Women in U.S. Can Now Collect Their Own Sample for Cervical Cancer Screening

FRANKLIN LAKES, N.J., May 15, 2024 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced U.S. Food and Drug Administration (FDA) approval for the use of self-collected vaginal specimens for human papillomavirus (HPV) testing when cervical specimens cannot otherwise be obtained. The approval allows women to self-collect vaginal specimens for HPV testing in a health care setting, which could include non-traditional locations such as a retail pharmacy or mobile clinic.

HPV is the cause of virtually all cervical cancer, and HPV testing is the preferred screening method by the American Cancer Society in the United States. The BD Onclarity™ HPV Assay is FDA-approved for HPV primary testing without the need for a traditional Pap smear performed with a speculum. This new approval of self-collected samples opens the door to a less invasive testing option, and it improves access to testing for individuals who face barriers to cervical cancer screening.

"Many patients are uncomfortable with the intimate nature of a pelvic exam," said DrJeff Andrews, board-certified gynecologist and vice president of Global Medical Affairs for Diagnostic Solutions at BD. "Also, many people live in areas without a local doctor or clinician trained to obtain a sample with a speculum. The option to self-collect in a clinical setting can help women overcome some of these barriers."

Cervical Cancer is Preventable
Cervical cancer is preventable, and screening plays a crucial role in early detection and prevention. According to the American Cancer Society, approximately 50% of cervical cancer diagnoses are in never-screened people, and 10% of diagnoses occurs in under-screened individuals. In addition, 25% of women in the U.S. do not receive regular cervical cancer screening, according to the National Cancer Institute.

Various factors contribute to inadequate screening, including physical and geographic inaccessibility, financial insecurity (including lack of health insurance coverage), lack of awareness about the importance of screening, social or religious preferences, physical disability, medical conditions, or history of sexual, physical or psychological abuse that may make a pelvic examination for sample collection by a clinician traumatizing.

Self-Collection Improves Access
Self-collection can improve cervical cancer screening access, especially in underserved populations. In the U.S., Black, Hispanic and American Indian women have higher rates of cervical cancer than women of other racial groups, with Black women having the highest rate of death. With vaginal self-collection as an option for cervical cancer screening, women are more inclined to participate in such care — with never-screened women demonstrating a more than two-fold increase in acceptance and participation — allowing health care providers an alternative option to identify a high-risk HPV infection in more convenient care settings.[1] [2]

The National Cancer Institute (NCI), part of the National Institutes of Health (NIH), has been working with BD in a public-private partnership called the Cervical Cancer "Last Mile" Initiative to address disparities in cervical cancer screening. As part of this initiative, BD will be a participant in the Self-collection of HPV testing to Improve Cervical Cancer Prevention (SHIP) trial, which will begin enrolling this summer, to evaluate accuracy of self-collection for HPV testing both in health care and other settings, including at home.

Some HPV Strains Carry a Higher Risk than Others
There are many strains (genotypes) of HPV viruses, with some strains posing a much higher risk for causing precancer and cancer than others. BD Onclarity™ is the first FDA-approved assay that reports six HPV strains individually, providing a more precise, accurate way to measure a women's risk for developing cervical precancer by showing results for an extended set of individual HPV strains and enabling those strains to be tracked over time. Most clinically validated tests report multiple strains in a single pooled result that prohibits monitoring of specific strains over time, which is an important determinant of cervical cancer risk in women who test positive for HPV.

"The integration of self-collection with testing for individualized strains of HPV represents a significant advancement in cervical cancer screening," said Dr. Shieva Ghofrany, a practicing OB-GYN and Fellow of the American Congress of Obstetricians and Gynecologists. "Self-collection provides greater access to testing and BD Onclarity™ allows health care providers to determine the specific HPV strains present in the samples and more precisely identify and treat individuals at high-risk and avoid unnecessary treatments for women at low risk."

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by

developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its more than 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) @BDandCo or Instagram @becton_dickinson.

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[1] MacDonald EJ, Geller S, Sibanda N, et al. Reaching under–screened/never–screened indigenous peoples with human papilloma virus self–testing: A community–based cluster randomised controlled trial.

[2] Australian and New Zealand Journal of Obstetrics and Gynaecology. 2020;61(1):135-141. doi:https://doi.org/10.1111/ajo.13285

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