

Aptima® HPV ASSAY

Helping you provide better patient care



The latest technology targeting mRNA for high-risk HPV detection to provide fewer false-positive results in cervical cancer screening¹

Studies show that HPV DNA is found in 99.7% of all cervical carcinomas.² When Pap testing is combined with high-risk HPV (HR HPV) DNA testing, the combined sensitivity for detecting high-grade cervical disease and cancer has been reported as more than 99%.^{3,4}

mRNA testing offers a new generation in HPV detection technology. The overexpression of HPV oncoproteins E6 and E7 has been linked to the progression of cervical disease, and overexpression plays a significant role in the growth of malignant cervical cells by shutting down tumor suppressor proteins.⁵⁻⁷

Aptima HPV Assay

The Aptima® HPV assay is the first FDA-approved test for HPV mRNA, and the test detects mRNA from 14 high-risk HPV types associated with cervical cancer.¹ The Aptima HPV assay can be used together with the Pap for women age 30 and older, as well as for reflex on ASC-US Pap results.¹

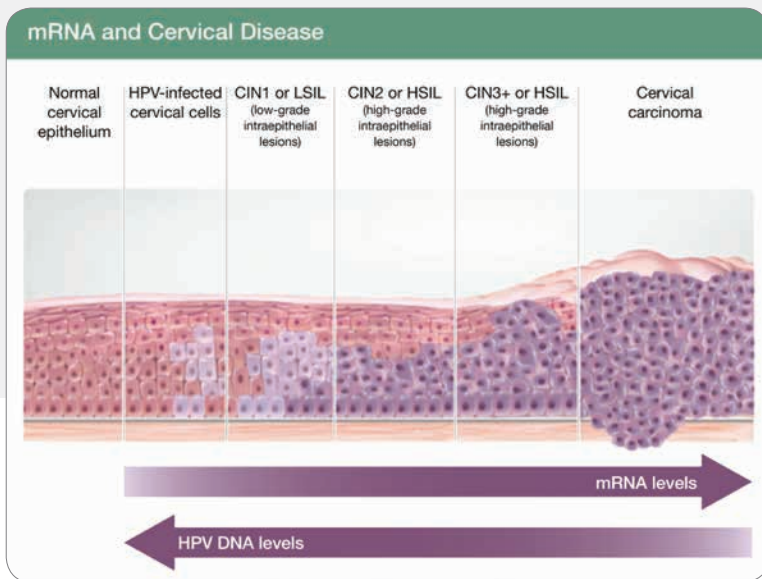
Aptima HPV Genotyping (16, 18/45)

This technology also offers the latest generation of testing for HPV genotype analysis by including HPV type 45 along with the HPV type 18 test.¹ The inclusion of both type 18 and type 45 in the Aptima HPV genotype test improves detection of adenocarcinoma compared with other HPV genotype tests that only detect type 18.⁸ The Aptima HPV assay has the option to reflex when positive to the Aptima HPV genotyping test for types 16 and 18/45. Approximately 94% of all cervical adenocarcinomas may be identified by reflex testing for types 16 and 18/45.⁸

DNA and mRNA – Clinical Gaps in Cervical Cancer Screening

While HR HPV DNA testing has been shown to have excellent sensitivity and negative predictive value; the specificity has been shown to be much lower than cytology, affecting positive predictive value.⁷ Aptima HPV mRNA testing has demonstrated equivalent sensitivity compared to HPV DNA-based tests, and HPV mRNA offers improved specificity and enhanced positive predictive value – as HPV infections persist, HPV mRNA overexpression increases.^{1,7,9} HR HPV mRNA may be more specific for assessing progression of cervical disease.^{1,5,7,9}

NO TWO PATIENTS ARE ALIKE



Transient HPV Infection or Transforming HPV Infection^{5,7,9}

In transient HR HPV infections, HPV DNA is present, but HPV mRNA may be too low for detection. In addition, transient infections may not cause cervical disease. In a transforming or persistent HPV infection, overexpression of HR HPV E6/E7 mRNA is detectable and indicates that this is not a transient infection and higher grade disease may occur.

Figure 1. mRNA and Cervical Disease
(Reprinted with permission from Hologic.)

Aptima® HPV Test Options

	Test No.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus</i> , NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45	199310
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus</i> , NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	199355
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus/Trichomonas</i> , NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45	199315
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus/Trichomonas</i> , NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	199360
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45	199305
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	199300
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS	199345
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus</i> , NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	199320
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and <i>Chlamydia/Gonococcus/Trichomonas</i> , NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U	199325
Human Papillomavirus (HPV) (Aptima®)	507800
Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45	507805
Human Papillomavirus (HPV) (Aptima®) Genotypes 16 and 18, 45	507810
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®)	199330

References

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7. Ratnam S, Coutlee F, Fontaine D, et al. Aptima HPV E6/E7 mRNA test is as sensitive as Hybrid Capture 2 assay but more specific at detecting cervical precancer and cancer. *J Clin Micro*. 2011 Feb;49(2):557-564.
8. de Sanjose S, Quint WG, Alemany L, et al. Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study. *Lancet Oncol*. 2010 Nov; 11(11): 1048-1056.
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