FDA Approves New HPV Test that Detects and Identifies HPV Genotypes that put Women at High Risk for Cervical Cancer

The BD Onclarity(TM) HPV Assay can detect 14 high-risk HPV types and provide additional information to guide physician decision-making

FRANKLIN LAKES, N.J., Feb. 13, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has received pre-market approval from the U.S. Food and Drug Administration (FDA) for the BD Onclarity(TM) HPV assay. The test detects 14 types of high-risk human papillomavirus (HPV) from specimens collected for cervical cancer screening ("Pap test") in the BD SurePath(TM) liquid based cytology vial. The BD Onclarity*(TM)* HPV assay also identifies HPV genotypes 16, 18, and 45, which are associated with the majority of cervical cancers worldwide, and are disproportionally responsible for up to 94 percent of glandular cervical cancer cases.(1,2) In evaluating the test, the FDA reviewed data collected during a multi-year, prospective, multi-center clinical trial conducted in the US that included more than 33,500 vaccinated and non- vaccinated women.

The BD Onclarity*(TM)* HPV assay may be used in accordance with clinical guidelines(3,4) for cervical cancer screening and management to identify the presence of high-risk HPV types. The test is clinically validated for use as a primary screening test, for triaging patients with abnormal Pap test results and to be used in combination with a Pap test. The BD Onclarity*(TM)* HPV assay provides information that together with the physician's assessment and professional guidelines, may be used to inform clinical decision-making.

BD intends to seek approval in future submissions for reporting of HPV types beyond 16, 18 and 45 consistent with the extended genotyping capabilities of the assay's design and aligned with evolving cervical cancer screening guidelines.

"Our goal is to provide laboratories and clinicians worldwide with comprehensive cervical cancer screening solutions that address the unique needs of individual healthcare providers and patients," said Dave Hickey, president, BD Diagnostics Systems. "The addition of the BD Onclarity*(TM)* HPV assay to BD's women's health and cancer portfolio will enable BD to continue to enhance the standard of patient care, representing the next milestone in cervical cancer screening."

Dr. Thomas C. Wright, Jr., professor emeritus of pathology and cell biology at Columbia University noted that "The approval of the BD Onclarity*(TM)* HPV assay provides clinicians and laboratories an FDA-approved option for HPV primary screening with the BD SurePath*(TM)* liquid based cytology vial. The BD Onclarity*(TM)* HPV assay also aligns with clinical screening guidelines from the American Cancer Society, the American Society for Colposcopy and Cervical Pathology and the American Society for Clinical Pathology."

The BD Onclarity*(TM)* HPV assay is performed on the BD Viper(TM) LT system, a bench top molecular platform which automates sample processing and is also FDA-cleared for chlamydia and/or gonorrhea infection (CT/GC) testing. The BD Onclarity*(TM)* HPV assay achieved the European CE-IVD mark in 2014, received regulatory approval in Canada and Japan in 2017, and is currently for sale in these and other markets.

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 improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose 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. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

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