

## HPV REFLEX TEST GUIDANCE

The American Society for Colposcopy and Cervical Pathology (ASCCP) provides the recommendations for the use of HPV Reflex Testing. CMC uses Cervista HPV methodology for HPV testing. Refer to the ASCCP website for complete guidelines for management of women with abnormal pap test results: <http://www.asccp.org/consensus/cytological.shtml>

### **FDA Approved Indications**

The FDA-approved clinical indications for Cervista™ HPV HR are similar to those of the Hybrid Capture® 2 HPV DNA Assay. These are:

#### **High Risk HPV Reflex Testing**

- 1. To screen patients with ASC-US cervical cytology results to determine the need for referral to colposcopy (Reflex testing for ASC-US pap results)*
- 2. Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.*

#### **HPV Genotype Testing for HR Types 16/18**

The FDA-approved indications for the Cervista™ HPV 16/18 test are:

- 1. In women 30 years and older the test may be used adjunctively with the Cervista™ HPV HR test in combination with cervical cytology to assess the presence or absence of specific high-risk HPV types.*
- 2. 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. The results of this test are not intended to prevent women from proceeding to colposcopy.*