New Laboratory Test Helps Hospitals Detect Newly Emerging Strains of Drug-Resistant Superbug

BD MAX(TM) MRSA XT Assay with eXTended Detection Technology Receives FDA Clearance

BALTIMORE, Jan. 13, 2014 /PRNewswire/ -- BD Diagnostics, a segment of BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced today it has received FDA clearance to market the BD MAX(TM) MRSA *XT* Assay for use on the fully-automated BD MAX(TM) System. This is the second assay from BD Diagnostics capable of detecting newly emerging MRSA strains with the novel *mecC* gene. Launched in 2013, the BD MAX(TM) StaphSR Assay reports results for both *Staphylococus aureus* (SA) and methicillin-resistant *Staphylococus aureus* (MRSA) and was the first commercially available assay in the U.S. to detect *mecC* strains of MRSA. Both assays use e*XT*ended Detection Technology to identify a broad range of SA strains including *mecA* and *mecC* dropout mutants and new strains of MRSA that may not be detected by other assays.

"Assay design is critical to detect MRSA accurately and ensure appropriate infection control interventions are applied," said Dr. Patrick Murray, Worldwide Director of Scientific Affairs, BD Diagnostics - Diagnostic Systems. "The BD MAX MRSA *XT* Assay helps improve patient safety by providing hospitals with a new solution to detect the latest strains of this drug-resistant superbug."

Molecular assays for MRSA are used in active surveillance programs to identify colonized patients rapidly. Active surveillance is a proven strategy to reduce transmission in healthcare settings and helps prevent infection in vulnerable patients.[i] Inaccurate detection may contribute to uncontrolled transmission of MRSA and inappropriate use of healthcare resources. With many commercial assays, SA strains carrying SCC*mec* where the *mecA* gene is absent (commonly called "dropout mutants") may be incorrectly classified as MRSA. These false positive results can lead to unnecessary and expensive isolation and treatment of patients.[ii] MRSA strains with the newly emerging *mecC* gene account for nearly three percent of all new MRSA cases[iii] in some communities but cannot be detected by all assays.[iv] These false negative results can lead to uncontrolled transmission of undetected strains of MRSA.[v]

As a pioneer in healthcare-associated infections (HAIs), BD has the insights and expertise to provide hospitals innovative solutions that can improve patient care. The BD MAX MRSA *XT* Assay is the latest milestone demonstrating BD's commitment to providing advanced assays to detect and prevent HAIs. Other HAI assays available on the BD MAX System include BD MAX(TM) Cdiff for the detection of toxigenic *Clostridium difficile* DNA, and BD MAX StaphSR. BD MAX(TM) HAI Solutions combine efficiency through system automation with the flexibility to perform multiple HAI assays in the same run, allowing hospital laboratories to customize testing in response to current and future challenges in the fight against HAIs.

About BD
BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving drug delivery, enhancing the diagnosis of infectious diseases and cancers, supporting the management of diabetes and advancing cellular research. We are nearly 30,000 associates in 50 countries who strive to fulfill our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of healthcare around the world. For more information, please visit *www.bd.com* .

[i]Jain et al., N Engl J Med 2011;364:1419-30. Veterans Affairs Initiative to Prevent Methicillin-Resistant*Staphylococcus aureus* Infections

[ii] Blanc et al., JCM 2011;49:722-724. High Proportion of Wrongly Identified Methicillin-Resistant*Staphylococcus aureus* Carriers by Use of a Rapid Commercial PCR Assay Due to Presence of Staphylococcal Cassette Chromosome Element Lacking the *mecA* Gene.

[iii] Petersen et al., Epidemiology of methicillin-resistant*Staphylococcus aureus* carrying the novel *mecC* gene in Denmark corroborates a zoonotic reservoir with transmission to humans Clin Micro Infect 2013;19:E16-E22

[iv] Shore et al., Antimicrobial Agents and Chemotherapy. 2011;55:3765-3773

[v] Worby et al., Am J Epidemiology advanced access published online April 16, 2013. Estimating the Effectiveness of Isolation and Decolonization Measures in Reducing Transmission of Methicillin-resistant Staphylococcus aureus in Hospital General Wards

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