BD Newsroom

BD Submits Pre-Market Approval Application to FDA for BD Onclarity(TM) HPV Test

PR Newswire

FRANKLIN LAKES, N.J., Sept. 6, 2016 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced today that it has submitted a pre-market approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the BD Onclarity(TM) HPV Assay, its human papillomavirus (HPV) test.

The BD Onclarity HPV Assay PMA is supported by data collected during a two-year, prospective, multi-center clinical trial with more than 33,000 women enrolled one of the largest clinical trials ever conducted by BD.

"The submission of BD's HPV PMA application marks the completion of a significant undertaking," said Doug White, vice president and general manager of Women's Health & Molecular Diagnostics for BD. "Our goal is to provide clinical laboratories and clinicians with comprehensive cervical cancer screening solutions that include BD Onclarity HPV Assay, BD SurePath(TM) Pap Test and BD Totalys(TM) System processing automation."

The submission seeks approval for use of the BD Onclarity HPV assay* with BD SurePath specimens for detection of 14 high-risk HPV types to determine the need for referral to colposcopy for women 21 and older with abnormal (ASC-US) Pap test results and in women 30 years and older, the use of BD Onclarity together with cervical cytology to adjunctively screen for high-risk HPV and individually identify HPV genotypes 16, 18 and 45. BD is also seeking the use of the test as a first-line primary cervical cancer screening test for women 25 years and older.

BD intends to ultimately seek approval using HPV genotyping beyond 16, 18 and 45, in line with the genotyping capabilities of the assay's design.

BD's submission seeks approval to use the assay on the BD Viper(TM) LT System, which is a bench-top molecular platform currently FDA-cleared for chlamydia gonorrhea infection (CT/GC) testing. The BD Viper LT System automates sample processing, nucleic acid extraction, Real-Time Polymerase Chain Reaction (RT-PCR) amplification/detection and result reporting with minimal user intervention. The BD Viper LT System is part of the BD Totalys System, which automates cervical cancer screening including BD SurePath Pap Test slide preparation, imaging and slide review, combined with automated aliquot capabilities for ancillary testing.

*The BD Onclarity HPV Assay is not currently available in the United States.

About BD
BD is a global medical technology company that is *advancing the world of health* by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance cellular studies and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, optimize respiratory care and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has more than 45,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit www.bd.com.

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