

**False positives and false negatives can both do harm to patients**

**False positives**

- Unnecessary treatment impacts patients' lives
- Needless emotional burden of patient<sup>5</sup>
- Unneeded procedures can cause pain and harm to the patient<sup>6,7</sup>
- Time lost by clinician and patient<sup>7</sup>
- Undue financial costs to patient<sup>7,8,9</sup>

**False negatives**

- False sense of security for patient
- Patient may go up to 5 years before being screened again<sup>10</sup>

**The cobas® HPV Test increases patient safety by striving to eliminate false negative and false positive results.**

**Why wait to get all the answers she needs?**

The **cobas®** HPV Test allows you to manage your patients with greater precision and efficiency by individually identifying the highest-risk genotypes, HPV16 and HPV18, while simultaneously providing pooled results for the twelve other hrHPV genotypes.



**800-423-0504**  
**www.ael.com**  
**AEL Test Code: HPVH**



**Do you have confidence in your HPV test?**

*The right test makes all the difference*



**For additional information, please visit [www.hpv16and18.com](http://www.hpv16and18.com) or call 1-877-906-8983.**

**References**

- 1 cobas HPV Test [package insert] Branchburg, NJ: Roche Molecular Systems, Inc; 2011.
- 2 Hybrid Capture 2 High-Risk HPV DNA Test [package insert] Gaithersburg, MD: Digene Corporation; 2004.
- 3 Cervista HPV HR [package insert] Madison, WI: Third Wave Technologies, Inc; 2009.
- 4 APTIMA HPV Assay [package insert]. San Diego, CA: Gen-Probe Incorporated; 2011.
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- 6 Summaries for patients. Screening for cervical cancer: recommendations from the U.S. Preventive Services Task Force. *Ann Intern Med.* 2012; 156(12):1-44.
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- 9 Centers for Medicare and Medicaid Services Website. <http://www.cms.gov/Medicare/Medicare.html> Accessed April 24, 2013.
- 10 Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *Am J Clin Pathol.* 2012; 137:516-542.

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# What determines cervical cancer risk?

When determining the risk of cervical cancer, you must have confidence in your HPV test to deliver the most accurate and reliable results.

Clinicians expect results that are accurate and reliable, and patients deserve them.

## The cobas® HPV Test gives you the confidence to deliver reliable results for all your HPV testing needs.

### Reflex testing



For women with ASC-US cytology

### Co-testing

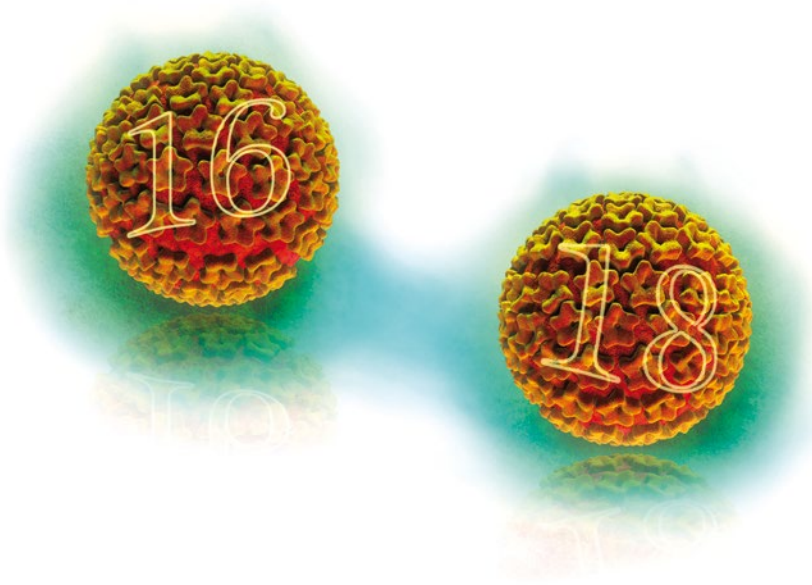


ACOG prefers over reflex testing for women 30 to 65 years old

### Genotyping



Identifying HPV16 and HPV18 for best risk assessment



# cobas® HPV Test

## Detects HPV DNA

Organizations such as ACOG, ACS, ASCCP, and NCCN base their screening guidelines on results obtained from HPV tests that detect DNA.

## Internal cellular control

A true negative result using the **cobas** HPV Test will show a negative result for HPV, but will always show the presence of human  $\beta$ -globin from the patient's cells. The internal control monitors the presence of human cells and the completion of the entire test process.

## No cross-reactivity

The design of the **cobas** HPV Test drives hrHPV genotype specificity to help eliminate cross-reactivity with low-risk HPV genotypes. The **cobas** HPV Test is the only IVD test without an FDA-required disclosure of low-risk cross-reactivity.

## Small 1 mL sample size

The **cobas** HPV Test uses a small sample size to help eliminate the inconvenience of patient call-backs, due to Quantity Not Sufficient (QNS) results.

## Identifies all 14 hrHPV genotypes

The **cobas** HPV Test detects all fourteen hrHPV genotypes – 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The oldest HPV test on the market, HC2 (Qiagen) only detects thirteen.

## 3 results in 1 test

The **cobas** HPV Test is the only clinically validated, FDA-approved assay that simultaneously provides individual results on the highest-risk genotypes – HPV16 and HPV18 – and a pooled result on the twelve other hrHPV genotypes. This allows genotyping to take place during co-testing. No other HPV test does this!

## FDA approved

The ATHENA Study is the largest US-based cervical cancer clinical trial. Using a test that is clinically-validated through the landmark ATHENA Study provides confidence in the clinical reliability, relevance, and accuracy of its performance.

# The right test makes all the difference

	cobas® HPV test <sup>1</sup>	digene HC2 HPV Test <sup>2</sup>	Cervista® HPV Test <sup>3</sup>	APTIMA® HPV Assay <sup>4</sup>
<b>Detects HPV DNA</b>	✓	✓	✓	○
<b>Internal cellular control</b>	✓	○	✓	○
<b>No cross-reactivity</b>	✓	○	○	○
<b>Small 1 mL sample size</b>	✓	○	○	✓
<b>Identifies all 14 genotypes</b>	✓	○	✓	✓
<b>3 results in 1 test</b>	✓	○	○	○

digene HC2 HPV Test is a product of QIAGEN. Cervista HPV Test and APTIMA HPV Assay are products of Hologic.

