**CYTOLOGY DIAGNOSIS**

**DIAGNOSIS:** NEGATIVE

**Specimen Adequacy:** Satisfactory for evaluation; endocervical/transformation zone component present.

**Interpretation:** Negative for intraepithelial lesion or malignancy

**Notes:** The cervical smear is a screening test with an inherent, but low probability of error. The irreducible false negative rate is approximately 5%. A negative report indicates a low probability of significant cervical pathology within the next year. Nevertheless, your patient should be encouraged to consult you promptly if she experiences new symptoms.

**CYTOLOGY & HPV-HR HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Cytology</th>
<th>HPV</th>
<th>Accession #</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/2014</td>
<td>ASCUS</td>
<td>POSITIVE</td>
<td>WHC-14-XXXXX</td>
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**MICROSCOPIC IMAGE**

**HPV PRIMARY SCREENING RESULT:**

**High Risk HPV:** POSITIVE

Assay of the patient's sample has detected one or more of the 14 high risk subtypes of HPV. Presence and persistence of HPV has been implicated in greater than 99% of cervical cancers. The pathologic diagnosis of dysplasia and cancer are, however, based on morphologic assessment, such as Pap test, biopsy, and/or excision. See auto-reflex HPV Genotype result.
HPV 16,18, OTHER 12 POOLED RESULT:*  

**HPV Subtype 16:** NEGATIVE  
**HPV Subtype 18:** NEGATIVE  
**HPV-Other 12 Pooled:** POSITIVE  

Assay of the patient's sample has detected one or more of the following 12 high risk subtypes of HPV: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. Presence and persistence with one or more of these other high risk genotypes is associated with increased risk for development of cervical cancer and its precursors. The pathologic diagnosis of dysplasia and cancer are, however, based on morphologic assessment, such as Pap test, biopsy, and/or excision. Assay of the patient's sample does NOT detect presence of high-risk HPV genotypes 16 or 18. These results do not exclude the possibility of HPV not detected due to sampling error or assay sensitivity. See auto-reflex to Pap test.

**Methodology:** The cobas® HPV test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16 and HPV 18, while concurrently detecting the rest of the HR HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). Other HR subtypes of HPV, either currently characterized or uncharacterized, exist but are not detected by this assay.

**CHLAMYDIA / GONORRHEA**

**CHLAMYDIA:** POSITIVE  
**GONORRHEA:** NEGATIVE  

Assay of the patient's specimen detects presence of DNA for Chlamydia trachomatis (CT). There is no evidence of DNA for Neisseria gonorrhoeae (NG). The current result for NG does not exclude the possibility of an infection not detected due to errors in sample collection, the presence of inhibitory substances, or levels of the organism not detected due to assay sensitivity. If clinical suspicion of infection remains, repeat collection and testing by culture based methodology is recommended. Confirmatory testing via culture-based methods, including antimicrobial susceptibility, is indicated for effective infection management of CT. Current guidelines recommend the importance of testing sexual partners of this individual for CT by nucleic acid assay, regardless of presence or absence of clinical symptoms. Routine testing for these two infections is part of the recommended standard of care by the Centers for Disease Control and Prevention and the American College of Obstetrics and Gynecology. This test is not recommended for the evaluation of suspected sexual abuse, for other medical-legal indications, or for evaluation of children under the age of consent. In these circumstances, culture is the test of choice.

**Methodology:** The cobas® CT/NG test automatically extracts nucleic acids, including DNA of CT and NG, and follows with real time PCR amplification of target DNA sequences for CT and NG using specific complementary primer pairs. The assay detects presence of fluorescent-labeled CT and NG specific oligonucleotide probes, along with simultaneous and continuous monitoring of an internal control, for detection of disease in both symptomatic and asymptomatic individuals.

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All ThinPrep Pap specimens are analyzed by the ThinPrep Imaging System (Hologic Corp.), an automated imaging and review system, which assists the cytotechnologist and/or pathologist in evaluation of cells on ThinPrep Pap Tests.