BD Submits Pre-Market Approval Supplement to FDA to Enable ThinPrep® Pap Test™ PreservCyt® Solution to be Used with the BD Onclarity™ HPV Assay

FRANKLIN LAKES, N.J., Sept. 23, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has submitted a pre-market approval (PMA) supplement to the U.S. Food and Drug Administration (FDA) for the use of the ThinPrep® Pap Test™ PreservCyt® Solution vial as an approved sample type for its BD Onclarity™ HPV Assay.

The PMA supplement would expand the sample claims that can be used in addition to the BD SurePath™ vial for the detection of human papillomavirus (HPV) using the BD Onclarity™ HPV Assay. The submission includes performance data for the BD Viper™ LT and the BD COR™ Systems. An additional supplement was submitted in January 2020 to seek approval for the BD Onclarity™ HPV assay on the BD COR™ System and the BD SurePath™ Liquid Based Cytology vial.

BD recently announced the FDA approval of a PMA supplement that included the expansion for genotype reporting beyond HPV genotypes 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.

"This PMA supplement to the FDA signifies BD's commitment to expanding the availability of the BD Onclarity™ HPV Assay in the U.S. to support better patient management by providing clinicians more data to inform treatment decisions across multiple collection devices," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "BD is dedicated to providing comprehensive screening solutions that are accessible globally in the fight to eliminate cervical cancer."

About BD Onclarity™ HPV Assay
The BD Onclarity™ HPV Assay detects and identifies 14 high-risk human papillomavirus (HPV) types in a single analysis and provides genotyping information from specimens collected for cervical cancer screening purposes in the BD SurePath™ Collection Vial and in the Hologic PreservCyt® Solution (not approved in the United States). The assay is for use in accordance with clinical guidelines and within the scope of local regulatory authorizations as part of a comprehensive approach to cervical cancer screening. The BD Onclarity™ HPV Assay has FDA approval for clinical use in cytology-based screening with ASC-US triage, in co-testing paradigm, and in primary HPV screening. 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.[7]

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 65,000 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.

Contacts:

Troy Kirkpatrick	Kristen Stewart
BD Public Relations	BD Investor Relations
858.617.2361	201.847.5378
troy.kirkpatrick@bd.com	kristen.stewart@bd.com

SOURCE BD (Becton, Dickinson and Company)

Additional assets available online: Photos (1)

https://news.bd.com/2020-09-23-BD-Submits-Pre-Market-Approval-Supplement-to-FDA-to-Enable-ThinPrep-R-Pap-Test-TM-PreservCyt-R-Solution-to-be-Used-with-the-BD-Onclarity-TM-HPV-Assay