

# GenomEra CDX™

Direct MRSA Rapid Test (PCR)



GenomEra CDX™: the automated PCR device for the rapid identification of Methicillin-resistant *Staphylococcus aureus* (MRSA) strains and *S. aureus* in various samples:

- Whole blood
- Blood culture
- Swabs from nose and throat
- Perineum, groin and wounds

The patented GenomEra CDX™ System offers a cost effective and easy solution for fast MRSA DNA testing in the clinical laboratory with high performance, quality and reliability results.

## Advantages:

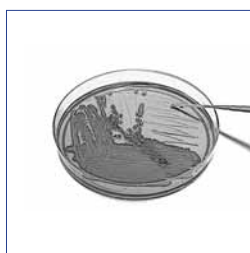
- ▶ **Rapid:**
  - simultaneous run of 4 samples in 50 minutes
- ▶ **Simplicity, robustness and reliability**
- ▶ **Safety:**
  - no DNA extraction
  - 'Ready-to-use /dried in' - PCR-reagents in the chip format
  - no risk of cross-contamination
- ▶ **Automatic interpretation of results:**
  - no expertise necessary
- ▶ **High specificity and sensitivity**
- ▶ CE approved for IVD use



*Staphylococcus aureus* is a bacterial species that commonly colonizes human and animal skin and mucosa (nasal passage). It can also cause disease through broken skin, mucosa lining or a medical procedure.

MRSA strains are among the most commonly identified antibiotic-resistant pathogens. Out-patients and nosocomial infections are a major cause of disease, prolonging hospitalization, mortality and increased health care costs.

In Germany MRSA rates are increasing year to year (In 2007, a resistance study done by the Paul Ehrlich Society showed a 20.3% increase). Since the 1st of July 2009, MRSA infections in blood or fluids must be reported to the health authorities.



1. Example: Touch a singular colony with an inoculation needle



2. Shake the cells into a sample buffer tube



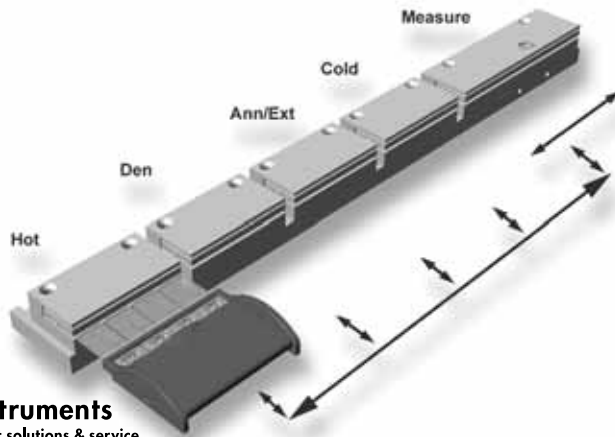
3. Pipette to test chips and start the GenomEra CDX™ assay run



# GenomEra CDX™



- ▶ Time-Resolved Fluorometry
- ▶ 2-step end-point detection technology
- ▶ Patented quantification of the fluorescence signal
- ▶ no interference of biological sample matrix
- ▶ Results: positive / negative / borderline
- ▶ 45 cycles in 50 minutes
- ▶ pre-heated blocks
- ▶ time-resolved measurement of fluorescence (Lanthanides)



Target genes:

- ▶ *mecA* gene (Methicillin resistance)
- ▶ highly conserved genomic *S. aureus*- (SA) sequence



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**ABACUS** Diagnostica

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## Literature:

- ▶ Hirvonen, J.J. et al.: „Rapid confirmation of suspected methicillin-resistant *Staphylococcus aureus* colonies on chromogenic agars by a new commercial PCR assay, the GenomEra MRSA/SA Diagnose“, *Eur J Clin Microbiol Infect Dis*. Published online 26 January 2012
- ▶ Hirvonen, J.J. Kaukoranta, S.-S.: „Rapid detection of methicillin-sensitive and resistant *Staphylococcus aureus* and methicillin-resistant coagulase-negative staphylococci from blood cultures by automated PCR assay“, Presented at International Conference on Prevention & Infection Control (ICPIC 2011). Published in *BMC Proceedings* 2011, 5 (Suppl 6): P204doi:10.1186/1753-6561-5-S6-P204.Poster 2011



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