

NEW TEST ANNOUNCEMENT

Notification Date: August 14, 2013

Effective Date: August 20, 2013

**HPV Genotyping for types 16 & 18 on Pap Cytology Specimens
Now available in the CVMC Laboratory***Why is testing for HPV 16 & 18 genotypes important?*

HPV types 16 & 18 are generally considered the two most highly oncogenic and persistent high-risk HPV types, associated with approximately 70% of cervical cancers. A prominent long-term study reported that types 16 and 18 are respectively 5.5 and 4.5 times more likely to cause CIN 3+ than all other high-risk HPV types combined.

Reference: Khan MJ, Castle PE, Lorincz AT, et al. 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. *J Natl Cancer Inst.* 2005; 97:1072-1079.

When is HPV 16 & 18 Genotyping recommended?

*** HPV 16/18 Genotyping should be used only in patients who have tested positive in the High-Risk HPV screening test.**

*** Current ASCCP guidelines recommend HPV 16/18 Genotyping in women over age 30 who have negative Pap cytology but a positive high-risk HPV screening test.** In this situation, presence or absence of HPV 16 or 18 can be clinically useful for determining which women should be referred for immediate colposcopy, and which could be followed-up with repeat cytology and high-risk HPV testing in 12 months.

Note that current guidelines do not recommend genotyping for HPV 16/18 in management of HPV positive patients with ASC-US Pap cytology (atypical squamous cells of undetermined significance). The guidelines state: "Colposcopy is indicated for all women with HPV and ASC-US, regardless of genotyping result".

Reference: 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors, ASCCP, *Journal of Lower Genital Tract Disease*, Volume 17, Number 5, 2013, S1-S27.

What type of specimen is needed for HPV 16/18 Genotyping?

Specific testing for HPV 16 and 18 genotypes is done in conjunction with testing for High-Risk HPV (which tests for all types of high risk HPV), performed on the Cervista platform using Invader chemistry. **All testing is done on the same ThinPrep specimen collected for Pap cytology.**

New Cytology Requisitions include updated options for HPV Testing which incorporate current ASCCP Guidelines:

- Pap plus HR-HPV Cotest (for women age 30 and over)
- Reflex to HR-HPV if ASCUS (for women age 21 and over)
- Reflex to HPV 16/18 Genotyping if HR-HPV positive / Pap negative
- Pap with HR-HPV testing regardless

We are pleased to offer this new test and encourage you to call the CVMC Laboratory with questions or comments regarding HPV Testing for your patients.