BD and Check-Points Announce Development and Global Distribution Agreement for BD MAX(TM) Assays that Detect Carbapenem-resistant Organisms

FRANKLIN LAKES, N.J., and WAGENINGEN, The Netherlands, June 16, 2016 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced a development and global distribution agreement with Check-Points for BD MAX(TM) assays that detect carbapenem-resistant organisms (CRO). As part of the agreement, BD will distribute the Check-Direct CPE Screen for the BD MAX assay (CE IVD) outside of the United States*, with Check-Points maintaining exclusivity in the Netherlands. Check-Points and BD plan to develop and commercialize a next-generation CRO assay for launch outside the U.S. in 2017 and in the U.S. at a later time.

The Check-Direct CPE Screen for the BD MAX assay is a real time PCR kit for the detection of CRO from rectal swabs. The Check-Direct CPE Screen for the BD MAX identifies and differentiates the presence of the four most common carbapenemase genes: KPC, NDM, VIM and OXA-48-like (including OXA-181 and OXA-232). In three prospective European studies, the assay demonstrated overall clinical sensitivity and specificity of 98.5 percent and 96.8 percent, respectively.

"We have used the Check-Direct CPE Screen for BD MAX in routine screening for nearly two years," said John Rossen, assistant professor of medical microbiology at the University Medical Center, Groningen (UMCG) in the Netherlands and scientific secretary of the ESCMID Study Group for Genomic and Molecular Diagnostics. "The assay on the BD MAX has improved our turn-around-time for CRO screening and has shown a very positive impact in our hospital."

Carbapenem-resistant organisms represent a global healthcare-associated infection (HAI) concern. In 2014, the average carbapenem resistance for K. pneumoniae in Europe was approximately 7.3 percent, with some countries reporting as high as 62.3 percent.(1) Rates of K. pneumoniae resistance to carbapenems range as high as 4-54% in other WHO regions.(2) In addition, the spread of CRO represents a unique antimicrobial stewardship challenge, with limited effective treatments(3) and mortality rates as high as 54.3 percent(4). In response, the European Centers for Disease Control (ECDC)(4) have launched active surveillance programs to assess CRO prevalence and monitor for outbreaks.

The Check-Direct CPE Screen for BD MAX assay is the latest offering in the BD MAX HAI portfolio, which includes IVD assays for the qualitative detection of Methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus* and *Clostridium difficile* (*C. difficile*). Together with other upcoming products on the BD Phoenix((TM)) platform, BD will offer a comprehensive genotypic and phenotypic CRO solution to support clinical microbiology customers in their antimicrobial resistance programs.

*Product not available for sale in the U.S.

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 (http://www.check-points.com) 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.

(1) European Centre for Disease Prevention and Control. Antimicrobial resistance surveillance in Europe 2014. Annual report of the European Antimicrobial Resistance Surveillance Network (EARS-Net). Stockholm: ECDC; 2015.
(2) 2014 WHO Antimicrobial Resistance Global Report on Surveillance.
(3) European Centre for Disease Prevention and Control. Carbapenemase-producing bacteria in Europe: interim results from the European Survey on carbapenemase-producing Enterobacteriaceae (EuSCAPE) project. Stockholm: ECDC; 2013.

(4) Tumbarello et al (2012). *Clin Infect Dis*. 55 (7): 943-950.

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