflex supported by a signed physician acknowledgement letter 2. By faxing a completed add-on request form to DCL Client Services at (317) 874-1404
Clinical Utility:	<ul style="list-style-type: none">• Monitoring disease progress in infected patient with HPV high risk.• Monitoring patient with negative cytology and positive HPV testing• Selecting best available therapy for infected patient• Treatment monitoring• HPV disease prevention
CPT: 87621 x2	Medicare Reimbursement*: \$51.25 x2

* Per Jan. 2009 Clinical Diagnostic Laboratory Fee Schedule for Indiana.

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DCL uses the Hologic Cervista™ HPV 16/18 genotyping assay. This test has been approved by the FDA for adjunctive use with the high risk HPV test and cervical cytology to assess the presence or absence of specific high-risk HPV types, and for adjunctive use with the high risk HPV test in patients with ASC-US cervical cytology results to assess the presence or absence of specific high-risk HPV types. The Cervista™ HPV 16/18 assay is based on Invader® chemistry that uses cleavase enzyme and is very specific for genotyping.

HPV 16/18 Genotyping may be ordered by submitting a DCL Add-On Request Form. Instructions for submitting the request appear at the top of the form. DCL also offers an automatic reflex for physicians who have signed a physician acknowledgement letter requesting the reflex. For more information about the HPV 16/18 Genotyping automatic reflex, please contact your account representative.

References

1. Eduardo L. Franco, Thomas E. Rohan, and Luisa L. Villa. Epidemiologic Evidence and Human Papillomavirus Infection as a Necessary Cause of Cervical Cancer. *J Natl Cancer Inst* 1999; 91: 506-511.
2. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 61, April 2005. Human papillomavirus. *Obstet Gynecol*. 2005 Apr; 105(4):905-18.
3. Wright TC, Jr., Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, and Solomon D. 2007. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *Am J Obstet Gynecol* 197(4): 346-355.
4. Meijer CJ, Snijders PJ, and Castle PE. 2006. Clinical utility of HPV genotyping. *Gynecol Oncol* 103: 12-17.
5. Cervista™ HPV 16/18 an in vitro diagnostic test for the detection of DNA from Human Papillomavirus (HPV) Type 16 and Type 18 in Cervical Specimens. 2009 Third Wave Technologies, Inc.