

Guidelines Recommend Co-testing as the Preferred Method

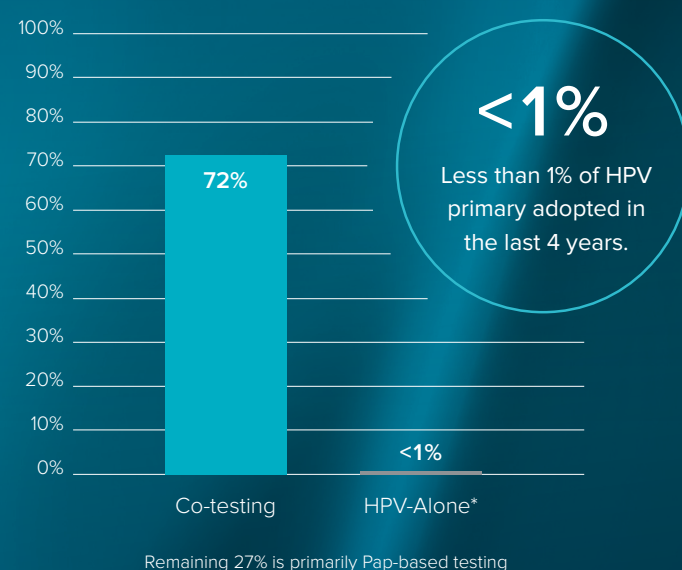
"...Expert guidelines recommend that for these women [ages 30-65], Co-testing with cervical cytology and hrHPV testing every 5 years is preferred, screening with cervical cytology alone every 3 years is acceptable, and hrHPV testing alone can be considered as an alternative screening strategy."¹⁵



Co-testing Adoption Rates at an All Time High

Because Pap + HPV together (Co-testing) provides more protection against CIN3+ and cervical cancer than screening with either HPV or Pap alone, Co-testing has become the most widely used screening method in the United States.¹⁶

Cervical Cancer Screening Method in the US for women ages 30 to 65



“Which Screening Prevents The Most Cervical Cancer?”



GO WITH CO-TESTING”

Forbes¹⁷

In many cases, Co-testing is covered by the Affordable Care Act. For patients, this may mean:¹⁸



No co-pay



No deductible



No out-of-pocket cost

Patients should consult their healthcare plans to verify coverage.

Method + Technology Together Define Performance

*A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.

References: 1. Blatt AJ, et al. Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. *Cancer Cytopathol.* 2015;123(5):282-288. doi:10.1002/ncy.21544 (Study included ThinPrep, SurePath and Hybrid Capture 2 assay). 2. Austin RM, et al. Enhanced detection of cervical cancer and precancer through use of imaged liquid-based cytology in routine cytology and HPV cotesting. *Am J Obstet Gynecol.* 2018;150(5):385-392. doi:10.1093/ajcp/acy114 (Study included ThinPrep Pap test, ThinPrep imaging, Digene HPV, Cervista HPV and Aptima HPV). 3. American Cancer Society. Cancer Statistics Center. https://cancerstatisticscenter.cancer.org/?_ga=2.150839477.2044751383.1547156654-294386523.1544563210#/. Published 2018. Accessed May 31, 2019. 4. Katki HA, et al. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. *Lancet Oncol.* 2011;12(7):663-672. doi:10.1016/S1473-045(11)70145-0 (Study included conventional Pap, Hybrid Capture 2 assay). 5. Li Z, et al. Screening test results associated with cancer diagnoses in 287 women with cervical squamous cell carcinoma. *Arch Pathol Lab Med.* 2012;136:1533-1540. (Study included ThinPrep, SurePath, Hybrid Capture 2, cobas HPV assay, Cervista HPV HR test). 6. Zhao Y, et al. Relationship between cervical disease and infection with human papillomavirus types 16 and 18, and herpes simplex virus 1 and 2. *J Med Virol.* 2012;84:1920-1927. doi:10.1002/jmv.23353 (Study included ThinPrep and Seaman triplex real-time PCR assay). 7. Zhao C, et al. Cervical screening test results associated with 265 histopathologic diagnoses of cervical glandular neoplasia. *Am J Clin Pathol.* 2013;140:47-54. doi:10.1309/AJCP13M8HPVSSC Published 2013. Accessed May 31, 2019. (Study included ThinPrep and Hybrid Capture 2 assay). 8. Zhao C, et al. Prior high-risk human papillomavirus testing and Papanicolaou test results of 70 invasive cervical carcinomas diagnosed in 2012. *Arch Pathol Lab Med.* 2014;184:188. (Study included ThinPrep, SurePath, Hybrid Capture 2 assay, Cervista Assay, and cobas assay). 9. Gage J, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. *J Natl Cancer Inst.* 2014;106(8). doi:10.1093/jnci/dju153 (Study included conventional Pap, Hybrid Capture[®] 2 assay). 10. Insinga RP, et al. Diagnoses and outcomes in cervical cancer screening: A population-based study. *Am J Obstet Gynecol.* 2004;191(1):105-13. doi:10.1016/j.ajog.2004.01.043 (Study included Pap smears). 11. Wright C, et al. The ATHENA human papillomavirus study: design, methods and baseline results. *Am J Obstet Gynecol.* 2012;206(1):46.e1-46.e11. (Study included cobas HPV and Hybrid Capture 2 assay). 12. Ronco G, et al. Efficacy of HPV-based screening for prevention of invasive cervical cancer: follow-up of four European randomised controlled trials. *Lancet.* 2014;383(9916):524-32. doi: 10.1016/S0140-6736(13)62218-7 (Study included conventional Pap, ThinPrep, Hybrid Capture 2 assay, LDT). 13. U.S. Census Bureau. 2010 Census Data. <http://www.census.gov/2010census/data/>. Accessed May 31, 2019. 14. CDC. Table 84. Use of Pap smears among women aged 18 and over, by selected characteristics: United States, selected years 1987-2010. <http://www.cdc.gov/nchs/data/hest/2013/084.pdf>. 15. ACOG. Practice Advisory: Cervical Cancer Screening (Update). <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Cervical-Cancer-Screening-Update>. Published August 21, 2018. Accessed May 31, 2019. 16. Hologic, Inc. Data on File. 17. Haele T. Which screening prevents the most cervical cancer? Go with co-testing. *Forbes.* <https://www.forbes.com/sites/tarahaele/2018/09/14/which-screening-test-to-prevent-cervical-cancer-go-with-co-testing/#50572ec67a23>. Published September 14, 2018. Accessed May 31, 2019. 18. CDC. Prevention Through Health Care: Preventive Service Tables. HPV. <https://www.cdc.gov/nchs/stp/preventionthroughhealthcare/preventiveservices/std.htm>. Updated May 2, 2018. Accessed May 31, 2019.

hologic.com | diagnostic.solutions@hologic.com | 888.484.4747

PB-00331-001 Rev. 005 ©2019 Hologic, Inc. Hologic, The Science of Sure, Aptima, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc., and/or its subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshow, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to diagnostic.solutions@hologic.com.



HOLOGIC[®]

1 IN 5

women with Cervical Cancer were missed by Screening with HPV-Alone.^{1,2*}

*A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.



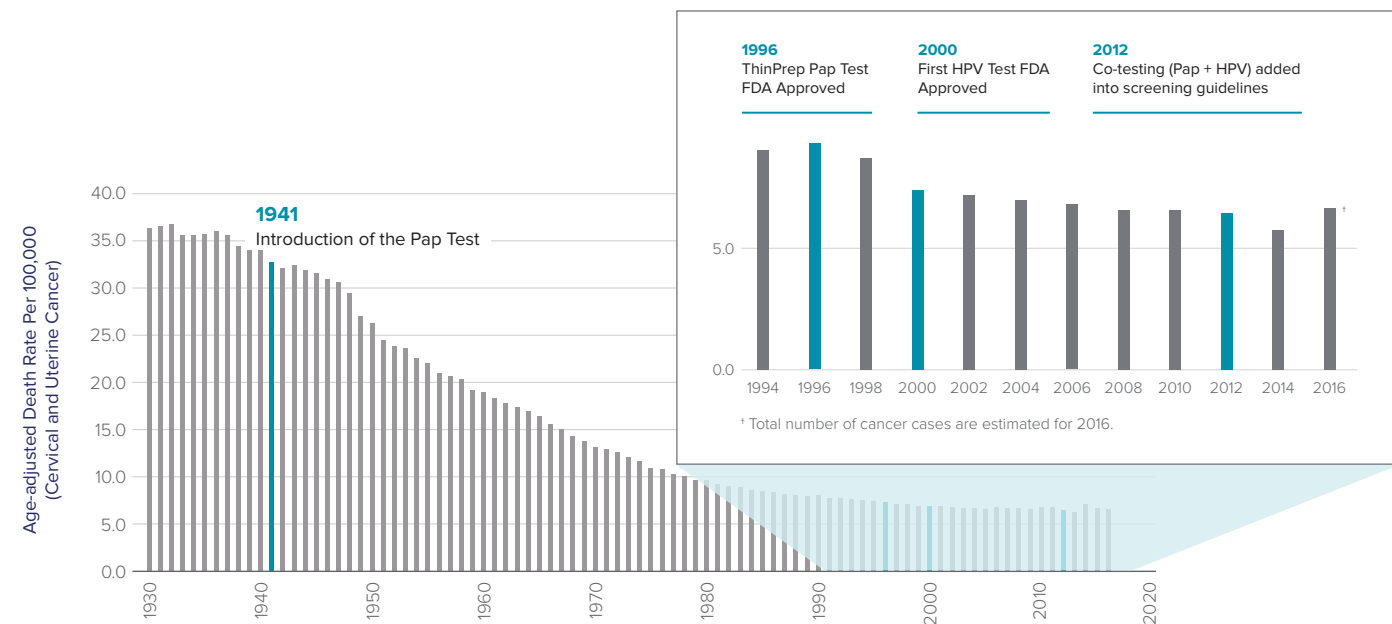
Know the facts

Choose Pap + HPV

Don't sacrifice

Paving the way for improved cervical care:

The Pap test, along with improvements in technology and advancements in cervical cancer screening guidelines are credited with significantly decreasing cervical cancer death rates.³



Regardless of the algorithm, the collection method is the same.

Samples are collected in liquid based cytology vials such as ThinPrep Pap Test vials or other FDA approved media.

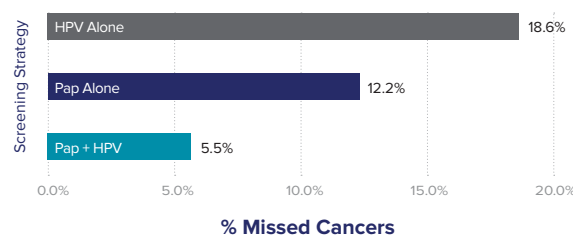
	Pap + HPV (Co-testing)	HPV-Along*
COLLECTION METHOD	Cervical Collection	Cervical Collection
RESULTS	<ul style="list-style-type: none"> HPV Test Result Cytology Result 	<ul style="list-style-type: none"> HPV Test Result Cytology Result

Recent publications representative of US clinical practice show Pap + HPV (Co-testing) misses the fewest cancers/precursors to cancer:

Key Study from 2015¹

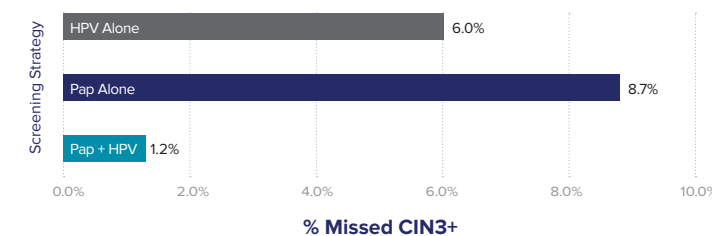
Pap + HPV together identified **70% of cancers missed**

by screening with HPV-Along.*



Pap + HPV together identified **80% of the CIN3+ cases missed**

by screening with HPV-Along.*



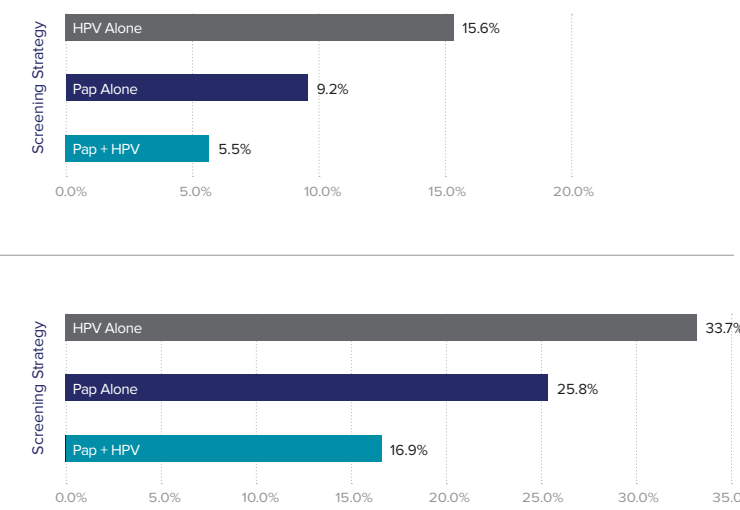
Key Study from 2018²

2x % Missed Cancers

AS MANY WOMEN WITH CERVICAL CANCER WOULD BE MISSED WITH HPV-ALONE* (PRIMARY) SCREENING VS. CO-TESTING (PAP + HPV)

1-12 MONTHS PRIOR TO DIAGNOSIS

12+ MONTHS PRIOR TO DIAGNOSIS



Several clinical studies confirm screening with HPV-Along* misses cervical cancer.

Proportion of HPV Negative Cancer Cases^{1-2,4-9}



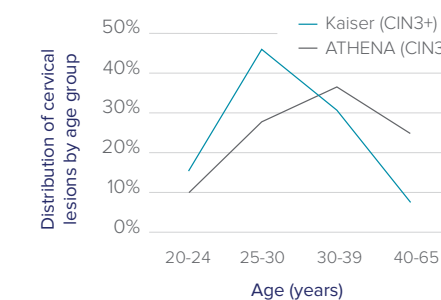
This chart is a representation of clinical data from multiple published sources. The clinical studies represented within these sources were conducted using different study designs with various assays.

Precancerous lesions are common but cancer is rare among females in their 20s.

High Prevalence, Rare Cancer^{10,11}

The high incidence of CIN in women in their 20s has been documented in literature for more than a decade, but rates of cervical cancer are very low.

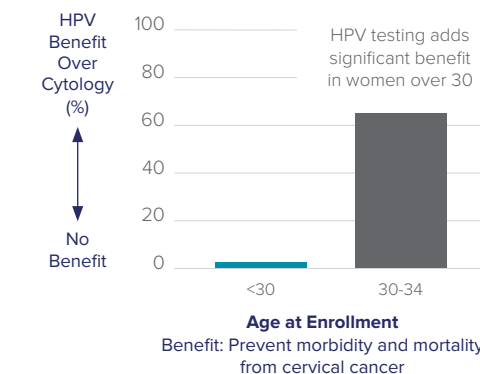
Cervical Lesions are Most Common Among Females in Their 20s



No Benefit¹²

Despite the high incidence of CIN, screening for HPV in patients under the age of 30 has not shown any meaningful benefit over cytology; however, HPV screening has shown significant benefit in patients older than the age of 30.

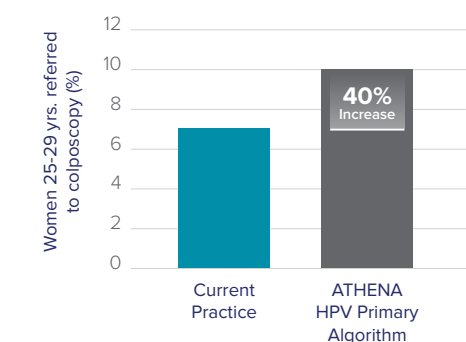
Percent Reduction in Cancer Incidence When Using HPV vs. Cytology



Potential Harm^{11,13,14}

It is also estimated that screening with HPV-Along* in women aged 25-29 will lead to more colposcopies in this young age group.

Estimated Increase in Colposcopies: ATHENA (1 in 5 tested positive for HPV)



95%

OF CERVICAL CANCERS WERE DETECTED BY TESTING WITH PAP + HPV TOGETHER (CO-TESTING).^{1,2}

"Liquid based cytology (LBC) enhanced cotesting detection of CxCa [...] to a greater extent than previously reported with conventional Pap smear and HPV cotesting." –Austin²