BD Onclarity™ HPV Assay on the BD Viper™ LT System Achieves CE-IVD Mark

BALTIMORE, MD, February 14, 2014– BD Diagnostics, a segment of BD (Becton, Dickinson and Company), a leading global medical technology company, announced today that the company has achieved CE/IVD marking for the BD OnclarityTM HPV Assay on the new BD Viper™ LT System.

The BD Onclarity HPV Assay targets E6/E7 DNA oncogenes and is designed to provide physicians access to broader High Risk (HR) HPV genotype information beyond types 16 and 18 to guide informed treatment decisions for their patients. The BD Onclarity HPV Assay reports results on six discrete HR HPV genotypes (16, 18, 31, 45, 51 and 52) with the remaining eight high-risk genotypes reported in three small groups: (33, 58), (35, 39, 68) and (56, 59, 66). Individual and grouped HR HPV genotype results are obtained from the same sample with no additional processing steps required.

“Cervical cancer continues to be a major health issue around the world and poses a significant threat to women’s health. The launch of our new platform and assay offers physicians a more complete assessment of a patient’s risk,” said Paul Holt, Global Business Leader, Women’s Health and Cancer, BD Diagnostics – Diagnostic Systems. “It is now clear that high-risk HPV genotypes differ in their ability to persist and lead to cervical cancer. The BD Onclarity HPV Assay screens for all 14 high-risk types and provides access to genotype information that is relevant to a patient’s risk for development of precursors to cervical cancer.”

The BD Onclarity HPV Assay was recently clinically evaluated according to International Guidelines for clinical HPV assay performance and met all acceptance criteria.[1] The study was conducted in three leading HPV laboratories in London, Copenhagen and Edinburgh, and compared the performance of the BD Onclarity HPV Assay to a clinically validated reference standard. The independent study also demonstrated excellent inter- and intra-laboratory assay reproducibility in the respective laboratories.

The BD Viper LT System is a bench-top molecular platform that automates sample processing, nucleic acid extraction, Real-Time Polymerase Chain Reaction (RT-PCR) amplification and detection and result reporting with minimal user intervention. The BD Viper LT system is designed to manage sample tubes with pierceable caps and ready to use reagents. The “load and go” capability and ease of use design of the BD Viper LT system delivers true walkaway potential that maximizes laboratory productivity.

The combination of the BD Viper LT system with the BD Onclarity HPV Assay brings to pathology and molecular labs an innovative solution that enhances clinical utility, increases flexibility and improves laboratory efficiency.

Virtually all cases of cervical cancer are caused by specific types of human papillomavirus (HPV).[2] Although there are more than 100 HPV genotypes, 14 HR genotypes are considered to be cancer-causing.[3] Many women with a positive HR HPV result will clear the infection on their own before it progresses towards cervical cancer.[4]

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

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