## Media Release



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# Roche to introduce new LightCycler<sup>®</sup> MRSA Advanced Test in the EU New test for detection of methicillin-resistant Staphylococcus aureus for better patient care

Roche announced today that its new LightCycler® test for the detection of methicillin-resistant *Staphylococcus aureus* (MRSA) is now available with the CE Mark, allowing it to be sold for clinical use in the European Union. The LightCycler® MRSA Advanced Test is a qualitative *in vitro* diagnostic test for the direct detection of nasal colonization with methicillin-resistant *Staphylococcus aureus*. The test will aid in the prevention and control of MRSA infections in healthcare settings resulting in better patient care.

"As more guidelines recommend or require aggressive screening, it is important that healthcare professionals have access to fast, reliable products that can help improve medical outcomes," said Daniel O'Day Head of Roche Molecular Diagnostics. "This new test will aid infection control programs, and ultimately result in better patient care."

Healthcare-associated infections (HAIs) caused by MRSA have recently become an important issue for healthcare facilities worldwide due to high rates of infection, mortality, and high costs of treatment. In addition, community-associated MRSA (CA-MRSA) has spread in the past few years, feeding the pipeline of infection in hospitals, and underscoring the need for comprehensive infection control programs.

Dr. Reinhard Frodl, Laboratory Head of the Molecular Biology Department of Medizinisches Versorgungszentrum Dr. Gärtner & Kollegen in Ravensburg, Germany commented: "The test showed good sensitivity and specificity in our hands and we believe it will bring more efficient MRSA screening to hospitals across Europe because of its batching flexibility and easy handling."

The LightCycler® MRSA Advanced Test is performed on Roche's LightCycler® 2.0 Instrument with nasal swab specimens from patients suspected of colonization, using Roche's patented real-time polymerase chain reaction (PCR) technology. Provided in a convenient, ready-to-use format, and designed for flexible batch sizes, the LightCycler® MRSA Advanced Test ensures safety and productivity of laboratory staff, flexible throughput, and accurate and reliable results.

### About methicillin-resistant Staphylococcus aureus (MRSA)

Staphylococcus aureus is responsible for many serious infections and is one of the most frequently isolated bacteria from patients with healthcare-associated infections (HAI). Estimates suggest that 4 million HAIs and 37,000 deaths are attributable to these infections each year in the EU, and that 1 out of 10 patients in an EU hospital acquires an HAI. Antimicrobial resistance and HAIs, either combined or separately, constitute a major infectious disease problem in the EU, and show signs of becoming more prevalent in the future. MRSA infections are a tremendous burden for healthcare systems and hospitals and are associated with significant healthcare costs. In 2004, the United Kingdom National Audit Office estimated that infections such as MRSA kill 5,000 people each year in the UK and hospital-associated infections cost the National Health Service around £1 billion a year.<sup>2</sup>

#### About the LightCycler @ 2.0 Instrument

With more than 6,600 LightCycler® Instruments in the market today, the LightCycler® System is among the most widely utilized real-time amplification systems available. The LightCycler® 2.0 Instrument was the first system to introduce hybridization probes, true melting curve analysis, automated absolute quantification, and relative quantification with efficiency correction. Combining the power of the LightCycler® 2.0 Instrument with the simple, flexible, and reliable design of the LightCycler® MRSA Advanced Test provides a powerful tool to support healthcare institutions in their fight against MRSA.

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2008 sales by the Pharmaceuticals Division totalled 36.0 billion Swiss francs, and the Diagnostics Division posted sales of 9.7 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested nearly 9 billion Swiss francs in R&D in 2008. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at <a href="https://www.roche.com">www.roche.com</a>.

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 $<sup>^{1}</sup>$  The First European Communicable Disease Epidemiological Report, European Centre for Disease Prevention and Control, Stockholm, 7

<sup>&</sup>lt;sup>2007</sup> Improving patient care by reducing the risk of hospital acquired infection: A progress report. REPORT BY THE COMPTROLLER AND AUDITOR GENERAL. HC 876 Session 2003-2004: 14 July 2004.