

## WOMEN'S HEALTH

# Aptima<sup>®</sup> HPV Assay

The latest technology targeting mRNA for high-risk HPV detection to provide fewer false-positive results in cervical cancer screening<sup>1</sup>



Studies show that HPV DNA is found in **99.7%** of all cervical carcinomas.<sup>2</sup>

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%**.<sup>3,4</sup>

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.<sup>5-7</sup>

### Aptima HPV Assay

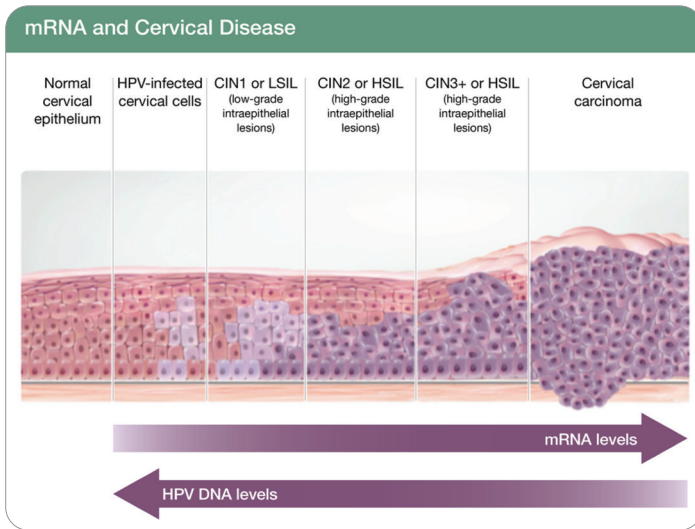
The Aptima<sup>®</sup> HPV assay is the first FDA-approved test for HPV mRNA, and the test detects mRNA from 14 high-risk HPV types associated with cervical cancer.<sup>1</sup> The Aptima HPV assay can be used together with the Pap for women age 30 and older, as well as for reflex on ASC-US Pap results.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

### 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.<sup>1</sup> 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.<sup>8</sup> 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.<sup>8</sup>

### 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.<sup>7</sup> 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.<sup>1,7,9</sup> HR HPV mRNA may be more specific for assessing progression of cervical disease.<sup>1,5,7,9</sup>



### Transient HPV Infection or Transforming HPV Infection<sup>5,7,9</sup>

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**

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## Aptima<sup>®</sup> HPV Test Options

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

### 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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Visit the online Test Menu at **Labcorp.com** for full test information, including CPT codes and specimen collection requirements.