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Roche receives FDA clearance for next generation cobas MRSA/SA Test

New test detects MRSA and SA, the leading causes of healthcare-associated infections worldwide

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has provided 510(k) clearance for the **cobas**[®] MRSA/SA Test for the early, simultaneous detection of methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-sensitive *Staphylococcus aureus* (SA) directly from nasal specimens. The **cobas**[®] MRSA/SA Test detects both organisms from a single specimen, providing accurate and reliable results for effective prevention and control of MRSA/SA infections.

"Numerous successful surveillance programs have led to a significant decrease in the rate of MRSA clinical infection in many organizations, and a dramatic reduction in postoperative surgical infections when screening for SA is done. Importantly, the fight against healthcare-associated infections continues to advance, as evidenced by this new test that can rapidly detect both MRSA and SA in a single assay" said Lance R. Peterson, MD, Director of Microbiology and Infectious Diseases Research at NorthShore University HealthSystem and Clinical Professor of Pathology and Medicine at the University of Chicago, Pritzker School of Medicine. "The **cobas**[®] MRSA/SA Test demonstrated excellent performance in detecting both MRSA and SA strains in samples collected throughout the US. Compared to culture testing, the **cobas**[®] MRSA/SA Test offers confidence in identifying colonized patients the first time they are evaluated, aiding in the prevention of MRSA disease and post-operative SA surgical infections."

"Healthcare-associated infections continue to be a leading cause of mortality in US medical settings," said Paul Brown, Head of Roche Molecular Diagnostics. "With the addition of the **cobas**[®] MRSA/SA Test to our expanding menu of tests for the **cobas**[®] 4800 System, Roche offers laboratories and clinicians a highly efficient molecular solution to aid in the overall management and prevention of healthcare-associated infections, leading to lower costs for hospitals and optimal patient care."

The **cobas**[®] MRSA/SA Test, a polymerase chain reaction (PCR)-based assay that runs on the automated **cobas**[®] 4800 System, offers labs the most simplified workflow available with a simple de-cap and loading of the primary sample vial onto the **cobas**[®] 4800 System. This approach requires less hands-on-time, enabling laboratory staff to spend time on other critical tasks. In addition, this streamlined workflow can help labs reduce costs and improve turnaround time.

About methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)

Approximately one third of the population carries *Staphylococcus aureus* as normal flora in the anterior nares, which can lead to opportunistic infections. *Staphylococcus aureus* has evolved resistance mechanisms due to frequent exposure to antibiotics in health care settings. Recent reports show up to 85% of invasive MRSA infections identified as healthcare-associated, resulting in over 90,000 infections and 18,000 deaths in 2005 alone¹. Surgical site infections, ventilator assisted pneumonia, and blood stream infections attributed to colonized central lines are the most frequent manifestations of disease. Active surveillance to identify carriers is helping to mitigate the potential consequences of disease, providing relief to patients and healthcare institutions facing the challenges of escalating costs.

About the cobas 4800 System

The **cobas**[®] 4800 System offers true walk-away automation of nucleic acid purification, PCR set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The expanding system menu in the U.S. currently includes the **cobas**[®] CT/NG Test (chlamydia/gonorrhea), **cobas**[®] HPV Test, **cobas**[®] BRAF V600 Mutation Test and **cobas**[®] EGFR Mutation Test.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012, Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly

owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

1. Klevens et al. Invasive Methicillin-Resistant Staphylococcus aureus Infections in the United States. JAMA. 2007;298:63–1771

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