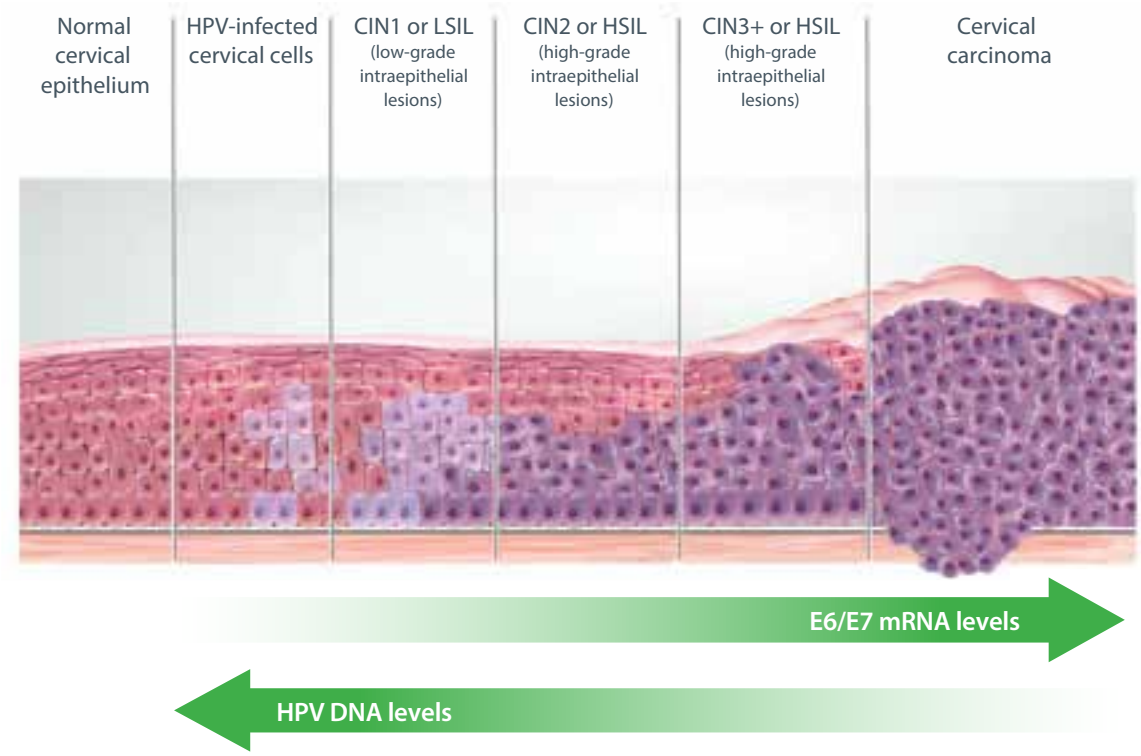
The future of HPV testing is here

The APTIMA® HPV test

With the FDA-approved APTIMA® HPV test, you can focus on more clinically relevant results

mRNA and Cervical Disease



HPV mRNA delivers significantly less false positives than DNA—up to 40% fewer.[1]

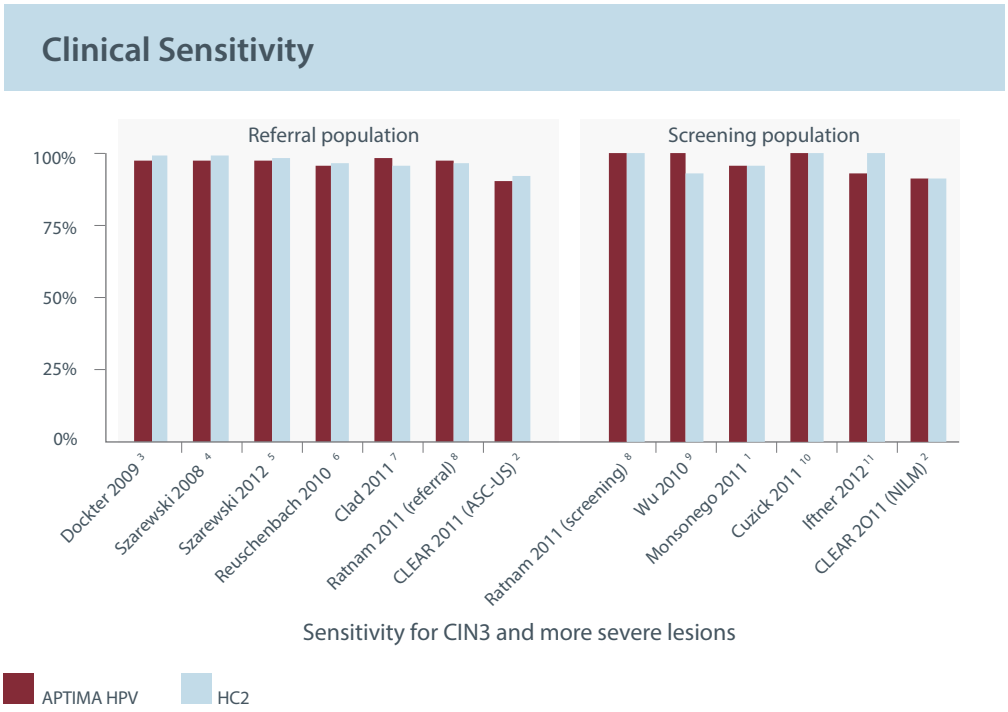
The APTIMA® HPV Assay detects E6/E7 viral mRNA from 14 high-risk types of human papillomavirus in cervical specimens (ThinPrep® Pap Test vials containing PreservCyt® Solution collected with broom-type or cytobrush/spatula devices). The test is indicated to screen women ≥21 years with ASCUS cytology to determine the need for colposcopy, and to screen women ≥30 years for high-risk HPV types.[2] This information with cytology history, other risk factors, and guidelines may be used to manage patients. See www.hologic.com for more details.

The APTIMA® HPV test

Highly sensitive and specific

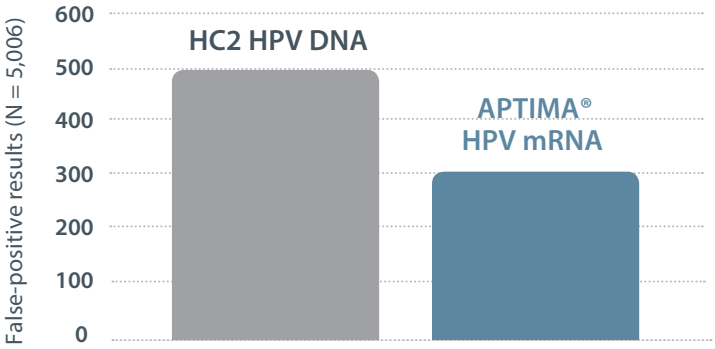
Offers excellent sensitivity...
so you can help minimize false-negative results

The APTIMA® HPV Assay, utilizing mRNA, has shown sensitivity comparable to common DNA-based tests [1-11]



Offers increased specificity, decreasing potential harms[1]

Fewer false-positive results [1]

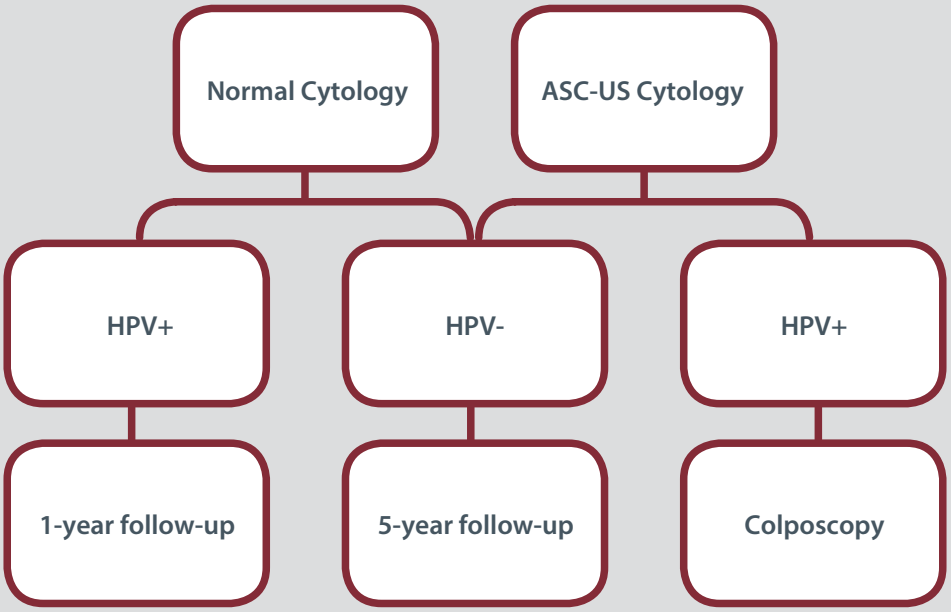


The APTIMA® HPV Assay has been shown to produce up to 40% fewer false-positive test results[1]:

- Decreasing difficult patient conversations
- Decreasing the potential for over-treatment

Pap with HPV Co-testing for Women 30–65 Years of Age

The best way to identify women most at risk of cervical cancer



Published guidelines[12] recommend the use of HPV co-testing in women ages 30–65. Persistent HPV infections occur more frequently in women age 30 or older.

The HPV result serves as the gatekeeper in the decision to advance to colposcopy.

Co-testing with Confidence

The HPV mRNA assay provides clinicians greater confidence in patient management, helping reduce the complaints that arise from the performance of unnecessary colposcopies and costly medical procedures.[13]

- ☑ FDA-approved for use with ThinPrep®*
- ☑ Offers excellent sensitivity*
- ☑ Offers increased specificity[2]*
- ☑ Complies with cervical cancer screening guidelines*
- ☑ Same price and coverage as DNA-based HPV tests
- ☑ No increased costs to you or your patients

Transition to APTIMA® Made Easy

Women 21-29 (Pap with Reflex to APTIMA® HPV mRNA)	
Test Name(s)	**Test Code(s)**
Pap, ThinPrep® w/Reflex HPV mRNA if ASC-US	704
Pap, ThinPrep® w/Reflex HPV mRNA if ASC-US & CT/NG	704 & 803509
Women 30-65 (Pap & APTIMA® HPV mRNA co-testing)	
Pap, ThinPrep® w/HPV mRNA	719
Pap, ThinPrep® w/HPV mRNA & CT/NG	719 & 803509
Pap, ThinPrep® w/HPV mRNA w/Reflex to Genotypes 16, 18/45 if Pap is Negative and HPV is Positive	435
Out-of-the-Vial Testing	
Chlamydia trachomatis (CT), ThinPrep® Vial	906394
Neisseria gonorrhoeae (NG), ThinPrep® Vial	906395
CT/NG, ThinPrep® Vial	803509
HPV mRNA	718
HPV mRNA w/Reflex to Genotypes 16, 18/45 if HPV is Positive	438
HPV Genotypes 16, 18/45	906546

Models used for illustrative purposes only.

*The CLEAR Trial was a prospective, multicenter clinical study that analyzed more than 11,000 women undergoing routine Pap testing at 18 US clinics. The CLEAR Trial comprised two arms: 1. The ASCUS Study population included 939 women ≥21 years with ASCUS cytology results; 2. The NILM (Adjunct) Study population included 10,871 women ≥30 years with normal cytology results. [2]

The assay is not a substitute for regular cervical cytology screening. The results of this test are not intended to prevent women from proceeding to colposcopy. The assay has not been evaluated for managing HPV vaccines, women with prior ablative or excisional therapy, hysterectomy, who are pregnant, or have other risk factors.[2]

References: 1. Monsonego J, Hudgens MG, Zerat L, et al. Evaluation of oncogenic human papillomavirus RNA and DNA tests with liquid-based cytology in primary cervical cancer screening: the FASE study. *Int J Cancer.* 2011;129:691-701. **2.** APTIMA HPV Assay (package insert). San Diego, CA: Gen-Probe Incorporated; 2011. **3.** Dockter J, Schroder A, Hill C, et al. Clinical performance of the APTIMA HPV Assay for the detection of high-risk HPV and high-grade cervical lesions. *J Clin Virol.* 2009;45(S1):S55-S61. **4.** Szarewski A, Ambroisine L, Cadman L, et al. Comparison of predictors for high-grade cervical intraepithelial neoplasia in women with abnormal smears. *Cancer Epidemiol Biomarkers Prev.* 2008;17(11):3033-3042. **5.** Szarewski A, Mesher D, Cadman L, et al. Comparison of seven tests for high-grade cervical intraepithelial neoplasia in women with abnormal smears: the Predictors 2 study. *J Clin Micro.* 2012;50(6):1867-1873. **6.** Reuschenbach M, Clad A, von Knebel Doeberitz C, et al. Performance of p16INK4a-cytology, HPV mRNA, and HPV DNA testing to identify high grade cervical dysplasia in women with abnormal screening results. *Gynecol Oncol*. 2010;119(1):98-105. **7.** 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;49(3)1071-1076. **8.** 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;49(2):557-564. **9.** Wu R, Belinson SE, Du H, et al. Human papillomavirus messenger RNA assay for cervical cancer screening: the Shenzhen Cervical Cancer Screening Trial I. *Intl J Gyn Cancer.* 2010;20(8):1411-1414. **10.** Cuzick J, et al. International Papillomavirus Conference; 2011. Data on file. **11.** Iftner T, et al. International Papillomavirus Conference; 2012. Data on file. **12.** *Am J Clin Pathol* 2012; 137: 516-542. **13.** Clad A, et al. *J Clin Microbiol*. 2001 Mar; 49(3): 1071-1076.

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