

Aptima HPV mRNA test

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

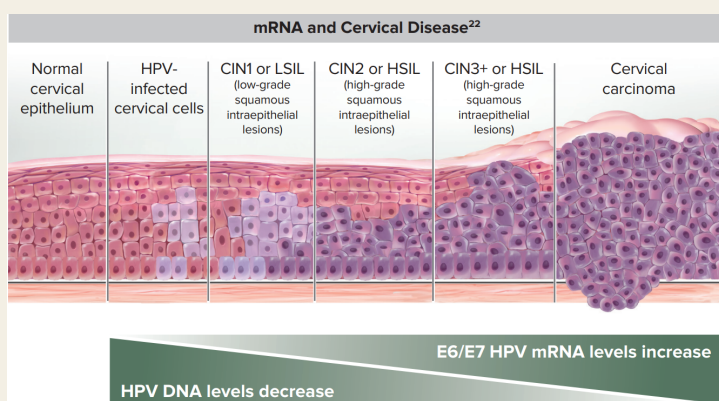
The Aptima® HPV assay:

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

The Aptima® HPV assay targets E6/E7 mRNA.

Sexually active men and women will have an HPV infection at some point in their lives. Very few will go on to develop cancer. The Aptima® HPV assay targets high-risk HPV mRNA. Studies have shown mRNA identifies the presence and activity of high-risk HPV infections.^{1,2}

The right targets to identify the right treatment



E6/E7 mRNA expression is indicative of the HPV infections most likely to lead to disease^{1,2}
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.³



The Aptima® HPV assay demonstrates the same excellent sensitivity and improved specificity over DNA-based tests to support better patient care.

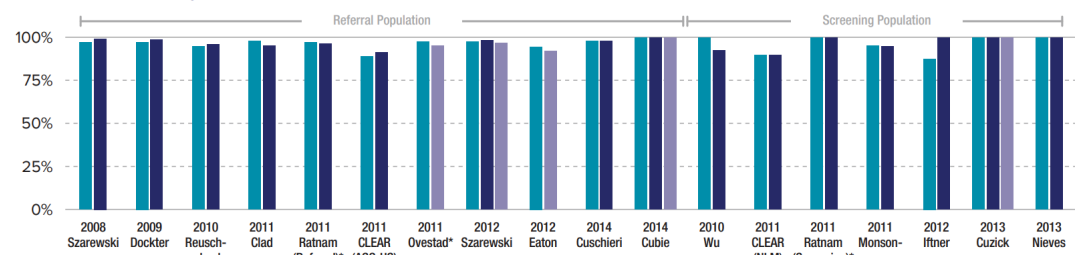
Sensitivity

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

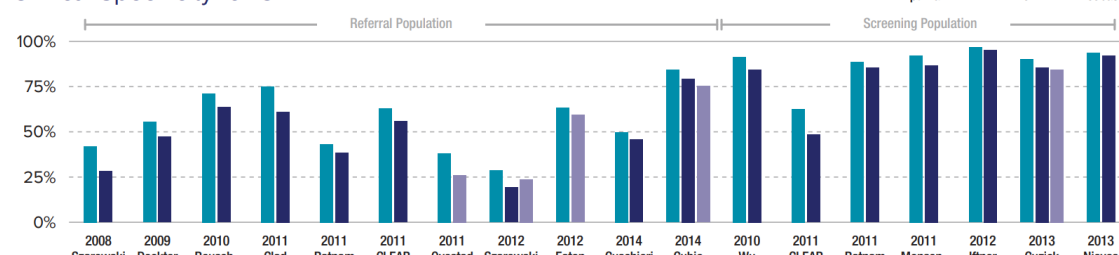
Specificity

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

Clinical Sensitivity for ≥ CIN3¹⁶



Clinical Specificity for CIN2¹⁶



The Aptima HPV assay showed 29% fewer false positives than DNA-based tests in the NILM arm of the CLEAR trial¹⁷ helping to:

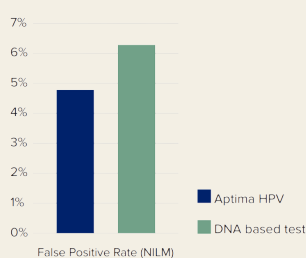
- Reduce uncomfortable patient conversations.
- Reduce the potential for overtreatment.

Based on the clinical evidence, the Aptima HPV assay's intended use is:

For the detection of E6/E7 mRNA from 14 HPV high risk types, specifically including:

- First-line primary screening
- Adjunctive testing together with cervical cytology (co-testing).
- Testing women with ASC-US Pap test results.

Fewer False-Positive Results¹⁴



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

The Aptima HPV assay offers a combination of the same excellent sensitivity and improved specificity as compared with DNA-based tests.

These performance characteristics align with current clinical practice guidelines, which are designed to maximize the benefits of cervical cancer screening while minimizing potential harm.

PAPER SUPPORT

6-year negative predictive value confirms longitudinal efficacy of the mRNA-based Aptima® HPV assay from Hologic in a routine screening population in Germany.¹ Data shows that the Aptima® HPV assay has the same sensitivity, but significantly improved specificity compared to a DNA-based test.

Itfner T, et al. The longitudinal clinical performance of the RNA-based AHPV Human Papillomavirus (HPV) Assay in comparison to the DNA-based Hybrid Capture 2 HPV Test in 2 consecutive screening rounds with a 6-year interval in Germany. J Clin Microbiol. 2018. doi:10.1128/JCM.01177-18 (GAST) [Accepted Manuscript]

Excellent and robust 7-year longitudinal evidence for the mRNA-based Aptima® HPV assay compared with HPV DNA testing.²

Forslund O, et al. HPV-mRNA and HPV-DNA detection in samples taken up to seven years before dysplasia of cervix uteri. Int J Cancer. 2018; doi: 10.1002/ijc.31819. [Epub ahead of print]

Comparative performance of human papillomavirus messenger RNA versus DNA screening tests at baseline and 48 months in the HPV FOCAL trial. Four year data further confirms that the Aptima® HPV assay has high sensitivity, and significantly improved specificity.³

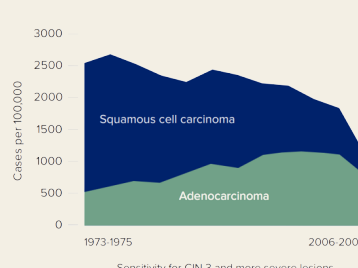
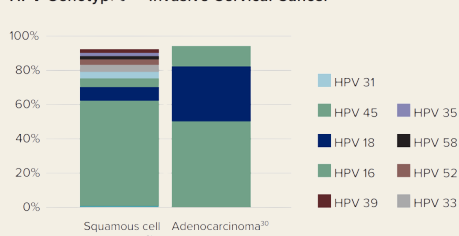
Cook D et al. Aptima HPV Assay versus Hybrid Capture® 2 HPV test for primary cervical cancer screening in the HPV FOCAL trial. J Clinical Virology 2017 87:23-29. Cook D et al. Comparative performance of human papillomavirus messenger RNA versus DNA screening tests at baseline and 48 months in the HPV FOCAL trial. J Clin Virol 2018;108:32-37. Itfner T et al. Longitudinal clinical performance of the RNA-based Aptima Human Papillomavirus (AHPV) Assay in comparison to the DNA-based Hybrid Capture 2 HPV Test in two consecutive screening rounds with a 6-year interval in Germany. J Clin Microbiol 2019;57(1) e01177-18. Forslund O et al. HPV-mRNA and HPV-DNA detection in samples taken up to seven years before severe dysplasia of cervix uteri. Int J Cancer 2018;144:1073-1081. Haedicke J & Itfner T, A review of the clinical performance of the Aptima HPV assay. J Clin Virol 2016;76:540-48

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



Adenocarcinoma is on the Rise
The Aptima HPV genotype assay targets HPV types 16, 18 and 45, which show higher carcinogenic potential relative to all other high-risk HPV types
• HPV types 16, 18 and 45 are responsible for 75% of all squamous cell carcinomas and 94% of all adenocarcinomas.²³
• HPV type 45 is the third most common HPV type in invasive cervical cancer

HPV Genotypes Invasive Cervical Cancer²³



HPV genotype test to meet all cervical screening algorithms:
• Can be ran as a reflex test after positive result from the original sample vial.
• Or run the Aptima high-risk and genotyping assays simultaneously—from a single patient sample—on the fully-automated Panther® system and deliver results for both assays at once.