BD Receives FDA 510(K) Clearance for Molecular Test for Harmful Intestinal Bacteria Causing Infectious Diarrhea

Extends BD MAX(TM) Enteric Panel Portfolio with latest Molecular Test that Targets Infectious Diarrhea

FRANKLIN LAKES, N.J., June 5, 2017 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that its newly developed molecular test for detecting harmful intestinal bacteria causing infectious diarrhea has received 510(k) clearance from the U.S. Food and Drug Administration (FDA).

According to the Centers for Disease Control and Prevention (CDC), one in six Americans suffers from infection due to food-borne illness each year.(1) With the availability of the BD MAX(TM) extended enteric bacterial panel, the majority of pathogens causing acute gastroenteritis(2) leading to hospitalization can be detected rapidly and accurately on the fully automated BD MAX molecular platform.

The BD MAX extended enteric bacterial panel is the latest offering in the suite of BD MAX(TM) enteric assays, which aid in the detection and diagnosis of acute gastroenteritis, an inflammation of the gastrointestinal tract. This panel joins the BD MAX enteric bacterial panel and the BD MAX(TM) enteric parasite panel, enabling individualized testing to be performed based on a patient's symptoms and health history.

"Thanks to the continued innovation and extended ability of the BD MAX enteric suite to adapt testing to the patient population, geography and clinical presentation, clinical laboratories are able to focus on what's truly important ? their patients," said Dr. Joel Mortensen, managing director for Mortensen and Associates, LLC, a microbiology and molecular diagnostics consulting firm.

Doug White, vice president and general manager of Molecular Diagnostics and Women's Health for BD said, "We continue to expand the BD MAX system menu of unique, clinically relevant panels. The BD MAX system allows the diagnostic laboratory to perform molecular testing in a flexible, automated manner, enabling timely results and more efficient patient management."

The BD MAX menu includes syndromic panels for health care associated infections, reproductive and sexually transmitted infections and enteric pathogens, aiding lab professionals in their efforts to deliver diagnostic results that positively impact patient care while improving lab operations and decreasing time to results as compared to conventional methods.

The BD MAX system automates real-time PCR testing by performing the necessary steps of sample extraction, amplification and detection on a single system. It also features open system capability, allowing for the automated performance of "in house" molecular assays.

About BD
BD is a global medical technology company that is *advancing the world of health* by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has nearly 50,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit bd.com.

(1) CDC Food Safety website, September 2016. http://www.cdc.gov/food safety/foodborne-germs.html
(2) Incidence and trends of infection with pathogens transmitted commonly through food - Foodborne Disease Active Surveillance Network, 10 US sites 1996-2012. MMWR April 2013; 62:15; 283-287.

Contacts:

Troy Kirkpatrick BD Public Relations 858.617.2361

Monique N. Dolecki BD Investor Relations 201.847.5378

troy.kirkpatrick@bd.com monique_dolecki@bd.com

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