

With mRNA-based HPV testing,  
the result comes straight  
from the messenger.

**The Aptima HPV Assay:**

Identifying the presence and activity of high-risk HPV infections.

**The Aptima HPV 16 18/45 Genotype Assay:**

The next-generation genotype test.

Worth it.

**Aptima® HPV**  
Assay

**Aptima® HPV 16 18/45 Genotype**  
Assay



## The Aptima® HPV assay targets E6/E7 mRNA.

Identifies high-risk HPV infections that are present and active.

Nearly all sexually active men and women will have an HPV infection at some point in their lives. Very few will go on to develop cancer.<sup>2</sup>

The Aptima HPV assay targets high-risk HPV mRNA.<sup>3</sup>

Studies have shown mRNA identifies the presence and activity of a high-risk HPV infection.<sup>3,4</sup>

HPV DNA tests only identify the presence of any of the 14 high-risk HPV types.

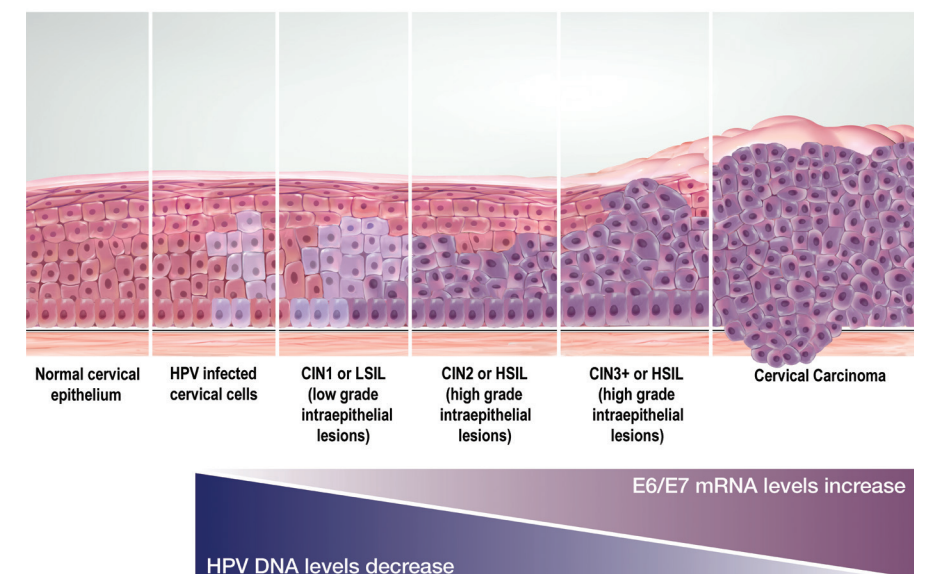
*“The optimal screening strategy should identify those cervical cancer precursors likely to progress to invasive cancers (maximizing the benefits of screening) and avoid the detection and unnecessary treatment of transient HPV infection and its associated benign lesions that are not destined to become cancerous (minimizing the potential harms of screening).”*

— Saslow, et al.<sup>1</sup>

# E6 E7

**E6/E7 mRNA** expression is indicative of the HPV infections most likely to lead to disease.<sup>3,4</sup>

### mRNA and Cervical Disease



Because HPV DNA levels may decrease as infections progress toward cancer, some HPV DNA tests may provide false-negative results in more than 10% of the most severe cervical disease cases.<sup>5</sup>



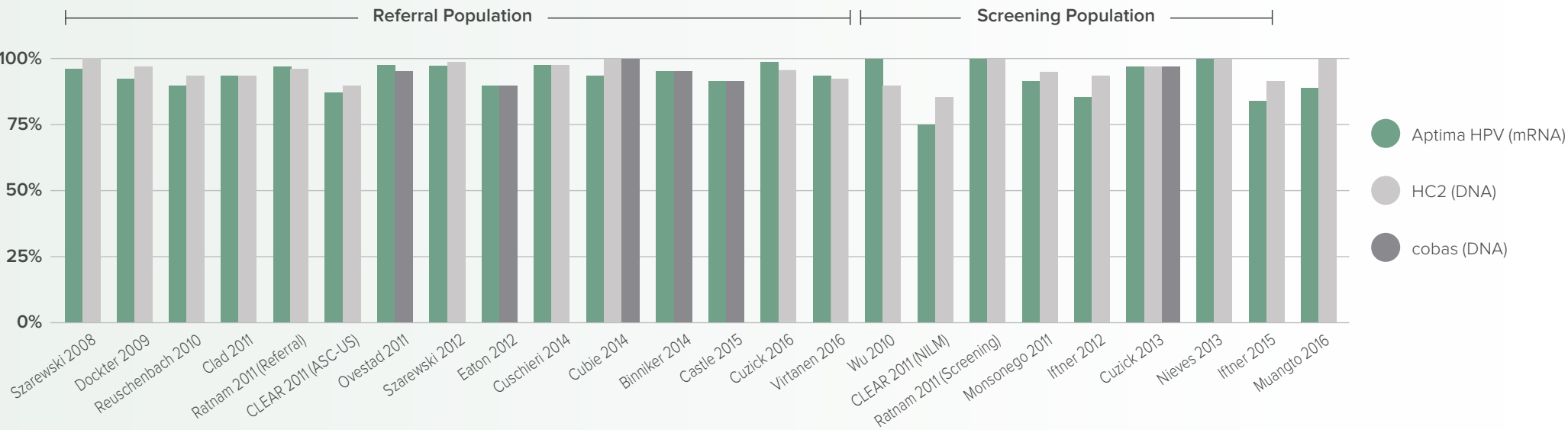
# Maximizing the Benefits

With intervals between recommended screenings for cervical cancer extended, identifying those patients at risk becomes increasingly important. Excellent sensitivity means minimizing false-negative test results. The Aptima HPV assay, which targets mRNA, has shown the same excellent sensitivity as DNA-based tests:

The Aptima HPV assay provides the same excellent sensitivity you’ve come to expect from DNA-based tests.

## Sensitivity†

Clinical Sensitivity for ≥ CIN3<sup>6-27</sup>



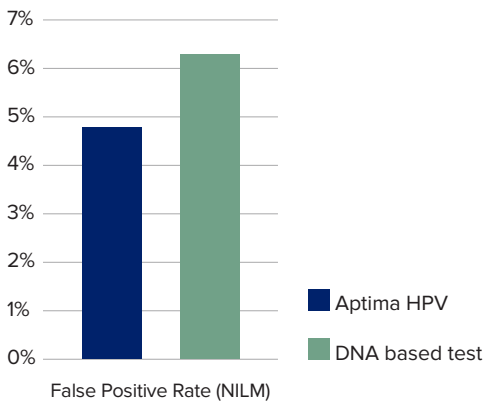
\*Clinical sensitivity for ≥ CIN2

†This chart is a representation of clinical data from multiple published sources. The clinical studies represented within these sources were conducted using different study designs with various assays.

## While Minimizing Potential Harms

Minimizing false-positives helps clinicians target the right patients for colposcopy. In the NILM arm of the CLEAR trial, the Aptima HPV assay showed 24%<sup>‡</sup> fewer false-positive test results compared to a DNA-based test.<sup>11</sup>

### Fewer False-Positive Results<sup>11‡</sup>



‡The graph above represents data adapted from the Aptima HPV Assay Package Insert Table 13.

## Aptima® HPV Assay Showed:

24%

fewer false-positive test results compared to a DNA-based test.<sup>11</sup>

- Minimizing difficult patient conversations
- Minimizing the potential for over-treatment

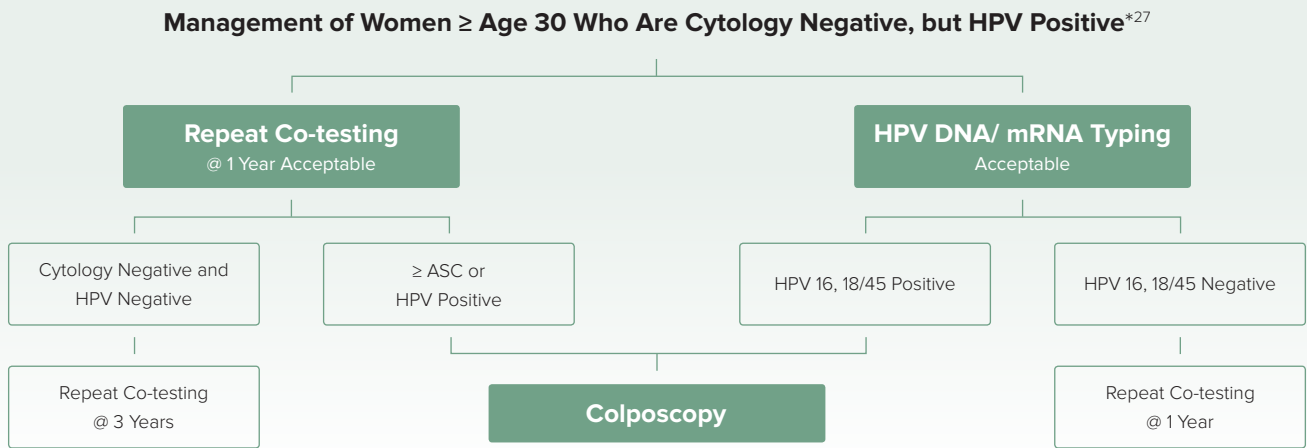
The **Aptima® HPV 16 18/45 Genotype** Assay:  
The next-generation genotype test.



- Amy D. (32 years)**
- Routine screening
  - No history of abnormal pap tests
  - Undergoes testing with Pap+HPV together
  - Screening result: normal cytology/positive hrHPV

*What is the most appropriate next step?*

**Genotyping** Algorithm



When Do Guidelines **Recommend Genotyping?**<sup>27,28</sup>

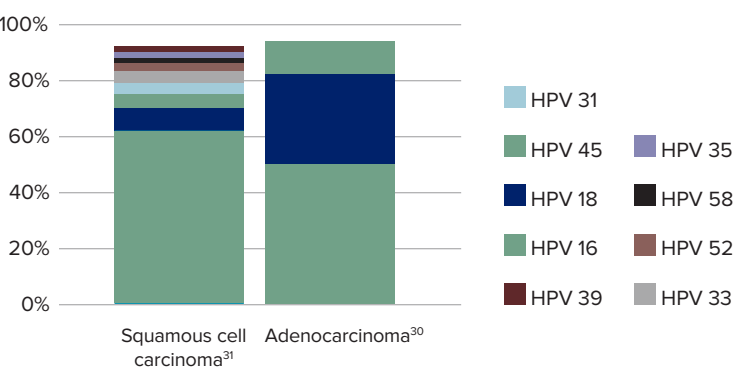
Only for women over 30 with a negative Pap and positive hrHPV test result.

3.7%

Cytology-negative and HPV-Positive co-test results occurred in 3.7% of women older than 30 years.<sup>29</sup> – ACOG PB157

The **Next-generation** Genotype Test

**HPV Genotypes In Invasive Cervical Cancer<sup>30</sup>**



**HPV Type 45:**

- Is uncommon and only prevalent in 0.4% of women with normal cytology.<sup>30</sup>
- Is the third most common HPV type in invasive cervical cancer.<sup>30-31</sup>
- Adenocarcinoma is associated with types 16, 18 and 45.<sup>32-33</sup>

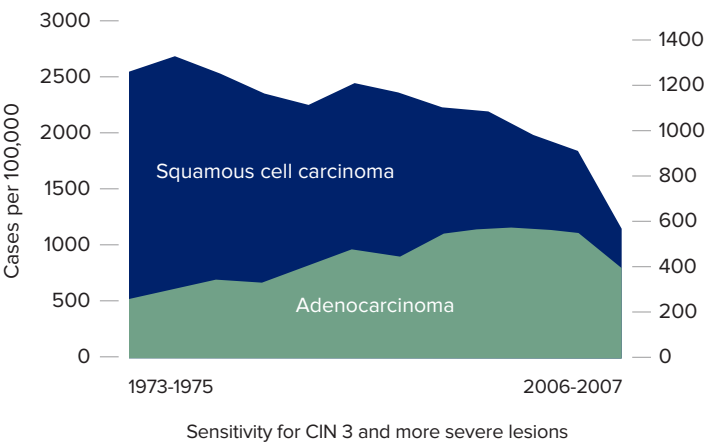
The Aptima HPV 16 18/45 genotype assay targets these genotypes. These genotypes identify more women at risk with minimal impact to colposcopy rates.<sup>30</sup>

**Adenocarcinoma** is on the Rise<sup>34</sup>

Pap+HPV Together™ (co-testing) can help identify patients at risk for cervical adenocarcinoma.<sup>34</sup>

Between 1973 and 2007<sup>34</sup>:

- 61% decrease in squamous cell carcinoma
- 32% increase in adenocarcinoma

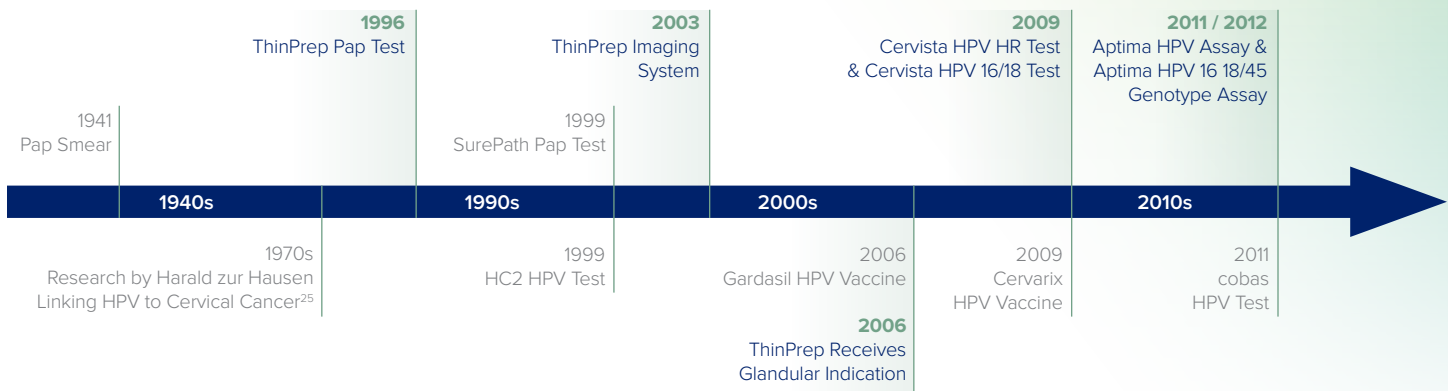


HPV types 16, 18, and 45 are associated with up to

94%

of HPV-related cervical adenocarcinomas.<sup>30</sup>

\* Adapted from: American Society for Colposcopy and Cervical Pathology. 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Test and Cancer Precursors. J Low Genit Tract Dis. 2013;17(5):S1-S27.



## ThinPrep® Pap test:

The only liquid-based Pap test with FDA approval/clearance for sample collection of Pap, HPV, chlamydia/gonorrhea and trichomoniasis testing from the same vial.



### FDA Approved

- ThinPrep® Pap test • Cervista® HPV HR test • Cervista® HPV 16/18 test
- Aptima® HPV assay • Aptima® HPV 16 18/45 genotype assay
- cobas® HPV test • cobas® AMPLICOR CT/NG test • Hybrid Capture 2 HPV test

### FDA Cleared

- Aptima Combo 2® assay • Aptima® *Trichomonas vaginalis* assay
- ProbeTec® *Chlamydia trachomatis* (CT) assay
- ProbeTec® *Neisseria gonorrhoeae* (GC) assay

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**Aptima® HPV Assay**

**Aptima® HPV 16 18/45 Genotype Assay**

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