

December 3, 2013

Novel Molecular Assay for Patient Screening Detects *S. aureus* and Newly Emerging MRSA Strains Available in the United States

BD MAX™ StaphSR Assay with eXTended Detection Technology Receives FDA Clearance

BALTIMORE, Dec. 3, 2013 /PRNewswire/ -- BD Diagnostics, a segment of BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has received FDA clearance to market the BD MAX™ StaphSR Assay for use on the fully-automated BD MAX™ System. The assay, with eXTended Detection Technology, accurately detects *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) DNA directly from nasal swabs, including *mecA* dropout mutants and new strains of MRSA that may not be detected by other assays.

The BD MAX StaphSR Assay is the first and currently the only commercially-available molecular assay in the United States that detects recently discovered MRSA strains with the *mecC* gene. Rapid, accurate detection of colonized patients enables effective strategies that can help reduce the risk of surgical-site infections (SSIs), improve patient safety and save healthcare costs.^{i,ii}

"Increased accuracy in determining patient colonization with either *S. aureus* or MRSA can enable clinicians to implement appropriate pre-surgical prophylaxis and direct appropriate utilization of isolation and decolonization," said Dr. Tobi Karchmer, Worldwide Vice President, Medical Affairs, BD Diagnostics. "With results available in approximately two hours compared to two or more days for culture methods, the BD MAX StaphSR Assay provides accurate and timely information to help physicians ensure safe and appropriate management of surgical patients."

SSIs are the most frequent healthcare-associated infection (HAI) in the United States, occurring in about one out of every 50 operations, and constitute the greatest portion of HAI-related costs nationally. SSIs due to MRSA increase hospital length of stay for patients by an average of 23 days and cost more than \$40,000 per case to treat.ⁱⁱⁱ Nasal carriage of *S. aureus*, including MRSA, is a well-defined risk factor for subsequent infection in surgical patients. Rapid screening and targeted decolonization decreases SSIs by nearly 60 percent and improves clinical and economic outcomes for surgical patients.^{iv,v}

With many commercial assays, SA strains carrying SCC*mec* where the *mecA* gene is absent (commonly called "dropout mutants") may be incorrectly detected as MRSA. These false positive results can lead to inappropriate use of vancomycin for surgical prophylaxis and unnecessary, expensive isolation of patients.^{vi} MRSA strains with the recently discovered *mecC* gene account for nearly three percent of all new MRSA cases^{vii} but cannot be

detected by assays that do not detect that gene.^{viii} These false negative results can lead to inappropriate surgical prophylaxis in patients who should receive vancomycin to cover for MRSA and lack of appropriate isolation precautions to prevent transmission in the operating room and during hospitalization.

The BD MAX StaphSR Assay represents an important milestone in BD's commitment to provide healthcare institutions with cutting edge assays to detect and prevent HAIs. Other HAI assays available on the BD MAX System include BD MAX™ MRSA for the detection of MRSA DNA and BD MAX™ Cdiff for the detection of toxigenic *Clostridium difficile* DNA. These BD MAX™ HAI Solutions combine efficiency 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 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 nearly 30,000 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.

ⁱ Bode et al., N Engl J Med 2010;362:9-17

ⁱⁱ Van Rijen et al., PLoS ONE 2012;7(8): e43065

ⁱⁱⁱ Zimlichman et al., JAMA Intern Med published online September 2, 2013

^{iv} Bode et al., N Engl J Med 2010;362:9-17

^v Van Rijen et al., PLoS ONE 2012;7(8): e43065

^{vi} Blanc et al., JCM 2011;49:722-724

^{vii} Petersen et al., Clin Micro Infect 2013;19:E16-E22

^{viii} Shore et al., Antimicrobial Agents and Chemotherapy. 2011;55:3765-3773

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