

## **HUMAN PAPILOMAVIRUS (HPV) TEST CHANGE**

The American Society for Colposcopy and Cervical Pathology (ASCCP) has developed specific algorithms for patients undergoing Pap smear and HPV testing. Their recommendations are in response to the FDA approval of the Cervista™ HPV High Risk Screen and Cervista™ HPV 16/18. The screen detects 14 high risk types including 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68 and 66, while the Cervista™ HPV 16/18 specifically detects only the 16 and 18 genotypes which account for 70% of cervical cancers.

The FDA Approved Indications are as follows:

### Cervista™ HPV High Risk Screen

1. To screen patients with ASC-US cervical cytology results to determine the need for referral to colposcopy.
2. In women 30 years and older the Cervista™ HPV HR test can be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV types.

### Cervista™ HPV 16/18

1. In women 30 years and older the Cervista™ HPV 16/18 may be used adjunctively with the Cervista™ HPV HR test in combination with cervical cytology to assess the presence or absence of high-risk HPV types 16 and 18.
2. To be used adjunctively with the Cervista™ HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of specific high-risk HPV types 16 and 18. The results of this test are not intended to prevent women from proceeding to colposcopy.  
(<http://www.cervistahpv.com/laboratory>)

Physicians Laboratory Services has offered HPV Genotyping High Risk/Low Risk for several years. This test has been well accepted by our clients and provided physicians with the necessary information to properly triage patients with abnormal Pap smear and HPV results. However, due to the changing guidelines that support the FDA approved Cervista platform, as well as the conversion to more stringent insurance reimbursement protocols based on the ASCCP algorithm, Physicians Laboratory will change our HPV testing methodology on June 1, 2012.

## **EFFECTIVE JUNE 1, 2012**

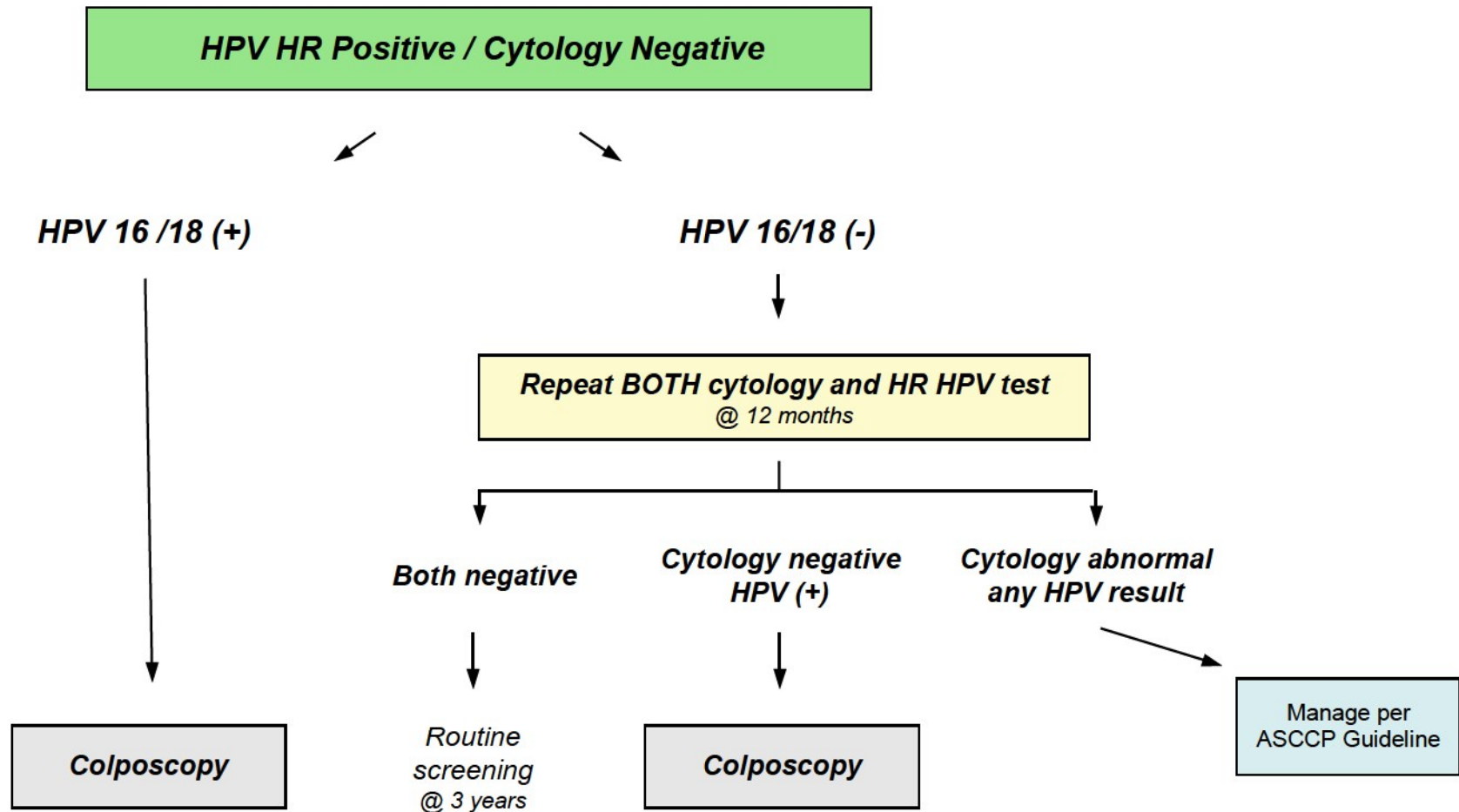
#7680 HPV High Risk Screen with Reflex to HPV 16/18 Genotypes  
CPT: 83621 Screen Only; 83621x2 If Screen & 16/ 18 Genotype Performed  
Specimen Type: ThinPrep® or SurePath™  
Performed: Monday – Friday (Molecular Department)

**\*\*TESTING WILL NO LONGER BE PERFORMED ON TISSUE SAMPLES\*\***

Any questions regarding this change may be directed to:

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## Use of HPV Genotyping to Manage HPV HR \* Positive / Cytology Negative Women 30 Years and Older



\* Test that detects any of the 14 high-risk (oncogenic) types of HPV