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.

With mRNA-based HPV testing, the result comes straight from the messenger.
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.\(^2\)

The Aptima HPV assay targets high-risk HPV mRNA.\(^3\)

Studies have shown mRNA identifies the presence and activity of a high-risk HPV infection.\(^3,4\)

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

E6/E7 mRNA expression is indicative of the HPV infections most likely to lead to disease.\(^3,4\)

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.\(^5\)
Minimizing false-positives helps clinicians target the right patients for colposcopy. In the NILM arm of the CLEAR trial, 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

<table>
<thead>
<tr>
<th>Clinical Sensitivity for ≥ CIN3</th>
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<tr>
<td>Referral Population</td>
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- **Aptima HPV (mRNA)**: [Data Adapted from the Aptima HPV Assay Package Insert Table 13.]
- **HC2 (DNA)**
- **cobas (DNA)**

*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% fewer false-positive test results compared to a DNA-based test.

Aptima® HPV Assay Showed:

- 24%

fewer false-positive test results compared to a DNA-based test.

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

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

Management of Women ≥ Age 30 Who Are Cytology Negative, but HPV Positive

- Repeat Co-testing @ 3 Years
- HPV DNA/ mRNA Typing
  - HPV 16, 18/45 Positive
  - HPV 16, 18/45 Negative
- Colposcopy
- Repeat Co-testing @ 1 Year
- Cytology Negative and HPV Negative
- ≥ ASC or HPV Positive

When Do Guidelines Recommend Genotyping?

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. — ACOG FP157

The Next-generation Genotype Test

HPV Genotypes In Invasive Cervical Cancer

HPV Type 45:
- Is uncommon and only prevalent in 0.4% of women with normal cytology.
- Is the third most common HPV type in invasive cervical cancer.
- Adenocarcinoma is associated with types 16, 18, and 45.

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

HPV types 16, 18, and 45 are associated with up to 94% of HPV-related cervical adenocarcinomas.

Adenocarcinoma is on the Rise

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

Between 1973 and 2007:
- 61% decrease in squamous cell carcinoma
- 32% increase in adenocarcinoma

HPV Genotypes In Invasive Cervical Cancer

Squamous cell carcinoma

Adenocarcinoma

Sensitivity for CIN 3 and more severe lesions

1973-1975

2006-2007
ThinPrep® Pap test:
The only liquid-based Pap test with FDA approval/clearance for sample collection of Pap, HPV, chlamydia/gonorhoea 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 16/45 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