New Molecular Assay Detects Rapidly Emerging Multidrug-Resistant Superbug

BD Diagnostics

Carbapenem-Resistant Enterobacteriaceae Assay Available for Research Use Only on the BD MAX™ System

BD Diagnostics, a segment of BD (Becton, Dickinson and Company) (NYSE: BDX), today announced the release of a research use only (RUO) molecular test designed to rapidly detect antibiotic resistance genes found in the superbug known as carbapenem-resistant Enterobacteriaceae (CRE). These deadly organisms are associated with high mortality rates, are easily spread from patient-to-patient and are resistant to nearly all antibiotics. In some cases there are no treatments that are effective against infections caused by CRE.

Rapid identification is critical to allow proper treatment and isolation of patients to prevent its spread. The assay, performed on the fully-automated BD MAX™ System, is designed to detect carbapenem resistance genes and produces results in just two hours. Conventional culture methods take several days to report results. BD is making the assay available, for research use only, to a limited number of infectious disease experts and researchers to gather feedback on its performance.

“BD has a strong scientific commitment to developing innovative diagnostics in response to the challenge of emerging pathogens,” said Patrick Murray, Ph.D., Worldwide Director of Scientific Affairs, BD Diagnostics – Diagnostic Systems. “We are offering this assay initially as a research tool to help BD and infectious disease researchers explore its clinical utility while we pursue development of an in vitro diagnostic solution.” The RUO assay is not for in vitro diagnostic (IVD) use.

Incidence of carbapenem-resistant organisms has increased dramatically over the past decade. The most concerning are CRE that have acquired carbapenemase genes including KPC, NDM, and OXA-48. The BD MAX assay is the first fully-automated assay to detect all three of these genes directly from specimens. In 2011, KPC strains were reported in 37 U.S. states. NDM strains, first discovered in 2008, have spread worldwide, while OXA-48 is now found throughout Europe, Northern Africa and India.

“Multiple antibiotic-resistant bacteria, including carbapenemase-producing strains, have emerged worldwide at an alarming rate and now routinely cause both community- and hospital-acquired infections,” said Dr. Brian Currie, Vice President and Medical Director for Research at Montefiore Medical Center and Assistant Dean for Clinical Research at the Albert Einstein College of Medicine. “The medical community urgently needs more rapid and accurate methods to detect carbapenemase-producing bacteria in order to prevent the further spread of these deadly organisms.”

Assays already available on the BD MAX System to address healthcare-associated infections include methicillin-resistant Staphylococcus aureus (MRSA) and toxigenic Clostridium difficile, both CE-marked for IVD use in Europe. The BD MAX MRSA assay was FDA-cleared with CLIA Moderate Complexity categorization earlier this year. The toxigenic Clostridium difficile assay has been submitted to the FDA for 510(k) review and clearance.

About BD MAX™ System

The BD MAX System is the first and only fully-automated, bench-top molecular system designed to perform a broad range of molecular tests. This includes IVD assays, as well as user-defined protocols and life science research applications. More than 15 state-of-the-art assays are currently under development.

About BD

BD is a leading global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents. The Company is dedicated to improving people's health throughout the world. BD is focused on improving drug delivery, enhancing the quality and speed of diagnosing infectious diseases and cancers, and advancing research, discovery and production of new drugs and vaccines. BD's capabilities are instrumental in combating many of the world's most pressing diseases. Founded in 1897 and headquartered in Franklin Lakes, New Jersey, BD employs approximately 29,000 associates in more than 50 countries throughout the world. The Company serves healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry and the general public. For more information, please visit www.bd.com [1].

Source URL (retrieved on *03/10/2014 - 1:28pm*):
http://www.mdtmag.com/news/2012/09/new-molecular-assay-detects-rapidly-emerging-multidrug-resistant-superbug?qt-recent_content=0&qt-most_popular=0

Links:
[1] http://www.bd.com