

ACOG, ASCCP, SGO, and USPSTF guidelines recommend:

For women ages 21-29 years old:¹⁶



Screening with cervical cytology alone every 3 years is recommended.

For women ages 30-65 years old:¹⁶



Co-testing with cervical cytology and high-risk HPV testing every 5 years is recommended.

For women ages 65 years and older:¹⁶



Do not require screening after adequate prior negative screening results.

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.

Learn why every woman is worth two tests at hologicwomenshealth.com/cervicalhealth



HOLOGIC®

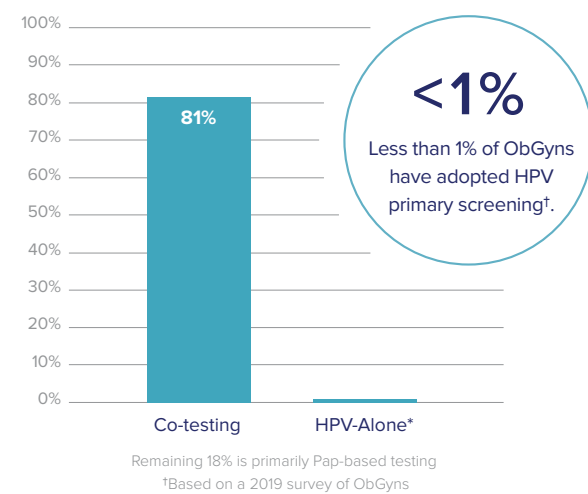
WHY IS IT ESSENTIAL TO KEEP THE PAP?
BECAUSE THEY'RE WORTH IT.

1 in 5 women with cervical cancer were missed by HPV-Alone* screening.¹
Pap + HPV (co-testing) empowers you to do everything you can to protect the health of your patients.

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 by ObGyns in the United States.¹⁷

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



Method + Technology
Together Define Performance

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

References: 1. Kaufman H, et al. Contributions of Liquid-Based (Papanicolaou) Cytology and Human Papillomavirus Testing in Cotesting for Detection of Cervical Cancer and Precancer in the United States. *Am J Clin Pathol.* 2020;XX:0-0. DOI: 10.1093/AJCP/AQAA074 (Study included ThinPrep Pap test, ThinPrep imaging, SurePath Pap test, SurePath imaging, Aptima HPV and Hybrid Capture 2). 2. American Cancer Society. The Pap (Papanicolaou) Test. <https://www.cancer.org/cancer/cervical-cancer/detection-diagnosis-staging/screening-tests/pap-test.html>. Published 2020. Accessed Aug 19, 2020. 3. American Cancer Society. Cancer Statistics Center. https://cancerstatisticscenter.cancer.org/?ga=2.150839477.20447513831547156654-2943865231544563210#. Accessed May 20, 2020. 4. North American Association of Central Cancer Registries. Fast Stats <https://faststats.naacr.org/selections.php?#Output>. Accessed May 10, 2021. 5. Kinney et al. Magnitude of increased lifetime risk of cervical cancer and death from cervical cancer with new screening recommendations. *Gyn Onc* 133(2014): 2(207): 38-6. 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/cncy.21544 (Study included ThinPrep Pap Test, SurePath Pap Test and Hybrid Capture 2 assay). 7. 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/aaq114 (Study included ThinPrep Pap test, ThinPrep imaging, Digene HPV, Cervista HPV and Aptima HPV). 8. Schiffman M, et al. Relative Performance of HPV and Cytology Components of Cotesting in Cervical Screening. *J Natl Cancer Inst.* 2018; 110(5):501-508. doi: 10.1093/jnci/djx225 (Study included conventional cytology, SurePath Pap test and Hybrid Capture 2). 9. Naucner P, et al. Efficacy of HPV DNA testing with cytology triage and/or repeat HPV DNA testing in primary cervical cancer screening. *J Natl Cancer Institute.* 2009; 101(2):88-99. doi.org/10.1093/jnci/djn444 (Study included conventional Pap, laboratory developed test for HPV detection). 10. de Sanjose S, et al. Human papillomavirus genotype attribution in invasive cervical cancer: retrospective cross-sectional worldwide study. *Lancet Oncol.* 2010;11(11):1048-56. doi:10.1016/S1470-2045(10)70230-8 (Study included laboratory developed test for HPV detection). 11. 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/S1470-2045(11)70145-0 (Study included conventional Pap, Hybrid Capture 2 assay). 12. 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.org/10.1002/jmv.23353. 13. 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.org/10.1309/AJCP19M8HPVBS5C. 14. 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. 15. 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). 16. American College of Obstetricians and Gynecologist. Women's Health Care Physicians. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines>. Released April 2021. Accessed May 10, 2021. 17. Hologic, Inc. Data on File. 18. CDC. Prevention Through Health Care: Preventive Service Tables. HPV. <https://www.cdc.gov/nchstp/preventionthroughhealthcare/preventiveservices/std.htm>. Updated May 2, 2018. Accessed August 20, 2020.

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

PB-00331-001 Rev. 007 © 2021 Hologic, Inc. Hologic, Aptima, ThinPrep, Pap+HPV Together 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 trade shows, 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.



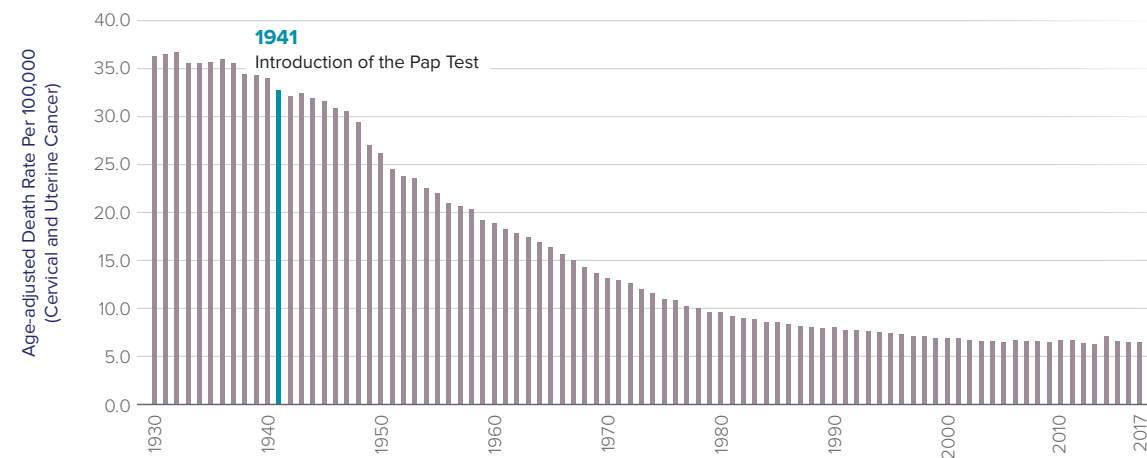
*A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.

* There are two additional screening methodologies also recommended in this age group. For more information, see the April 2021 ACOG Practice Advisory.

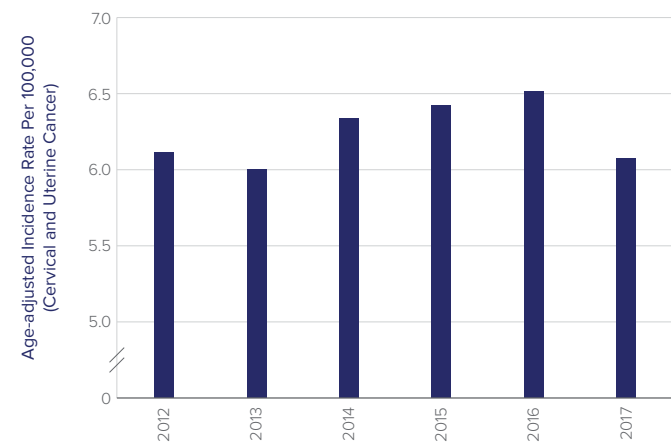
KNOW THE FACTS

The Pap test has been the most successful cancer screening program in history.²

The rate of cervical cancer, which was a leading cause of death among women, has fallen by more than 70 percent since the Pap test was introduced over 50 years ago.³ Previously, cervical cancer was the leading cause of cancer death in women, but now it is the fifteenth most frequent.



Cervical cancer is no longer decreasing⁴



Is this the right time to make more drastic changes to screening?

“At no point in the publications describing the new guidelines [2012 consensus guidelines] it is acknowledged that we are now recommending more cancer and more death from cancer than the previously recommended 3-year cotesting provides, and that we are doing so presumably for the purpose of avoiding a cervical treatment that is not associated with detectable increased mortality.”

- Kinney W, et al.⁵

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

The difference is in the results – with HPV-Along*, you will receive less information with the same collection.

Samples may be collected in FDA approved liquid based cytology medium such as ThinPrep® Pap Test.

| | Pap + HPV (Co-testing) | HPV-Along* |
|--------------------------|--|--|
| COLLECTION METHOD | ✓ Cervical Collection | ✓ Cervical Collection |
| RESULTS | ✓ HPV Test Result ✓ Cytology Result | ✓ HPV Test Result ✗ Cytology Result |



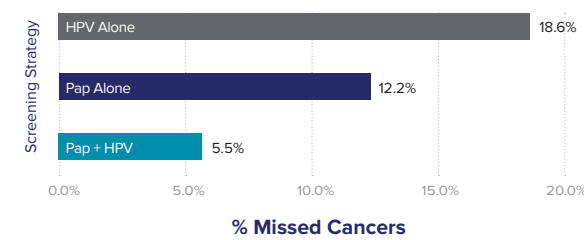
CHOOSE PAP + HPV

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

Key study from 2015⁶

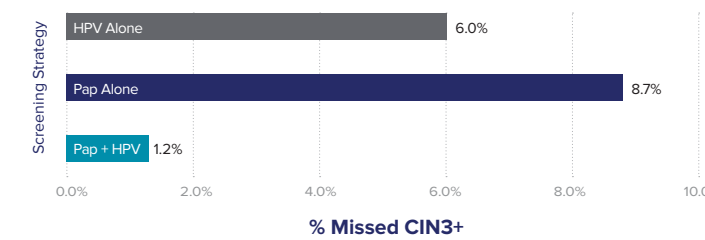
Pap + HPV together identified

70% of cancers missed by screening with HPV-Along*



Pap + HPV together identified

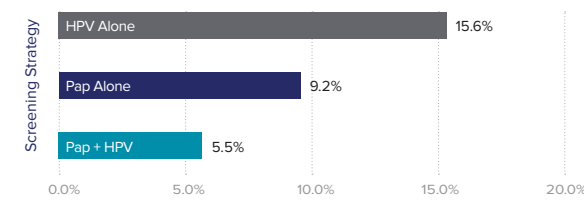
80% of the CIN3+ cases missed by screening with HPV-Along*



Key study from 2018⁷

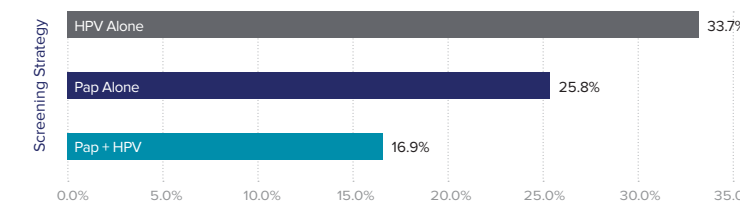
1-12 Months prior to Diagnosis

% Missed cancers



12+ Months prior to Diagnosis

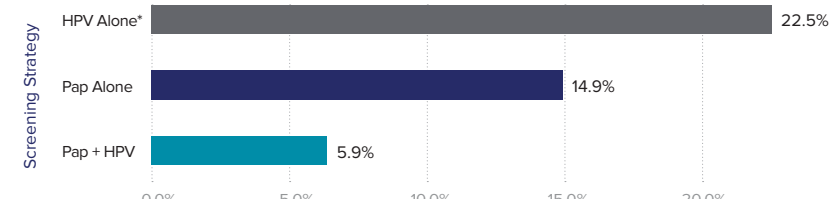
% Missed cancers



Key study from 2020¹

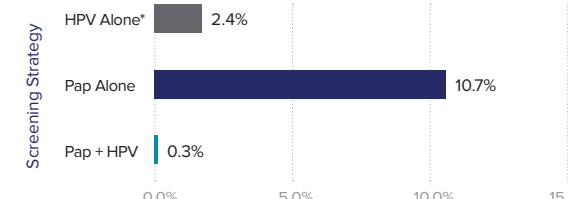
94.1% of cervical cancers were detected by Pap + HPV (co-testing)

% Missed cancers < 12 months



99.7% of pre-cancers were detected by Pap + HPV (co-testing)

% Missed pre-cancers < 12 months



DON'T SACRIFICE

Studies demonstrated the contribution of cytology at detecting cervical cancer cases.

Comparison of Three Longitudinal Co-Testing Studies

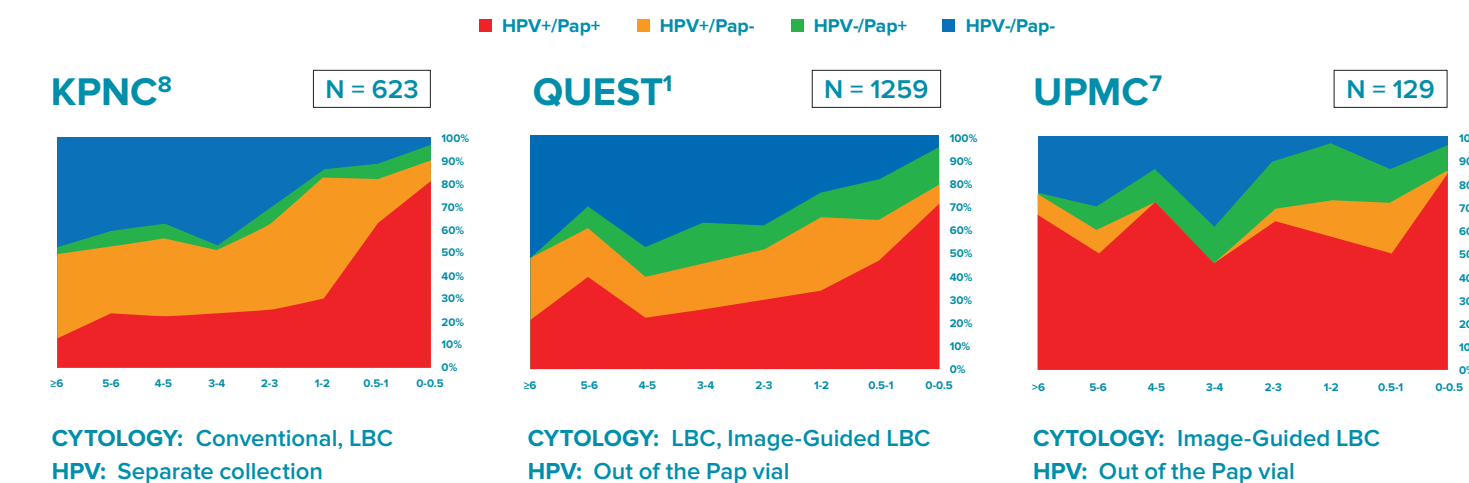
Kaiser Permanente Northern California (KPNC): Regional laboratory and Integrated Delivery Network

University of Pittsburgh Medical Center (UPMC): Large academic medical center

Quest Diagnostics: National reference laboratory

| | KPNC ⁸ | QUEST ¹ | UPMC ⁷ |
|--|-------------------|--------------------|-------------------|
| Inclusive of patients from a variety of health plans | | ✓ | ✓ |
| Opportunistic screening more reflective of current US practices | | ✓ | ✓ |
| Methods and technologies more reflective of current US practices | | ✓ | ✓ |
| Data used to inform guideline decisions | ✓ | | |
| Relative Contribution of Cytology over HPV-Along* for cervical cancer diagnosis (>12 months) | 7.3% | 20.7% | 25.3% |

~3x increase in Cytology contribution at Quest vs KPNC^{1,8}



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

Proportion of HPV Negative Cancer Cases^{1, 6, 7, 11-15}



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.

“Liquid based cytology (LBC) enhanced co-testing detection of cervical cancer ... to a greater extent than previously reported with conventional Pap smear and HPV co-testing.”

- Austin RM, et al.⁷