The BD MAX(TM) Enteric Bacterial Panel Receives FDA Clearance to Detect the Most Common Causes of Bacterial Gastroenteritis

SPARKS, Md., May 7, 2014 /PRNewswire/ -- BD Diagnostics, a segment of leading global medical technology company BD (Becton, Dickinson and Company) (NYSE: BDX), announced today the availability of the FDA-cleared BD MAX(TM) Enteric Bacterial Panel for use on the BD MAX System. The BD MAX Enteric Bacterial Panel is a qualitative IVD test detecting DNA from C*ampylobacter* spp. (*jejuni* and *coli)*, *Salmonella* spp., *Shigella* spp. / Enteroinvasive *E. coli* (EIEC) as well as *stx* 1 and *stx* 2 genes in stool specimens. These pathogens are responsible for up to 95% of the bacteria causing gastroenteritis, accounting for millions of deaths annually.(1)

The BD MAX Enteric Bacterial Panel is designed to detect bacterial pathogens in line with widely recommended clinical algorithms for testing. These algorithms utilize patient history and clinical presentation in selecting diagnostic tests(.2) The use of focused panels enables the implementation of enteric molecular testing in a cost effective manner. Additionally, the use of the BD MAX Enteric Bacterial Panel allows laboratories to implement CDC recommended and Joint Commission required STEC screening. (3,4) Specimen types include unpreserved and Cary-Blair preserved stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis or colitis, adding to the flexibility of use for the laboratory. The assay was CE-marked in March 2013 and has demonstrated excellent performance in Europe.

"The BD MAX Enteric Bacterial Panel will provide clinicians with fast, accurate results that will enable more rapid diagnosis compared with conventional culture methods and will help improve standard of care and clinical efficiencies," said Doug White, Vice President and General Manager, Molecular Diagnostics & Women's Health, BD Diagnostics. "The BD MAX Enteric Bacterial Panel is the first FDA-cleared assay in the BD MAX Enteric portfolio and we plan to add additional panels that include viral, parasite and extended bacterial detection."

Recently, the BD MAX Enteric Parasite Panel* has been CE marked for the qualitative detection of the parasitic enteric pathogens *Giardia lamblia*, *Cryptosporidium* spp*. (C. hominis* and *C. parvum*), and *Entamoeba histolytica* directly from stool specimens.

Infectious gastroenteritis accounts for approximately 1.7 billion cases of diarrhea globally and more than 2 million deaths annually.((5)) These infections may be caused by viruses, bacteria or parasites and often take two to four days or more to identify in the clinical laboratory using conventional methods. In the laboratory a high level of expertise and labor are associated with traditional stool culture. Multiple methods, materials and environments are required to detect the pathogens included in the BD MAX Enteric Bacterial Panel. Using the BD MAX Enteric Bacterial panel can result in the reduction of labor and 60% of material and environments typically required for stool cultures. Additionally, results are available in approximately 3 hours with minimal technologist intervention. The improved availability of results may positively impact the clinical management of these patients.

"The traditional use of bacterial cultures and immunoassays for processing stool specimens is time-consuming, labor intensive and technically subjective," said Patrick Murray, Ph.D. WW Director, Scientific Affairs, BD Diagnostics. "Use of the BD MAX Enteric Bacterial Panel is a cost-effective approach to improve workflow for the laboratory and provide rapid, accurate results for physicians."

The BD MAX System offers a highly efficient path to improved clinical outcomes through flexible molecular solutions. 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, minimizing variability in results.

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 drug delivery, enhancing the diagnosis of infectious diseases and cancers, supporting the management of diabetes and advancing cellular research. We are nearly 30,000 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 healthcare around the world. For more information, please visit www.bd.com.

* The BD MAX Enteric Parasite Panel is not approved for sale or use in the US

(1)MMWR, CDC, April 19, 2013, Vol. 62:15.

(2) Guerrant, Richard L, *Practice Guidelines for the Management of Infectious Diarrhea* Clinical Infectious Diseases; 2001: 32:331-50.
(3)CDC, MMWR Recommendations and Reports, October 16, 2009.
(4) The Joint Commission Prepublication Requirements, December 10, 2012.
(5)WHO Fact Sheet, April 2013

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