BD and Check-Points Receive FDA Clearance for Molecular Screening Test to Detect Antibiotic-Resistant Bacteria

FRANKLIN LAKES, N.J., and WAGENINGEN, THE NETHERLANDS, October 29, 2019– BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, along with Check-Points Health B.V., announced today that FDA 510(k) clearance was obtained for a molecular screening test for antibiotic-resistant carbapenemase-producing organisms (CPOs) on the fully-automated BD MAX™ System.

The BD MAX™ Check-Points CPO assay provides detection of the five most common carbapenemase genes directly from the patient specimen in approximately 2.5 hours, as compared to traditional methods that can take up to 24 hours to confirm a negative or longer for a final positive result. Early detection of patients colonized with these organisms can provide the necessary information to implement proper infection control measures.

Together with the BD Phoenix™ CPO Detect Panels, BD provides solutions for screening and infection management to support clinical microbiology laboratories in detecting CPOs, and helping hospitals implement robust programs to address antimicrobial resistance (AMR).

“The launch of the BD MAX Check-Points CPO assay in the US is another example of BD’s commitment to helping prevent and reduce the spread of healthcare associated infections (HAIs),” said Nikos Pavlidis, vice president and general manager, molecular diagnostics and women’s health for BD. “Our solutions for CPO detection and identification are an important part of our portfolio of products for infection prevention, diagnostics, and surveillance and monitoring that help hospitals combat antimicrobial resistance.”

This assay joins BD’s comprehensive healthcare-associated infections diagnostics portfolio, which aims to reduce transmission and outbreak of deadly pathogens. The BD MAX™ product menu also includes syndromic panels for gastrointestinal infections, as well as reproductive and sexually transmitted infections, which aid laboratory professionals in their efforts to deliver diagnostic results that inform clinicians to help enhance patient outcomes, while improving laboratory efficiency. The BD MAX™ system also features an open system capability, allowing for streamlined workflow of laboratory developed tests and for additional assays via BD partner collaborations.

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, optimize respiratory care 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 more than 45,000 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 healthcare safety and expand access to health. For more information on BD, please visit bd.com.

About Check-Points
Check-Points is a privately owned diagnostics company in Wageningen, The Netherlands and a leading developer and marketer of molecular assays for gram-negative drug-resistant bacteria. Check-Points offers a range of IVD and RUO products for the detection of carbapenemases, ESBLs and AmpCs. In addition, the Check&Trace product line allows for fast and reliable routine molecular confirmation and serotyping of Salmonella for food and veterinary diagnostics. For more information,contact Karin Hendrikx, Management Assistant at +31 (0)317 453 908 or karinhendrikx@check-points.com

Gwen Gordon
858 812 3724
Email Gwen

Monique N. Dolecki
201 847 5378
Email

Antibiotic-Resistant-Bacteria