BD and Check-Points Receive CE Mark for Next-generation Resistant Bacteria Screening Test

New Test Provides Diagnostic Results Up to 10 Times Faster Than Traditional Tests

FRANKLIN LAKES, N.J., and WAGENINGEN, The Netherlands, Jan. 15, 2018 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, along with Check-Points Health B.V., announced today that the companies obtained CE Mark for a next-generation molecular screening test for antibiotic-resistant carbapenemase-producing organisms (CPOs) on the fully-automated BD MAX(TM) System.

It is estimated by the year 2050, as many as 10 million people could die annually from antimicrobial resistance (AMR) if no action is taken[1]. AMR is the ability of a microorganism (such as a bacteria) to survive despite being treated with antimicrobial drugs that should destroy it. As a result, patients with these infections are more likely to develop complications and up to three times more likely to die[2].

The spread of CPO represents a major challenge to antimicrobial stewardship because these organisms have acquired the ability to produce the enzyme carbapenemase. This enzyme renders carbapenems, considered a drug of last resort, ineffective. This has brought about limited effective treatments resulting in high mortality rates[3].

The BD MAX(TM) Check-Points CPO assay* provides detection of the five most common carbapenemase genes in less than 2.5 hours, as compared to traditional methods that can take up to 24 hours. Early detection of patients colonized with these organisms can provide the necessary information to implement proper infection control measures. This assay replaces an earlier version of the test from Check-Points, and offers an improved workflow and an additional target.

"We have been using the Check-Points assay on the BD MAX system for routine screening of CPO for nearly two years, because it provides us the information we need to isolate or de-isolate our high-risk patients shortly after admission," 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. "This assay has not only improved our turn-around-time, but it also gives us the confidence that we will reduce the risk of transmission and outbreak because patient safety is our number one goal."

Together with BD BBL(TM) CHROMagar(TM) CPE plated media* and BD Phoenix((TM)) CPO detect panels*, BD provides comprehensive solutions for screening and infection management to support clinical microbiology laboratories in their AMR programs.

"The launch of the BD MAX Check-Points CPO assay is another example of BD's commitment to helping prevent and reduce the spread of healthcare associated infections (HAIs) and support better antimicrobial stewardship," said Nikos Pavlidis, vice president of molecular diagnostics and women's health for BD.

This assay joins BD's comprehensive healthcare-associated infections diagnostics portfolio, which aims to reduce transmission and outbreak of deadly pathogens. The BD MAX system 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 help enhance patient outcomes, while improving laboratory efficiency. The instrument also features an open system capability, allowing for streamlined workflow of laboratory developed tests and for additional assays via BD partner collaborations.

*Products are not available for sale in the U.S.

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 health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose 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 health care. In 2017, BD welcomed C. R. Bard and its products into the BD family. 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.

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[1] O'Neill. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations The Review on Antimicrobial Resistance Chaired, December 2014.

[2] Organisation for Economic Co-operation and Development. Antimicrobial Resistance in G7 Countries and Beyond: Economic Issues, Policies and Options for Action. Paris: OECD; 2015.

[3] Centers for Disease Control and Prevention (CDC). Vital signs: carbapenem-resistant *Enterobacteriaceae. MMWR Morb Mortal Wkly Rep.* 2013; 62(9):165-170.

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