BD MAX MRSA Assay Receives FDA Clearance

BD Diagnostics, a segment of BD (Becton, Dickinson and Company), announced it received FDA clearance to market the BD MAX(TM) MRSA molecular test in the United States. The assay is performed on the fully-automated BD MAX(TM) System and is designed to rapidly and accurately identify patients colonized with methicillin-resistant Staphylococcus aureus (MRSA). Rapidly and accurately identifying patients enables infection control measures to be implemented faster to reduce transmission and help prevent infection in vulnerable patients.

"The BD MAX MRSA assay is an easy-to-use, cost-effective method to identify patients colonized with this deadly superbug, which may support better outcomes for the patient and a safer hospital environment," said Tom Polen, President, BD Diagnostics - Diagnostic Systems. "FDA clearance of the BD MAX MRSA test gives our customers a new level of automation to optimize MRSA surveillance testing."

According to the Institute for Healthcare Improvement, the total cost burden to the U.S. healthcare system from MRSA infections is estimated at more than $2.5 billion annually. MRSA infections primarily occur in people who have been in hospitals or other healthcare settings. MRSA can spread among patients or healthcare workers via direct contact with colonized patients and/or hospital surfaces. Early identification of patients colonized with MRSA helps reduce the risk of transmission and infection, and helps to improve patient outcomes.

"BD MAX is an automated, bench-top molecular system designed to perform a broad range of molecular testing, offering unmatched flexibility and versatility," said Thomas Davis, M.D., Ph.D., Professor, Pathology and Laboratory Medicine at the Indiana University School of Medicine, and Pathologist with Wishard Health Services and Indiana University Health Laboratories. "As the BD MAX assay portfolio continues to grow, the walk-away automation, standardized workflow and ease-of-use of the BD MAX System will allow laboratories to increase both the menu and efficiency of molecular testing to better meet the demands of clinicians."

The BD MAX MRSA assay is the second test cleared this year by the FDA on the BD MAX System. This milestone represents further confirmation of BD's commitment to rapidly expand its menu, enabling laboratories to offer a broad range of molecular tests that meet both their current and future clinical needs.

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].

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