HOLOGIC®
The Science of Sure

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

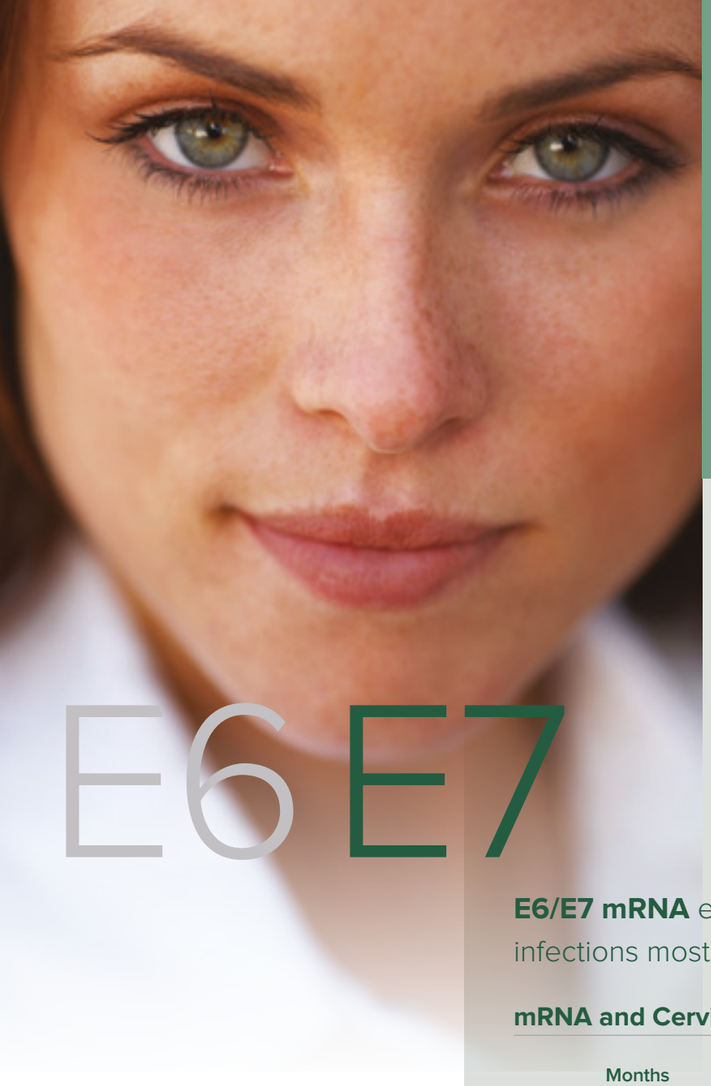
The Aptima® HPV Assay:
Identifying the presence and threat of a high-risk HPV infection.

The Aptima® HPV 16 18/45 Genotype Assay:
Enhanced detection for improved management of HPV positive patients.

Worth it.

Aptima® HPV Assay

Aptima® HPV 16 18/45 Genotype Assay



The Aptima® HPV assay targets E6/E7 mRNA.

Don't just sense a presence.
Sense a threat.

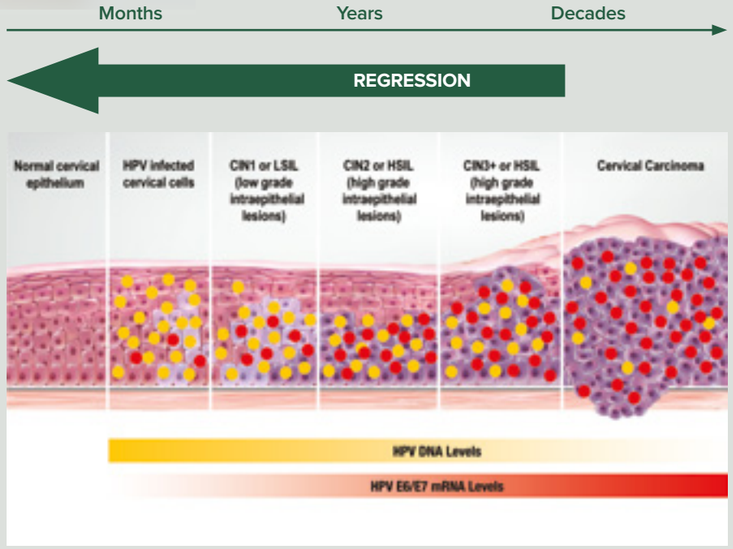
Nearly all sexually active men and women will have an HPV infection at some point in their lives. Very few will go on to develop cancer.[2]

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]

E6/E7 mRNA expression is indicative of the HPV infections most likely to lead to disease.[3,4]

mRNA and Cervical Disease Progression[5]



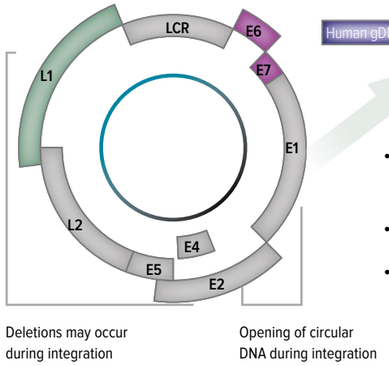
Because HPV DNA levels may decrease as infections progress toward cancer, some HPV DNA tests may provide false-negative results in more than 10% of the most severe cervical disease cases.[6]

*"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).**"* [1]

Test Design

Aptima® HPV targets oncogenic activity of the HPV virus by detecting E6/E7 mRNA.[7] Tests that target only the L1 gene are detecting an area that is not needed for disease progression and that can be deleted during integration. There is a risk of up to 10-15% of the most severe disease cases being missed with a L1-based DNA HPV test.[8-10]

Why E6/E7



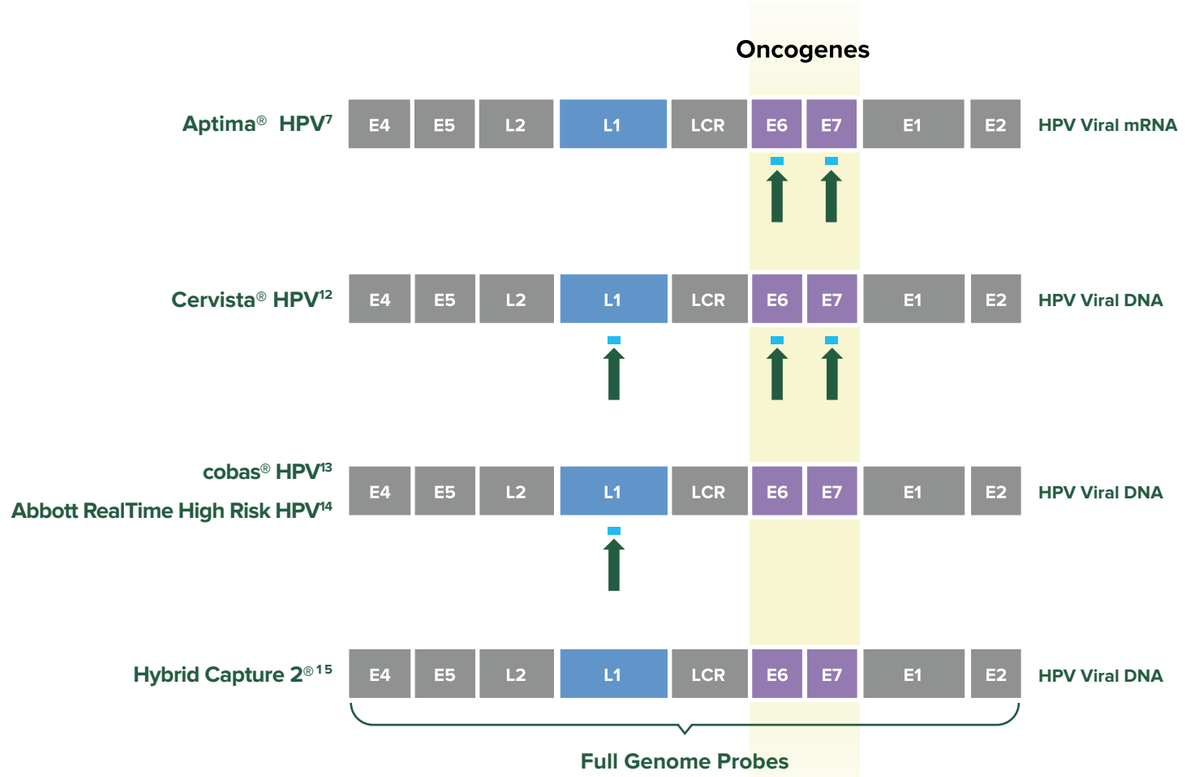
HPV genome – genotype 16 example

HPV Integration

HPV DNA

- HPV DNA must linearize to integrate into human DNA.
- L1 region can be deleted.
- HPV assays that only target the L1 region are at risk for false negative results.[11]

HPV Detection Strategies



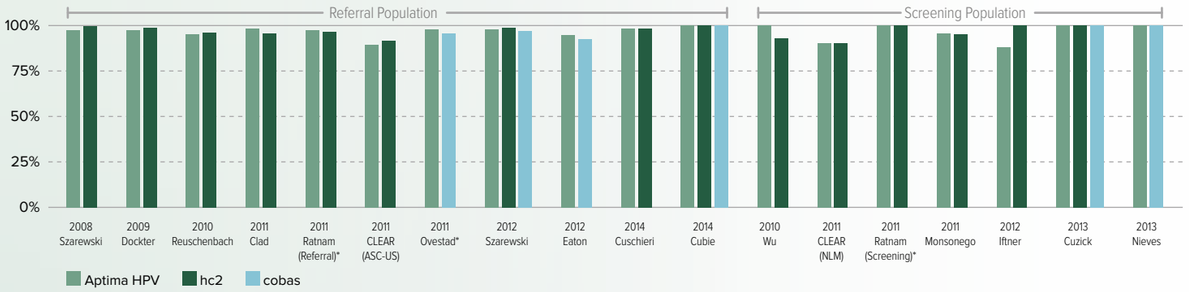
Maximizing the Benefits

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 have come to expect from DNA-based tests.

Sensitivity†

Clinical Sensitivity for ≥ CIN3 [7,16-30]

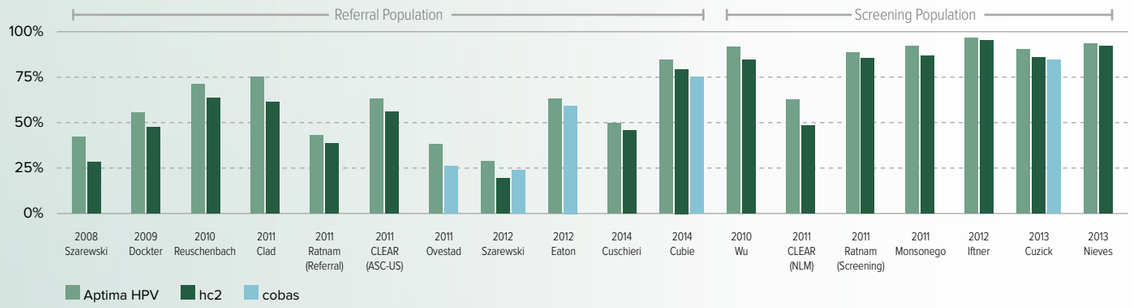


*Clinical Sensitivity for ≥ CIN2

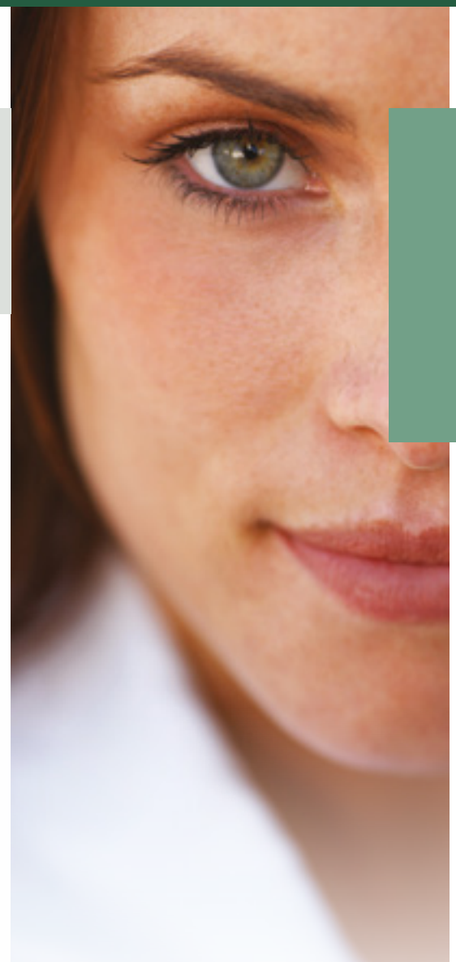
Specificity†

The Aptima HPV assay has been shown to deliver fewer false-positive test results compared with DNA-based tests.

Clinical Specificity for CIN2 + [2-4,6-7,16-26]



†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.



Aptima® HPV assay showed

24%

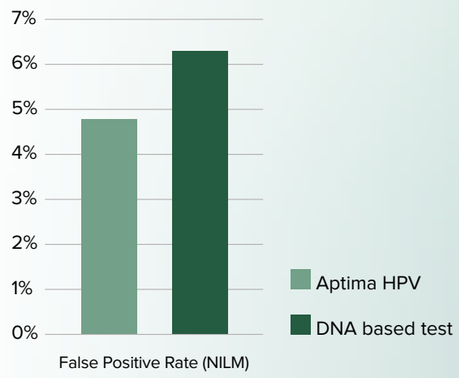
fewer false-positive test results compared to a DNA-based test.[7]

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

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.[7]

Fewer False-Positive Results[7‡]



‡The graph above represents data adapted from the Aptima HPV Assay Package Insert Table 22.[7]

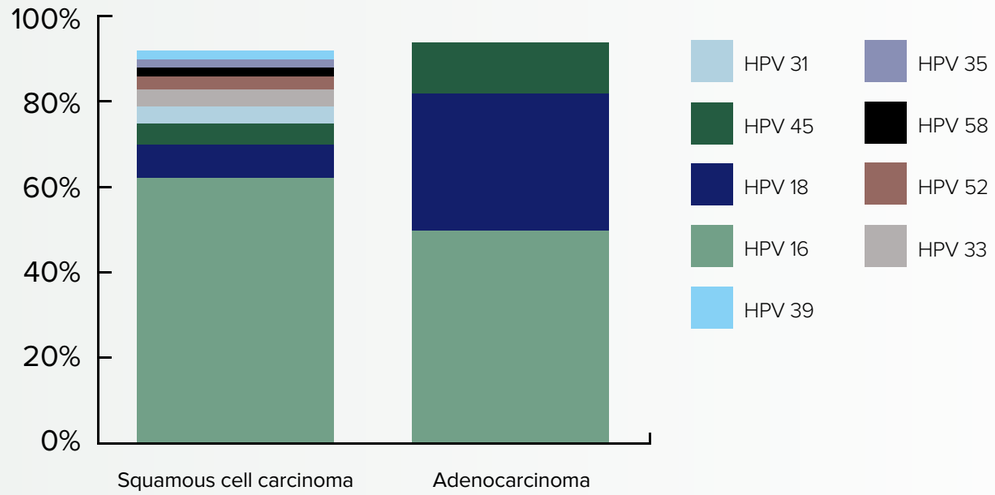
Aptima® HPV 16 18/45 Genotype Assay

Enhanced detection for improved management of HPV positive patients.

The Next-Generation Genotype Test
Result for type 16 with separate combined result for HPV types 18 and 45.

Reflex positive Aptima HPV assay results to genotyping for types 16, 18 and 45. Identification of these types as part of reflex testing may identify up to 94% of all cervical adenocarcinomas.[2]

HPV Genotypes in Invasive Cervical Cancer[1]



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

94%

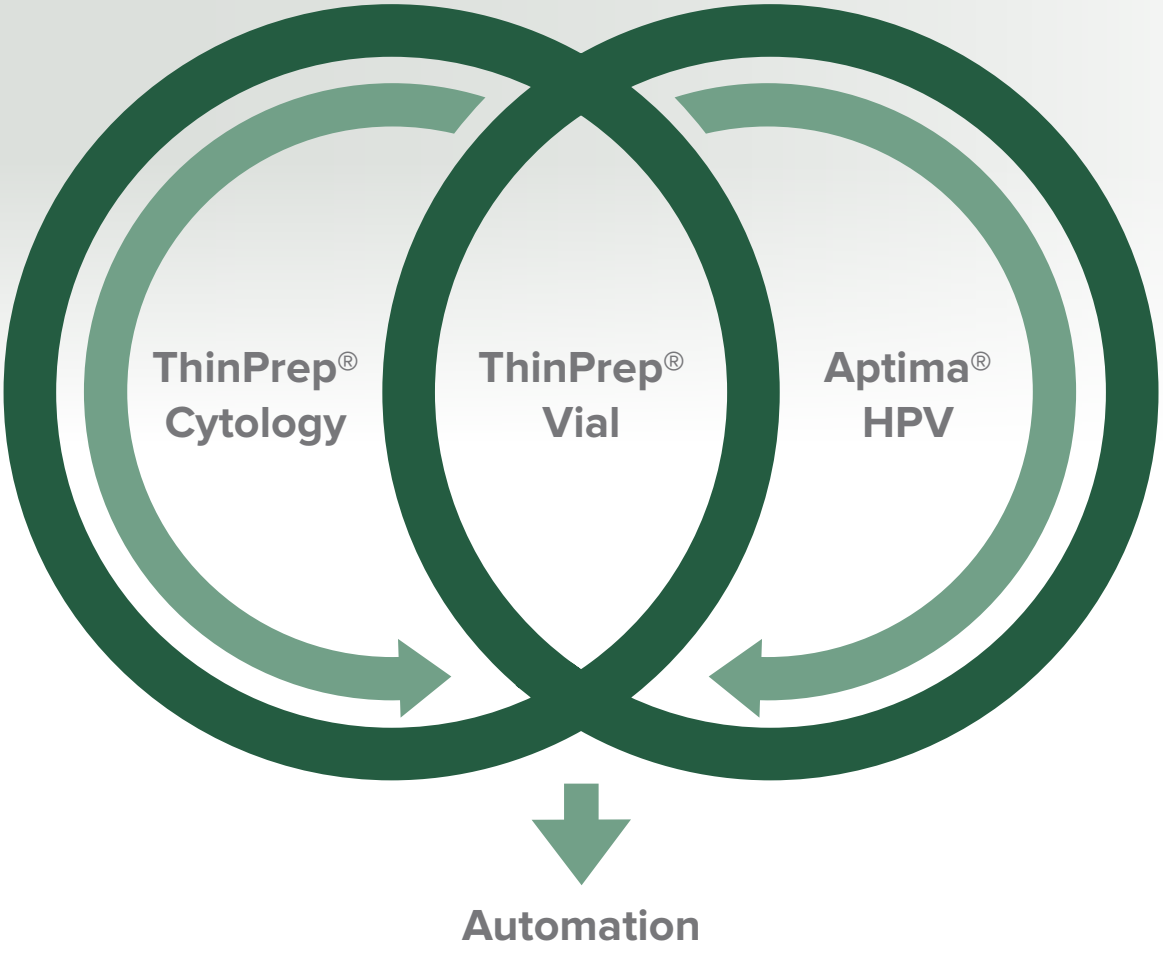
of HPV-related cervical adenocarcinomas.[31]

HPV type 45:

- Is uncommon and only prevalent in 0.4% of women with normal cytology.[31]
- Is the third most common HPV type in invasive cervical cancer.[31,32]
- Types 16, 18 and 45 show higher carcinogenic potential relative to all other high-risk HPV types.[30,33]
- The addition of HPV type 45 in the Aptima HPV 16 18/45 genotype assay identifies more women at risk for adenocarcinoma, with minimal impact to colposcopy rates.[31]

Worth it.

Hologic's Complete Solutions for all Cervical Screening Algorithms



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Aptima® HPV Assay

Aptima® HPV 16 18/45 Genotype Assay

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