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Final USPSTF Cervical Cancer Screening Recommendations Retain "A" Grade for Pap + HPV for Women Ages 30 to 65

MARLBOROUGH, Mass., Aug. 21, 2018 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX), a pioneer in cervical cancer screening, commends the United States Preventive Services Task Force (USPSTF) for retaining in their final cervical cancer screening recommendations released today "A" grades for Pap tests in women 21 to 29 years old, and Pap + HPV in women ages 30 to 65 years old.¹

Hologic manufactures the leading cervical cancer screening products in the United States: the ThinPrep® Pap test, which helps healthcare providers detect the presence of abnormal cervical cells; and the Aptima® HPV assay, which identifies the high-risk HPV (human papillomavirus) infections most likely to lead to cervical disease.²⁻⁴ Both tests are performed from a single patient sample.

Data from multiple, large studies conducted among women over 30 years of age in the United States demonstrate that screening with Pap+HPV Together™ identifies more cervical pre-cancer and cancer than either test used alone.^{5,6,7,8,9,10} Guidelines from leading professional societies such as the American College of Obstetricians and Gynecologists (ACOG)¹¹, the American Cancer Society¹², the Society for Gynecological Oncology¹³, and the American Society for Colposcopy and Cervical Pathology¹⁴ recommend Pap + HPV for women between the ages of 30 and 65.

"We believe all women deserve access to the best healthcare strategies for monitoring and preserving their health and well-being," said Steve MacMillan, Hologic's chairman, president and chief executive officer. "The A grade recommendation for Pap+HPV Together ensures that women will continue to have access to the most commonly used cervical cancer screening method in the United States, an approach that we believe is simple, highly accurate and cost-effective."¹⁵

About Pap+HPV Together™

Both Hologic's ThinPrep® Pap test and its Aptima® HPV Assay are the market-leading products for cervical cancer screening in the U.S.¹⁶ More information about the value of Pap+HPV Together is available at PapPlusHPV.com.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's cervical cancer screening products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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References

1. <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening2>. Accessed August 21, 2018.
2. ThinPrep 2000 Processor [instructions for use]. MAN-02624-001, Rev. 005. Marlborough, MA:

- Hologic, Inc.; 2017.
3. Aptima HPV assay [package insert]. AW-12820-001, Rev. 001. San Diego, CA: Hologic, Inc.; 2015.
 4. Aptima HPV Genotype 16 18/45 assay [package insert]. AW-12821-001, Rev. 001. San Diego, CA: Hologic, Inc.; 2015.
 5. Zhou, H., Mody, R. R., Luna, E., Armylagos, D., Xu, J., Schwartz, M. R., Mody, D. R. and Ge, Y. (2016), Clinical performance of the Food and Drug Administration–Approved high-risk HPV test for the detection of high-grade cervicovaginal lesions. *Cancer Cytopathology*. doi: 10.1002/cncy.21687 [Study included ThinPrep®, SurePath® and cobas® HPV assay]
 6. Blatt, A. J., Kennedy, R., Luff, R. D., Austin, R. M. and Rabin, D. S. (2015), Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. *Cancer Cytopathology*, 123: 282–288. doi: 10.1002/cncy.21544 [Study included ThinPrep®, SurePath, Hybrid Capture 2 assay].
 7. Katki HA, Kinney WK, Fetterman B, 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):663-72. PMID: 21684207. [https://doi.org/10.1016/S1470-2045\(11\)70145-0](https://doi.org/10.1016/S1470-2045(11)70145-0). [Study included FocalPoint™ Slide Profiler, Hybrid Capture® 2 assay]
 8. Gage JC, Hunt WC, Schiffman M, et al. Similar risk patterns after cervical screening in two large U.S. populations. *Obstet Gynecol*. 2016;128(6):1248-57. <https://doi.org/10.1097/AOG.0000000000001721>. [Study included SurePath® assay, Hybrid Capture® 2 assay, FocalPoint™ Slide Profiler]
 9. Gage JC, Schiffman M, Katki HA, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. *J Natl Cancer Inst*. 2014;106(8). PMID: 25038467. <http://dx.doi.org/10.1093/jnci/dju153>. [Study included Hybrid Capture® 2 assay]
 10. Katki HA, Schiffman M, Castle PE, et al. Five-year risks of CIN 3+ and cervical cancer among women who test Pap-negative but are HPV-positive. *J Low Genit Tract Dis*. 2013;17(5 Suppl 1):S56-63. <https://doi.org/10.1097/LGT.0b013e318285437b>. [Study included FocalPoint™ Slide Profiler, SurePath® assay, Hybrid Capture® 2 assay]
 11. Cervical cancer screening and prevention. Practice Bulletin No. 168. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2016;128:e111-30. <https://doi.org/10.1097/AOG.0000000000001708>.
 12. Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin*. 2012;62:3:147-172. <https://doi.org/10.3322/caac.21139>.
 13. Society of Gynecologic Oncology. Cervical Cancer Screening Recommendations. <https://www.sgo.org/newsroom/position-statements-2/cervical-cancer-screening-recommendations/>. Updated March 2012. Accessed August 8, 2018.
 14. Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and Early Detection of Cervical Cancer. *Am J Clin Pathol*. 2012;137:516-42. <https://doi.org/10.1309/AJCPTGD94EVR SJCG>.
 15. Felix JC, Miller JD, Lenhart GM, et. al. The Clinical and Economic Benefits of Co-Testing Versus Primary HPV Testing for Cervical Cancer Screening: A Modeling Analysis. *J Women's Health* 2016; 25(6): 606–616. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4900245/> [Study included ThinPrep®, Aptima® HPV, and cobas® HPV test]
 16. Hologic, Inc. Data on File. Estimated Unit Share through 2017 Emmes Data.

SOURCE Hologic, Inc.