HOLOGIC®

WHEN IT COMES TO HPV TESTING, TRUST THE *Messenger.*

Aptima® HPV Assay

Aptima® HPV 16 18/45 Genotype Assay

Extensive Aptima HPV Longitudinal Data[16,17,26-28]

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"

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]

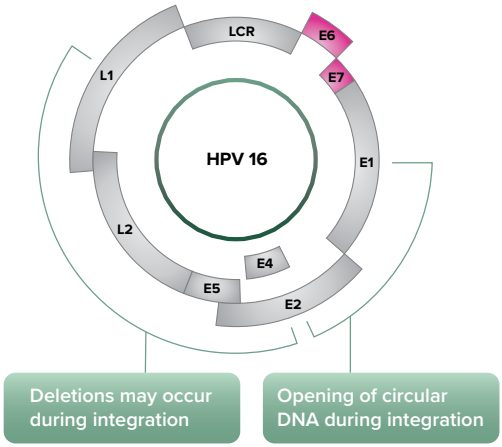
HPV DNA tests only identify the presence of any of the 14 high-risk HPV types.

> ***"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]

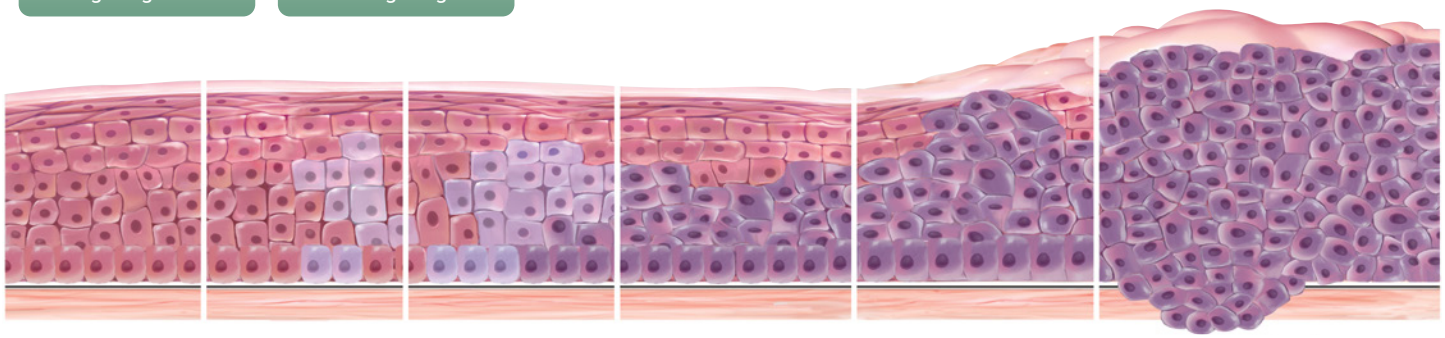
HPV Genome – Genotype 16 Example



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.



Normal cervical epithelium	HPV infected cervical cells	CIN1 or LSIL (low grade intraepithelial lesions)	CIN2 or HSIL (high grade intraepithelial lesions)	CIN3+ or HSIL (high grade intraepithelial lesions)	Cervical Carcinoma

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."

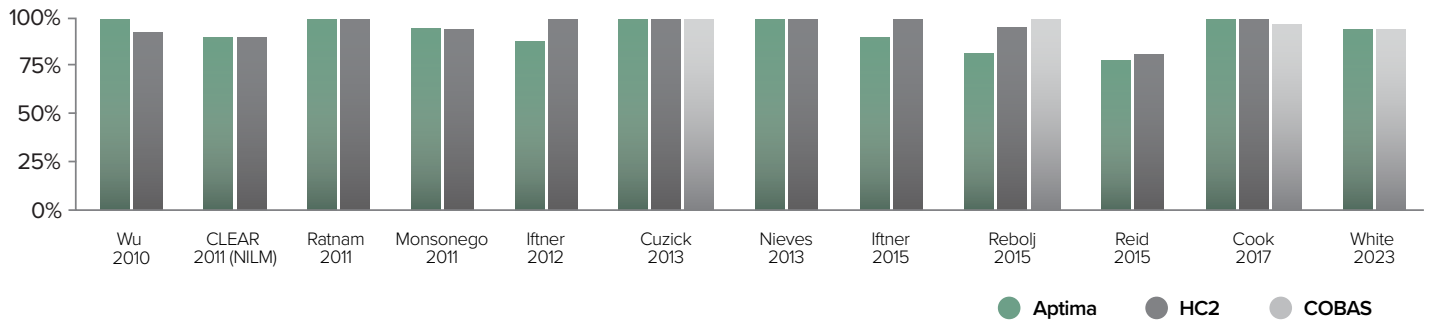
– Rebolj, et al.[7]

Maximizing Benefits & Minimizing Harms[4,6,8-20]

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

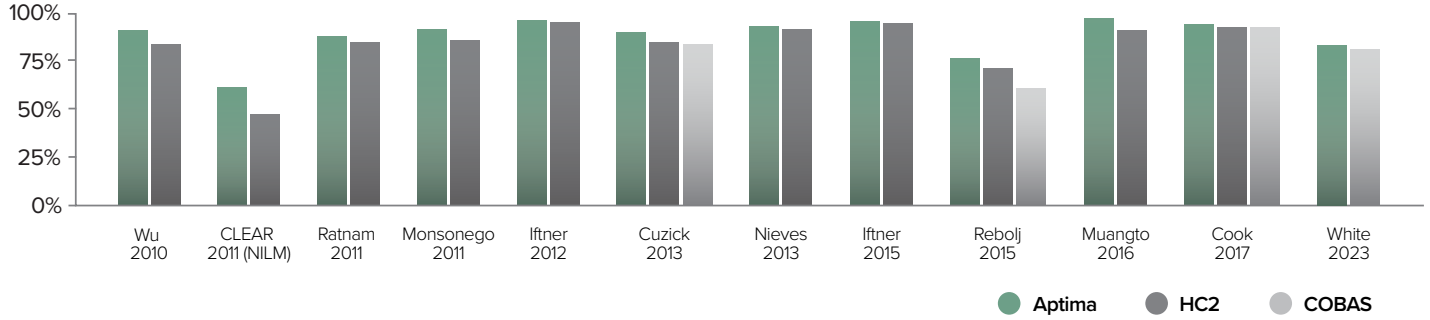


HPV Test Clinical Specificity for <CIN2

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

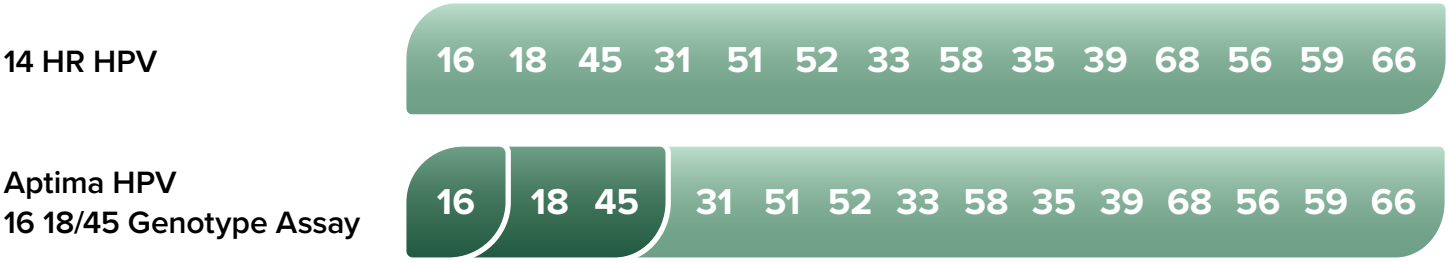
Screening Population

- ***Minimize difficult patient conversations.***
- ***Reduce the potential for overtreatment.***
- ***Minimize unnecessary cost to the patient.***



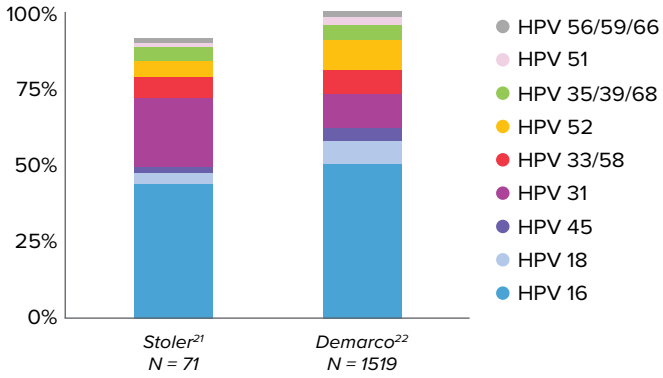
A Targeted Approach with Aptima® 16 18/45 Genotype Assay

Aptima HPV Detects All 14 HR HPV Genotypes[6]

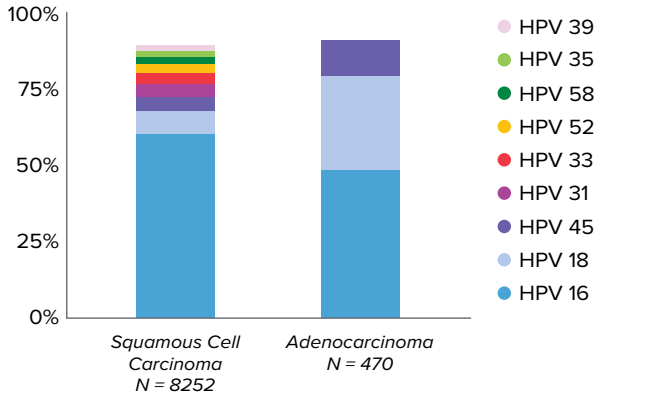


HPV Genotypes in Cases of CIN3+ and Cervical Cancer

CIN3+ Cases by Genotype



Squamous & Adenocarcinoma by Genotype[23]



HPV types 16, 18 & 45 associated with[23]

- Up to 75% of Squamous Cell Carcinomas
- 94% of HPV-related cervical Adenocarcinomas

HPV type 45[23,24]

- Is uncommon and only prevalent in 0.4% of women with normal cytology
- Third most common HPV type in invasive cervical cancer
- Identifies more women at risk for Adenocarcinoma, with minimal impact to colposcopy

HPV type 16 associated with[23]

- 62% of Squamous Cell Carcinomas
- 50% of Cervical Adenocarcinomas

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

— Monsonego, ATHENA trial[25]

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