



bioMérieux Receives FDA Clearance for NucliSENS EasyQ[®] MRSA, Automated, Rapid Molecular Screening Test

Company Offers Most Comprehensive, Cost-Effective Suite of Solutions to Detect and Screen for Methicillin Resistant *Staphylococcus aureus* (MRSA)

Marcy l'Etoile, France — May 24, 2011 — bioMérieux, a world leader in the field of *in vitro* diagnostics, announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its NucliSENS EasyQ[®] MRSA, an automated molecular test for Methicillin Resistant *Staphylococcus aureus* (MRSA).

The test detects seven MRSA types¹, covering the most prevalent strains. The test also simultaneously detects two targets, which provides added confidence to the screening results. The EasyQ system will support efficient batch processing of up to 46 MRSA screening tests in a compact space with a rapid turn-around time of only three hours. Real-time actionable results enable more informed clinical decisions, which play an essential role in the management of antimicrobial resistance. Helping clinicians to take faster action to isolate patients and limit transmission is a critical issue, since MRSA is one of the leading causes of healthcare-associated infections (HAI). MRSA is also on the rise and has spread into the community. In the United States, MRSA infections alone kill nearly 19,000 people a year.² Studies have shown that the frequency of MRSA transmission is reduced 38-fold if patients are identified and isolated.³ Systematic infection control measures, including MRSA screening, reduce the MRSA rate by 50%.⁴

“bioMérieux is committed to bringing innovative solutions to the microbiology lab that reduce the time to results so that clinicians can treat patients more rapidly,” said Stéphane Bancel, bioMérieux Chief Executive Officer. “bioMérieux has the most comprehensive diagnostic product offering in the fight against MRSA, from chromogenic media to molecular assays. Our strategy is to lead the microbiology market by offering the greatest total value proposition for our customers and, at a time when reducing HAIs and related healthcare costs is paramount, we are proud to make a highly automated, rapid and cost-effective molecular MRSA screening solution available to U.S. clinicians.”

NucliSENS EasyQ MRSA complements chromID[™] MRSA, bioMérieux’s chromogenic media, which enables direct, color-specific visual observation of the bacterial colonies in patient samples. bioMérieux can now offer hospitals and healthcare providers cost-effective alternatives for both culture-based and molecular-based MRSA screening. The complete suite of bioMérieux MRSA solutions also includes VITEK[®] 2 for rapid identification and antibiotic susceptibility testing, Etest[®] for extended dilution MICs (minimum inhibitory concentration), and DiversiLab[®] for strain typing.

The NucliSENS EasyQ MRSA test was cleared with a clinical sensitivity of 94.7% and a clinical specificity of 96.5% when testing nasal samples from adult patients. Additionally, the assay also received clearance with a clinical sensitivity of 100% and a clinical specificity of 97.3% when testing nasal samples from pediatric patients.

bioMérieux is actively committed to the fight against bacterial resistance and offers a complete range of products for the detection and screening of the most frequently found resistance mechanisms. (Visit www.biomerieux.com/besmart for more information.) The company is constantly adapting its product portfolio to address ever-changing healthcare challenges and is currently developing solutions for a more targeted screening of carbapenemases such as KPC and NDM-1. bioMérieux is gathering 70 leading experts to propose solutions to address the growing threat of multi-drug resistant bacteria at the third

edition of its World Healthcare-Associated Infection (HAI) Forum, scheduled June 27-29, 2011 in Annecy, France. (to learn more visit www.biomerieux.com/hai-resistance)

References:

1. MREJ types 1,2,3,4,5,7 and 12
2. Klevens RM. et al. Invasive Methicillin-resistant *Staphylococcus aureus* infection in the United States. JAMA 2007; 298:1763-1771
3. Vriens MR et al. Is methicillin-resistant *Staphylococcus aureus* more contagious than methicillin-susceptible *S. aureus* in a surgical intensive care unit? Infect Control Hosp Epidemiol 2002; 23:491-494
4. Harbarth S et al. Effect of delayed infection control measures on a hospital outbreak of methicillin-resistant *Staphylococcus aureus*. J Hosp Infect 2000; 46:43-49

About the NucliSENS EasyQ MRSA Assay

NucliSENS EasyQ MRSA is designed for screening patients colonized with Methicillin-resistant *Staphylococcus aureus*. The assay utilizes bioMérieux's nucleic acid sequence-based amplification (NASBA™) combined with real-time detection of amplified targets by molecular beacon probes. Specifically designed fluorophore-labeled probes are employed to independently detect amplified gene sequences of the following: *S. aureus* methicillin resistance (mec A gene), the SCC mec (cassette) junction and an amplification inhibition control. This permits the detection of strains that have, in some cases, been found to lose their mec-A region resulting in false positive results. Multiple amplification reaction primers are used to ensure detection of a variety of MRSA types.

NucliSENS EasyQ MRSA is part of bioMérieux's complete range of Full Microbiology Lab Automation (FMLA®) solutions and services. The company focuses on building a close partnership with microbiologists to address the unique needs of their laboratory. Committed to improving patient care, bioMérieux introduced FMLA in 2008 to streamline the workflow of the microbiology laboratory, from sample reception and distribution, organism identification and antimicrobial resistance analysis, to result management and interpretation.

About bioMérieux

Advancing Diagnostics to Improve Public Health

A world leader in the field of *in vitro* diagnostics for over 45 years, bioMérieux is present in more than 150 countries through 39 subsidiaries and a large network of distributors. In 2010, revenues reached €1.357 billion with 87% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris market (Symbol: BIM – ISIN: FR0010096479). Other information can be found at www.biomerieux.com.

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