BD Completes Molecular Portfolio for GI Infection With New Viral Panel

BD MAX(TM) Enteric Viral Panel Receives 510(k) Clearance from U.S. Food and Drug Administration

FRANKLIN LAKES, N.J., Dec. 20, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the U.S. Food and Drug Administration 510(k) clearance of its BD MAX(TM) enteric viral panel, a molecular diagnostic test for the direct qualitative detection and differentiation of enteric viral pathogens that cause viral gastroenteritis. The company now offers a broad suite of solutions for the detection of intestinal conditions of bacterial, viral, and parasitic origin, in clinically relevant, targeted panels.

Acute viral gastroenteritis can be contracted by virtually any patient and spread within close community settings such as daycare centers, nursing facilities, and cruise ships. Norovirus is the most common viral cause and accounts for 19 to 21 million cases of diarrheal illness annually in the United States, and 50 percent of all foodborne diarrheal outbreaks. Other viral causes include rotavirus, adenovirus, astrovirus and sapovirus to varying degrees of prevalence. Diagnosing the underlying cause of diarrhea can play a critical role in patient management to isolate patients at risk of spreading infectious diarrhea to others and rule out other causes of infection in children, the elderly or immunocompromised patients.

The BD MAX(TM) enteric suite of molecular tests for the detection of gastrointestinal bacteria, parasitic or viral pathogens enable clinicians to perform targeted testing for patients based upon their symptoms and health history or exposure. This testing approach is supported by the Infectious Diseases Society of America (IDSA) guidelines. Compared to more generalized tests, this test provides the most clinically useful and necessary information to better diagnose and treat patients.

The BD MAX (TM) enteric viral panel is designed for targeted detection of the viral cause of infectious diarrhea symptoms in all care settings and can detect norovirus, rotavirus, adenovirus, human astrovirus, and sapovirus.

The enteric panels run on the BD MAX(TM) molecular system and can return results in less than 3.5 hours, dramatically shortening time to results over traditional test methods. This shortened time to results allows clinicians to more quickly understand the cause of the patient's illness.

"We continue to expand our menu of unique, clinically relevant, molecular diagnostics panels to aid in diagnosis of a range of infectious diseases," said Nikos Pavlidis, vice president and general manager of Molecular Diagnostics & Women's Health for BD. "With this launch, BD's suite of assays for diagnosing gastrointestinal conditions will provide clinicians with greater flexibility for more efficient and cost-effective patient management. We also offer panels for diagnosis of hospital acquired infections including C. diff and MRSA as well as vaginal infections, common sexually transmitted infections, and group B streptococcal disease."

About BD MAX(TM) MOLECULAR SYSTEM(
*)*The BD MAX(TM) system is a fully-integrated, automated molecular diagnostics platform that performs nucleic acid extraction and real-time PCR. The system can multiplex up to 24 samples across multiple test applications and provide test results for most assays in less than three hours. Using BD MAX(TM) products, laboratories can test for a range of conditions including women's health and sexually transmitted infections, enteric conditions, and healthcare associated infections.

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 healthcare by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare 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 healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

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