WOMEN'S HEALTH

Aptima® HPV Assay

The latest technology targeting mRNA for high-risk HPV detection to provide fewer false-positive results in cervical cancer screening[1]

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]

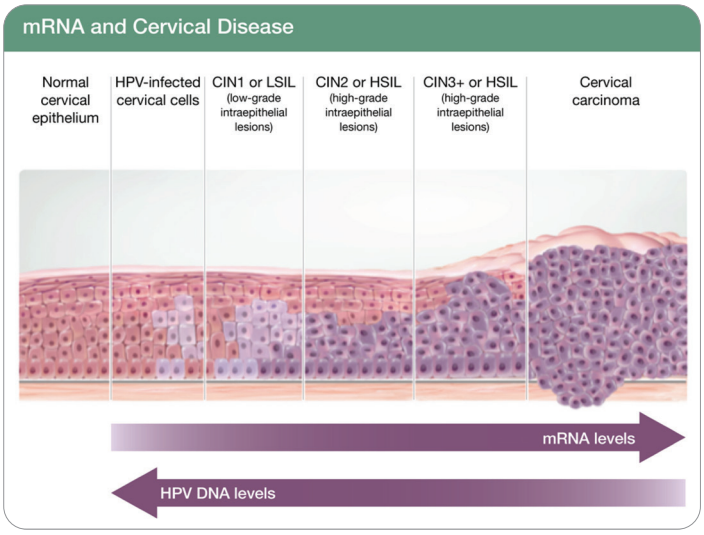
Aptima HPV Genotyping (16, 18/45)

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 and18/45. Approximately 94% of all cervical adenocarcinomas may be identified by reflex testing for types 16 and18/45.[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]

labcorp



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.	Test Description
199310	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45
199355	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS
199315	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45
199360	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS
199305	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®) 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®) When ASC-U
199345	Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U, ASC-H, LSIL, HSIL, AGUS
199320	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U
199325	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/Trichomonas*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U
507800	Human Papillomavirus (HPV) (Aptima®)
507805	Human Papillomavirus (HPV) (Aptima®) With Reflex to HPV Genotypes 16 and 18, 45
507810	Human Papillomavirus (HPV) (Aptima®) Genotypes 16 and 18, 45
199330	Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®)

References
1. Aptima HPV Assay [package insert]. San Diego, Calif: Gen-Probe; 2011. Rev 502170.
2. Walboomers JMM, Jacobs MV, Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *J Pathol*.1999;189:12-19.
3. Cuzick J, Szarewski A, Cubie H, et al. Management of women who test positive for high-risk types of human papillomavirus: the HART study. *Lancet*. 2003; 362:1871-1876.
4. Lorincz A, Richart R. Human papillomavirus DNA testing as an adjunct to cytology in cervical screening programs. *Arch Pathol Lab Med*. 2003;127:959-968.
5. Cuschieri K, Wentzensen N. HPV mRNA and p16 detection as biomarkers for the improved diagnosis of cervical neoplasia. *Cancer Epidemiol Biomarkers Prev*. 2008 October;17(10):2536-2545.
6. Hausen HZ. Papillomaviruses and cancer: from basic studies to clinical application. *Nature*. 2002; May (2):342-350.
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.
9. Clad A, Reuschenbach M, Weinschenk J, et al. Performance of the Aptima high-risk human papillomavirus mRNA assay in a referral population in comparison with Hybrid Capture 2 and cytology. *J Clin Micro*. 2011 Mar;49(3):1071-1076.

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

labcorp