

HOLOGIC

WHEN IT
COMES TO
HPV TESTING,
TRUST THE
Messenger.



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.¹

Studies have shown mRNA identifies the presence and activity of a high-risk HPV infection.^{2,3}

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

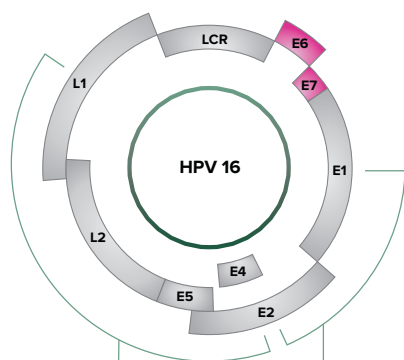
“The optimal screening strategy should identify those cervical cancer precursors likely to progress to invasive cancers (maximizing the benefits of screening) and avoid the detection and unnecessary treatment of transient HPV infection and its associated benign lesions that are not destined to become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

— Saslow, et al.⁴

Cervical Cancer Progression Model

E6/E7 mRNA expression is indicative of the HPV infections most likely to lead to disease.^{2,3,5}

HPV Genome – Genotype 16 Example



Deletions may occur during integration

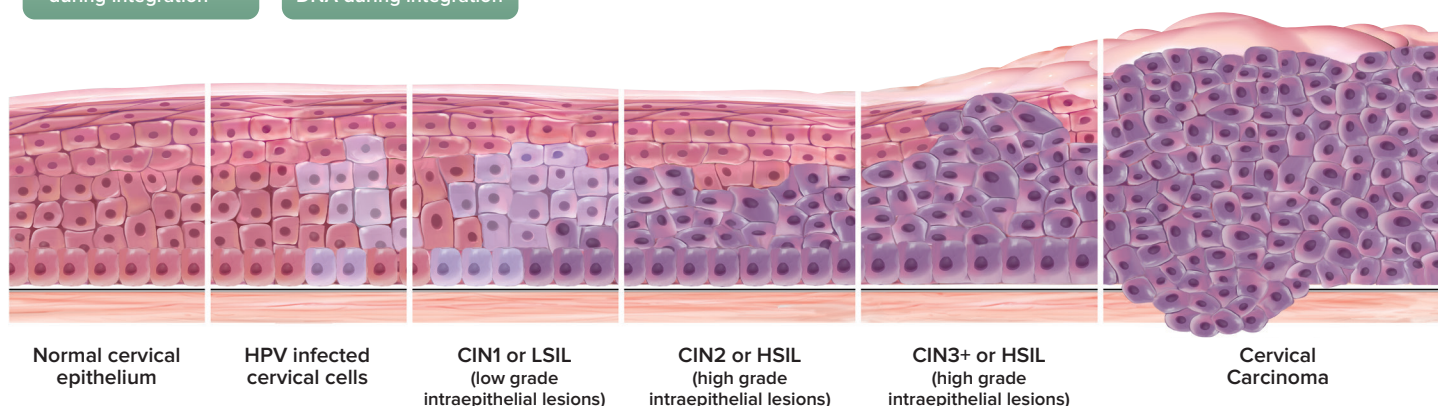
Opening of circular DNA during integration

HPV Viral mRNA



The Aptima® HPV assay targets E6/E7 mRNA and identifies high-risk HPV infections that are present and active.

Studies show mRNA identifies the presence and activity of a high-risk HPV infection. HPV DNA tests only identify the presence of any of the 14 high-risk types.



HPV DNA levels decrease

E6/E7 mRNA levels increase

HPV Detection Strategies^{6,7}

DNA vs. mRNA Assays

Improved Specificity	DNA Tests	mRNA Tests
High Sensitivity	✓	✓
Improved Specificity		✓
Low Colposcopy Referral rate		✓
Negative predictive value 10 years	✓	✓

“A major systematic review recently concluded that, compared with validated DNA assays, APTIMA mRNA was similarly sensitive, but more specific, for CIN2+. Rebolj and colleagues’ findings broadly accord with, and add to, this body of evidence.”

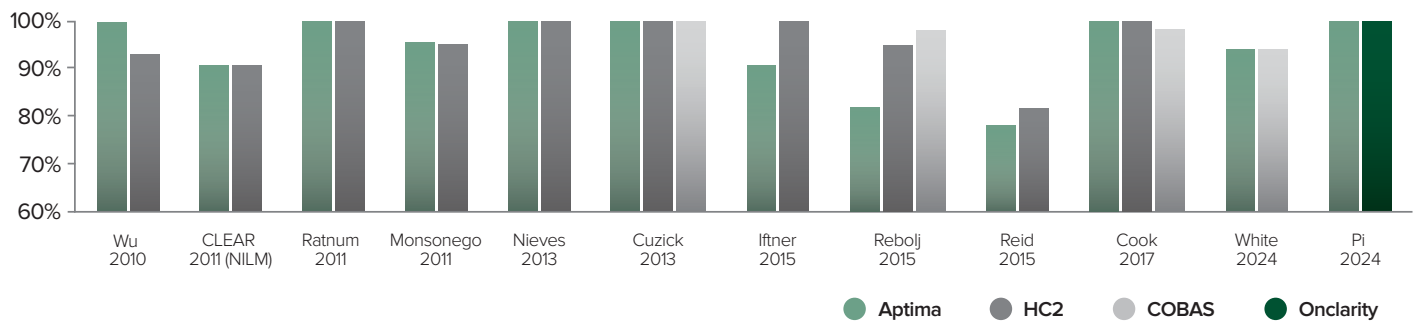
– Rebolj, et al.⁷

Maximizing Benefits & Minimizing Harms^{4,6,8-21}

HPV Test Clinical Sensitivity for ≥CIN3

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

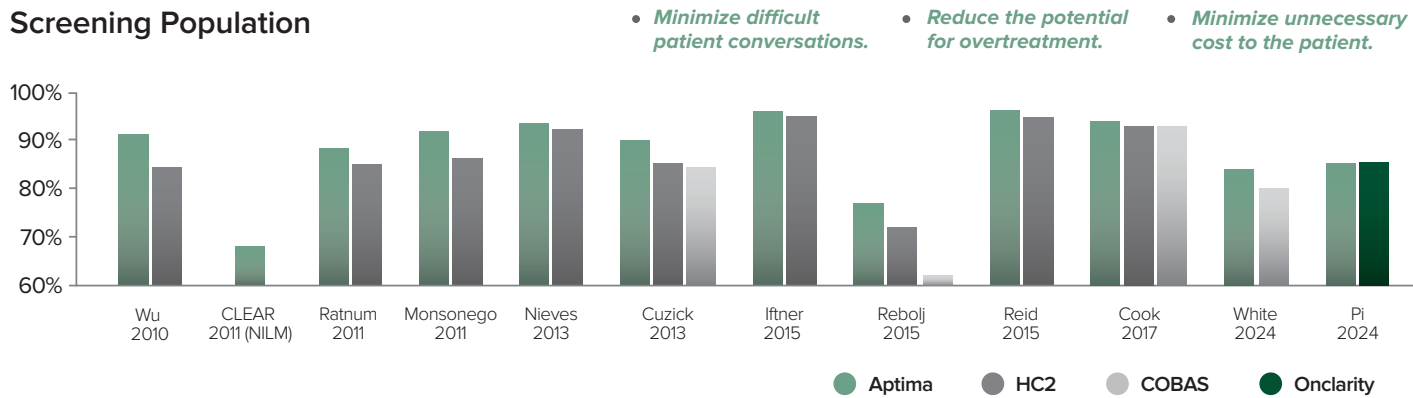
Screening Population



HPV Test Clinical Specificity for <CIN2

mRNA-based tests show equivalent sensitivity to DNA-based tests with superior specificity.

Screening Population



A Targeted Approach with Aptima® 16 18/45 Genotype Assay

Aptima HPV Detects All 14 HR HPV Genotypes⁶

14 HR HPV

16 18 45 31 51 52 33 58 35 39 68 56 59 66

Aptima HPV

16 18/45 Genotype Assay

16 18 45 31 51 52 33 58 35 39 68 56 59 66

“We confirmed the utility of 16/18 genotyping in cervical cancer screening strategies, while pooled detection of non-16/18 genotypes is sufficient”

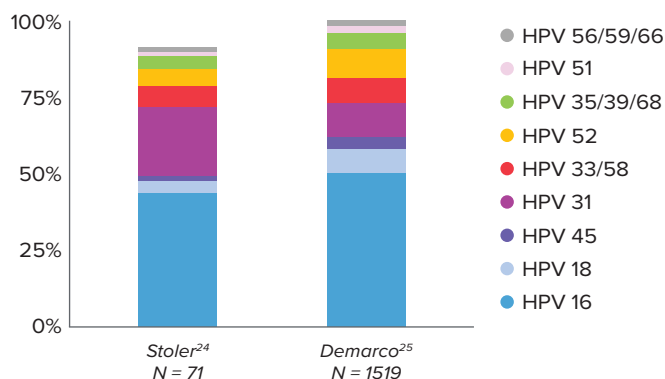
- Monsonego, et. al. ATHENA trial²²

“The IARC combines carcinogenic HPV types into 4 groups based on their risk of progression and attribution to cancer: HPV16, HPV18/45, HPV16-related types (HPV33, 31, 52, 58, 35), and the remaining other carcinogenic or probable carcinogenic types (HPV 39, 51, 59, 56, 68).”

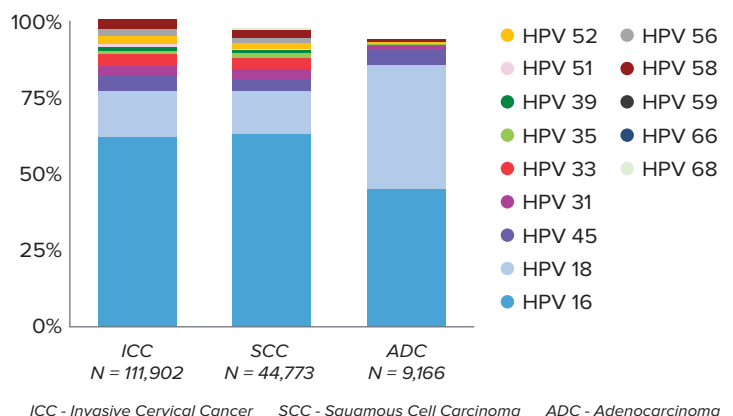
— Massad et. al.²³

HPV Genotypes in Cases of CIN3+ and Cervical Cancer

CIN3+ Cases by Genotype



Cervical Cancer Cases by Genotype²⁶



HPV type 16 associated with²⁶

- ▶ Up to 62% of Squamous Cell Carcinomas
- ▶ Up to 45% of Cervical Adenocarcinomas

HPV types 16, 18 & 45 associated with²⁶

- ▶ Up to 80% of Squamous Cell Carcinomas
- ▶ Up to 92% of HPV-related cervical Adenocarcinomas

HPV type 45^{26,27}

- ▶ Third most common HPV type in invasive cervical cancer
- ▶ Identifies more women at risk for Adenocarcinoma, with minimal impact to colposcopy

“While HPV52 and HPV33/58 were observed as the second most common types in CIN2/3, their prevalence significantly decreased in SCC/ADC, underscoring the primary impact of HPV16, 18, and 45 in these more severe cases. The importance of HPV51, HPV31, HPV59/56/66, or HPV39/68/35 was not as significant as the others, which was also reported by previous studies.”

— Pi, et al.²¹

Extensive Aptima® Assay HPV Longitudinal Data^{16,17,28-30}

mRNA based HPV assay shows safety over 10 years of longitudinal data.

1
Year



2
Years



3
Years



4
Years



5
Years



6
Years



7
Years



8
Years



9
Years



10
Years

Reid - 3 Years

"After 3-years of follow-up, women negative by either HPV test had a very low risk for CIN2+ (<0.3%)..."

Cook - 4 Years

"There was no significant difference in CIN2+ detection for AHPV vs. HC2 at baseline or at 48 months."

Forslund - 7 Years

"The observed performance of the HPV-mRNA assay suggests that the evaluated assay is non-inferior to HPV-DNA testing and can be used in cervical screening programs that target women above 30 years of age for 5-7 yearly screening."

Strang - 10 Years

"Our study found that, among this population, a negative baseline HPV test by any one of the three assays used in the HPV FOCAL Trial (HC2, CG, or AHPV), resulted in statistically similar CIN2+ and CIN3+ detection over ten years follow-up"

Visit **HologicWomensHealth.com** for more information.

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