BD Onclarity™ HPV Assay Receives FDA Approval for Use with Both BD SurePath™ Liquid-based Pap Test and Hologic ThinPrep® Pap Test

Expands Access to BD HPV Test that More Precisely Identifies Patients' Risk for Cervical Cancer

FRANKLIN LAKES, N.J., Feb. 21, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced U.S. Food and Drug Administration (FDA) market approval for the BD Onclarity™ HPV Assay to be used with the ThinPrep® Pap Test.

The BD SurePath™ Liquid-based Pap Test vial and the Hologic ThinPrep® Pap Test PreservCyt® Solution vial are the two most common Pap vials used by laboratories in the United States. The inclusion of the ThinPrep® Pap Test improves access to the benefits of the BD human papillomavirus virus (HPV) assay, which is the only FDA-approved assay that tests for an extended set of HPV types individually, and particularly for HPV31, a specific type of HPV that poses a high-risk for causing cervical cancer. Individual identification of HPV31 can help better determine risk for cervical pre-cancer, which may lead health care providers to different clinical decision-making than when assessing risk when multiple genotypes are reported collectively.

"Most tests report multiple HPV types in a single pooled result, which can mask the true risk of developing cervical cancer," said Brooke Story, worldwide president of Integrated Diagnostics Solutions for BD. "Being able to identify high-risk HPV31 individually is critical to the detection and prevention of cervical cancer. HPV31 poses the second-highest risk for cervical pre-cancer, and the BD Onclarity™ HPV Assay is the only FDA-approved assay that screens for it individually."

This important milestone supports BD's strategy to penetrate the large and growing molecular diagnostics market through its expanded installed base and providing additional testing solutions for women's health.

The BD Onclarity™ HPV Assay detects and identifies 14 high-risk human papillomavirus (HPV) types in a single analysis. The assay reports genotypes beyond HPV types 16, 18, and 45 to include types 31, 51, 52, 33/58, 35/39/68, and 56/59/66, making the BD Onclarity™ HPV Assay the only FDA-approved assay to individually identify and report these genotype results. The BD Onclarity™ HPV Assay has FDA approval for use in vaccinated women. As the previously vaccinated subpopulation ages, the screening population will progressively include women with reduced prevalence of HPV 16 and 18, increasing the value of extended genotype reporting in a mixed population of vaccinated and unvaccinated women.

The evidence generation for the clinical validation of BD Onclarity™ HPV Assay out of PreservCyt® media was achieved by one of the largest real-world evidence studies of its kind, conducted by Dr. Cosette Wheeler, with the New Mexico HPV and Pap Registry, including a random sample of 19,879 women's preserved samples who had undergone opportunistic cervical screening and follow-up in routine clinical practice, with known clinical outcomes.

"Cervical cancer is preventable," said Dr. Jeff Andrews, vice president of medical affairs for BD. "When more people with a cervix are better able to manage their health through more accurate and precise testing, we are taking another step forward toward eliminating cervical cancer in our lifetimes."

The ThinPrep® Pap Test with the BD Onclarity™ HPV Assay can be used on the BD COR™ or BD Viper™ LT instrument platforms without the need to change current cytology equipment. The BD COR™ System offers integrated and automated workflows, designed to free up time in the high-throughput laboratory, and the extended claim for the BD Onclarity™ HPV Assay allows mid- to low-throughput labs to leverage the benchtop BD Viper™ LT instrument to enhance their HPV test offering.

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 77,000 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/ and Twitter @BDandCo.

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