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BD MAX™ Enteric Parasite Panel Receives FDA Clearance for Detection of Common and Pathogenic Intestinal Parasites

SPARKS, Md., Sept. 24, 2015 /PRNewswire/ -- BD Life Sciences, a segment of global medical technology company BD (Becton, Dickinson and Company) (NYSE: BDX), today announced the availability of the U.S. Food and Drug Administration (FDA) cleared BD MAX™ Enteric Parasite Panel for use on the BD MAX System.

The BD MAX Enteric Parasite Panel is the latest panel in the BD MAX Enteric suite of assays that aid in the diagnosis of infectious gastroenteritis. This panel joins the BD MAX Enteric Bacterial Panel detecting the pathogens that are responsible for up to 95 percent of the bacteria causing gastroenteritis.ⁱ 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 both unpreserved and 10 percent formalin-fixed stool specimens.

"What we see as the value it will bring to us is the speed with which we can accurately provide patient results," said Kate Buehler, molecular specialist at Aspirus Wausau Hospital Reference Laboratory. "Coupled with the BD MAX Enteric Bacterial panel, it allows us to provide a flexible diagnostic solution with ease."

Doug White, vice president and general manager, Molecular Diagnostics & Women's Health, BD Life Sciences said, "We continue to expand the BD MAX System menu of unique, clinically relevant panels. 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.ⁱⁱ 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 the US.ⁱⁱⁱ

"The BD MAX assays for *Clostridium difficile* (*C. diff*) and selected enteric bacterial and parasitic pathogens are the first commercial assays for selective, targeted diagnosis of enteric infectious diseases, an approach that is consistent with the recommendations of the American Society of Microbiology and the Infectious Disease Society of America," said Patrick Murray, Ph.D., senior director of Worldwide Scientific Affairs, BD Diagnostics.^{iv v}

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, to minimize variability in results.

"The BD MAX Enteric Parasite Panel addition to the menu will further streamline our workflow, improve turnaround time and free up staff that were previously running EIA testing manually," said Annette Monterrubio, Microbiology & Molecular Biology System technical coordinator at St. Luke's Health System, Boise, Idaho. "I believe this will greatly benefit patient care."

The BD MAX menu includes syndromic panels for Healthcare Associated Infections, Reproductive & Sexually Transmitted Infections and Enteric Pathogens, enabling lab professionals in their efforts to deliver diagnostic results that improve lab operations.

About BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving medication management and patient safety; supporting infection prevention practices; equipping surgical and interventional procedures; improving drug delivery; aiding anesthesiology and respiratory care; advancing cellular research and applications; enhancing the diagnosis of infectious diseases and cancers; and supporting the management of diabetes. We are more than 45,000 associates in 50 countries who strive to fulfill our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of health care around the world. In 2015, BD welcomed CareFusion and its products into the BD family of solutions. For more information on BD, please visit www.bd.com.

ⁱ MMWR, CDC, April 19, 2013, Vol 62:15 :pdf

ⁱⁱ WHO Fact Sheet, April 2013

ⁱⁱⁱ <http://www.cdc.gov/parasites/crypto/diagnosis.html>

^{iv} Manual of Clinical Microbiology, 11th ed., ch.18, 2015

^v Guerrant RL et al., Practice Guidelines for the Management of Infectious Disease, Clin Infect Dis,2001.

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