NEWS RELEASE

Hologic Receives FDA Approval for Aptima® HPV Assay Primary Screening Option, Expanding Cervical Health Portfolio

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Expanded FDA approval across multiple cervical cancer screening modalities supports clinical flexibility and provider choice

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that its Aptima® HPV Assay received FDA approval for clinician-collected HPV primary screening. Hologic's human papillomavirus (HPV) test is the only FDA-approved mRNA-based assay, designed specifically to detect infections most likely to lead to cervical cancer.

Screening for cervical cancer is critically important to women's health. In the United States, it is estimated that in 2026, approximately 13,490 new cases of invasive cervical cancer will be diagnosed, and about 4,200 women will die from the disease.1 However, many of these deaths are preventable with regular screening and appropriate follow-up on abnormal results. Timely follow-up is essential for early detection and treatment to reduce cervical cancer cases and deaths.1

"Hologic has been at the forefront of cervical cancer screening for decades, and the additional indication of the Aptima HPV Assay reflects our ongoing commitment to advancing women's health through innovative, evidence-based solutions," said Jennifer Schneiders, Ph.D., President of Diagnostic Solutions at Hologic. "Our commitment to providing comprehensive cervical health solutions that meet provider and patient needs is unwavering, and by offering providers more choice and flexibility, we can help them deliver the most personalized care for each patient."

The additional indication for the Aptima HPV Assay expands Hologic's offerings to now include Pap + HPV (co-

testing), Pap testing, and HPV primary testing — three major FDA-approved and guideline-recommended methods for cervical cancer screening. This additional approval for the Aptima HPV Assay follows the clearance of the Genius® Digital Diagnostics System with the Genius® Cervical AI Algorithm, which leverages advanced digital imaging and artificial intelligence to help detect cytologic abnormalities and precancerous lesions.

The approval comes following the completion of one of the largest real-world evidence HPV screening studies, involving over 650,000 women across multiple U.S. health systems that reflect diverse, real-life patient populations and clinical settings. This innovative study compared the Aptima HPV Assay to an FDA-approved DNA-based HPV test for primary screening and found that the sensitivity of the Aptima HPV Assay is clinically comparable to the comparator test. The Aptima HPV Assay is effective for use in primary screening for the detection of CIN2+ and CIN3+.

While co-testing remains the most comprehensive screening modality — with more than 90% of providers reporting strong confidence for women ages 30 to 65, and data showing that co-testing (Pap + HPV) detected up to 95% of cervical cancers — Hologic's range of testing options gives providers greater flexibility in selecting an approach based on a patient's age, access and risk factors.2-5

About Hologic's Cervical Health Solutions

Hologic offers a broad portfolio for cervical cancer screening, supporting both cytology and molecular workflows from sample collection to results. The portfolio includes innovations such as the ThinPrep® Pap Test, the first liquid-based cytology test, the Aptima HPV Assay, the first and only approved mRNA-based HPV tests, and the Genius Digital Diagnostics System, the first and only FDA-cleared digital cytology system. These technologies are designed to support clinicians and laboratory professionals in the detection and prevention of cervical cancer, all backed by Hologic's support and partnership. To learn more, please visit **Hologic.com**.

About Hologic, Inc.

Hologic, Inc. is a global leader in women's health dedicated to developing innovative medical technologies that effectively detect, diagnose and treat health conditions and raise the standard of care around the world. To learn more, visit **www.hologic.com** and connect with us on **LinkedIn**, **Facebook**, **X**, **Instagram** and **YouTube**.

Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's and its subsidiaries' 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, as the actual effect of the use of the products can only be determined on a case-by-case basis. 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 data or statements are based.

References: 1. American Cancer Society. Cancer Statistics Center. Accessed January 2026. **https://cancerstatisticscenter.cancer.org/types/cervix**. 2. Austin et al. Enhanced Detection of Cervical Cancer and Precancer Through Use of Imaged Liquid-Based Cytology in Routine Cytology and HPV Cotesting. Am J Clin Patho 2018; 150:385-392 1. 3. 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. 4. 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). 5. Kruse G, et al. Provider beliefs in effectiveness and recommendations for primary HPV testing in 3 health-care systems. JNCI Cancer Spectrum. 2023;7(1).

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