

BD MAX™ Enteric Parasite Panel Achieves CE Mark to Detect Common and Pathogenic Intestinal Parasites

Supports comprehensive screening for infectious gastroenteritis with the BD MAX™ System

SPARKS, MD, May 12, 2014— BD Diagnostics, a segment of global medical technology company BD (Becton, Dickinson and Company), announced today the availability of the CE-marked BD MAX™ Enteric Parasite Panel for use with the BD MAX System. The BD MAX Enteric Parasite Panel is the latest panel in the BD MAX Enteric suite for the diagnosis of infectious gastroenteritis. This panel joins the BD MAX Enteric Bacterial Panel and the Diagenode™ Enteric Viral Panel primers and probes kit that is used with the BD MAX RNA 3 extraction kit to detect gastrointestinal pathogens. With the availability of the BD MAX Enteric Parasite Panel, the majority of pathogens causing this disease can be detected with a fully automated, rapid and accurate platform.

The BD MAX Enteric Parasite Panel is a qualitative IVD test detecting DNA from *Giardia lamblia*, *Cryptosporidium (C. hominis and C. parvum)* and *Entamoeba histolytica* in stool specimens, both unpreserved and formalin-fixed (10%). These pathogens represent commonly isolated and highly pathogenic organisms. Results from this assay are available in approximately 4 hours, require minimal technologist time, and may replace traditional methods such as microscopy and immunoassay which can be complex, labor intensive and inaccurate.

“We continue to expand the BD MAX System menu and open system capabilities. Full automation and standardized workflow will enable laboratories to consolidate a broad range of molecular tests to meet their current and future clinical needs,” said Doug White, Vice President and General Manager, Molecular Diagnostics & Women’s Health, BD Diagnostics. “BD’s suite of enteric assays will allow flexibility for specific testing needs based on patient and clinical presentation, enabling more efficient patient management and laboratory processes.”

Globally, there are approximately 1.7 billion cases of diarrhea accounting for more than 2 million deaths annually. Children less than 5 years of age are particularly at risk with around 760,000 deaths each year.ⁱ These infections may be caused by viruses, bacteria or parasites and often take two to three days or more to identify in the clinical laboratory using conventional methods. Infections caused by the parasites *Giardia* and *Cryptosporidia*, while relatively common, may be subject to under diagnosis and reporting in Europe.ⁱⁱ

The BD MAX System offers a highly efficient path to improved clinical outcomes through flexible molecular solutions. In the laboratory, the BD MAX System automates sample preparation, extraction, amplification and detection on a single system, saving time and improving lab efficiency. Molecular testing on the BD MAX System is simplified and standardized, eliminating variability in results. Menu options include both CE marked assays and Open System Reagents that are used for user defined protocols.

In addition to panels detecting enteric parasite, viral and bacterial pathogens, other BD MAX enteric panels are in development for the qualitative detection of additional viral and bacterial pathogens directly from stool specimens in patients with signs and symptoms of gastroenteritis and/or colitis.

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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*The BD MAX Enteric Parasite Panel is not available for sale or use in the U.S.

ⁱ WHO Fact Sheet, April 2013

ⁱⁱ ECDC Annual Epidemiology Report, 2012.

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