uniogen

GenomEra® MRSA/SA AC Assay Kit

Comprehensive test for detection and differentiation of *S. aureus* and MRSA

Why choose our test?

The GenomEra® MRSA/SA AC Assay Kit offers a rapid and simple high-performance molecular assay for detecting methicillin-resistant *Staphylococcus aureus* (MRSA) or methicillin-susceptible *S. aureus* (SA or MSSA) directly from blood cultures or other cultured samples. Results are reported in less than one hour as compared to hours or even days spent with conventional identification methods.

Key benefits of the test:

- Fast results: 1-4 results in 50 minutes
- Provides a solution for reliable detection and differentiation of MRSA and SA when time is of the essence
- Simple sample preparation and ready-to-use Test Chips make the test suitable for every type of laboratory, regardless of whether or not there is previous experience with PCR diagnostics

SA infections range from minor skin infections to life-threatening diseases such as pneumonia, meningitis, osteomyelitis, endocarditis, and bacteremia. SA is known for its capability to acquire resistance to antibiotics by the acquisition of exogenous genes such as mecA and mecC. For bloodstream infections, both MRSA and SA are amongst the most common causative agents and associated with high morbidity and mortality.

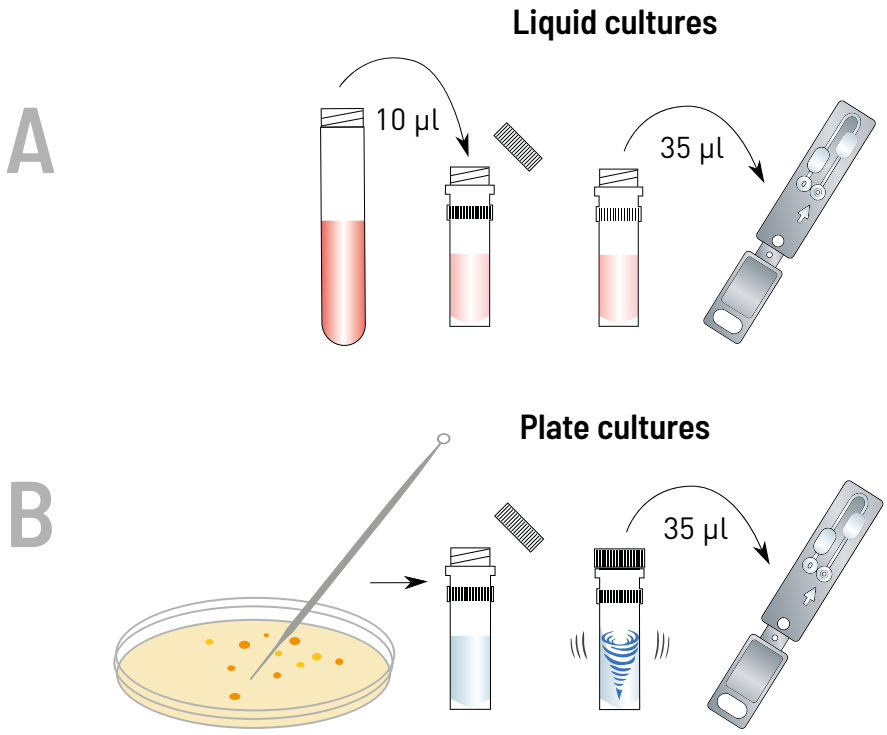
Key facts

- Dual-target detection - Identification of *S. aureus* combined with detection of the gene encoding for methicillin resistance (mecA and mecC)
- Possibility to detect both mecA and mecC genes enables comprehensive coverage of various MRSA strains
- Suitable for direct testing of both liquid cultures and culture plates.
- Extremely simple sample preparation and total turnaround time of less than one hour ensure timely results to aid in diagnosis

Assay principle

The GenomEra MRSA/SA AC Assay Kit is a qualitative polymerase chain reaction (PCR) test intended for the detection of MRSA and SA DNA target sequences from positive blood cultures, other microbial liquid cultures that are determined as gram-positive cocci by Gram staining, and culture plates. The test utilizes automated end-point PCR on the GenomEra® CDX instrument to detect a highly conserved nucleic acid sequence specific for SA and the mecA and mecC genes encoding for methicillin resistance. The GenomEra MRSA/SA AC assay is not intended to monitor treatment for MRSA/SA infections.

Test procedure



1a. Liquid cultures
Dispense 10 µL of liquid culture into the buffer tube.

Prepare all samples before continuing. Ensure that the Instrument is in standby.

2. Pipette 35 µL of sample per Test Chip (reverse pipetting technique).

1b. Plate cultures
Touch a single colony and shake the cells into the buffer.

Prepare all samples before continuing. Ensure that the Instrument is in standby.

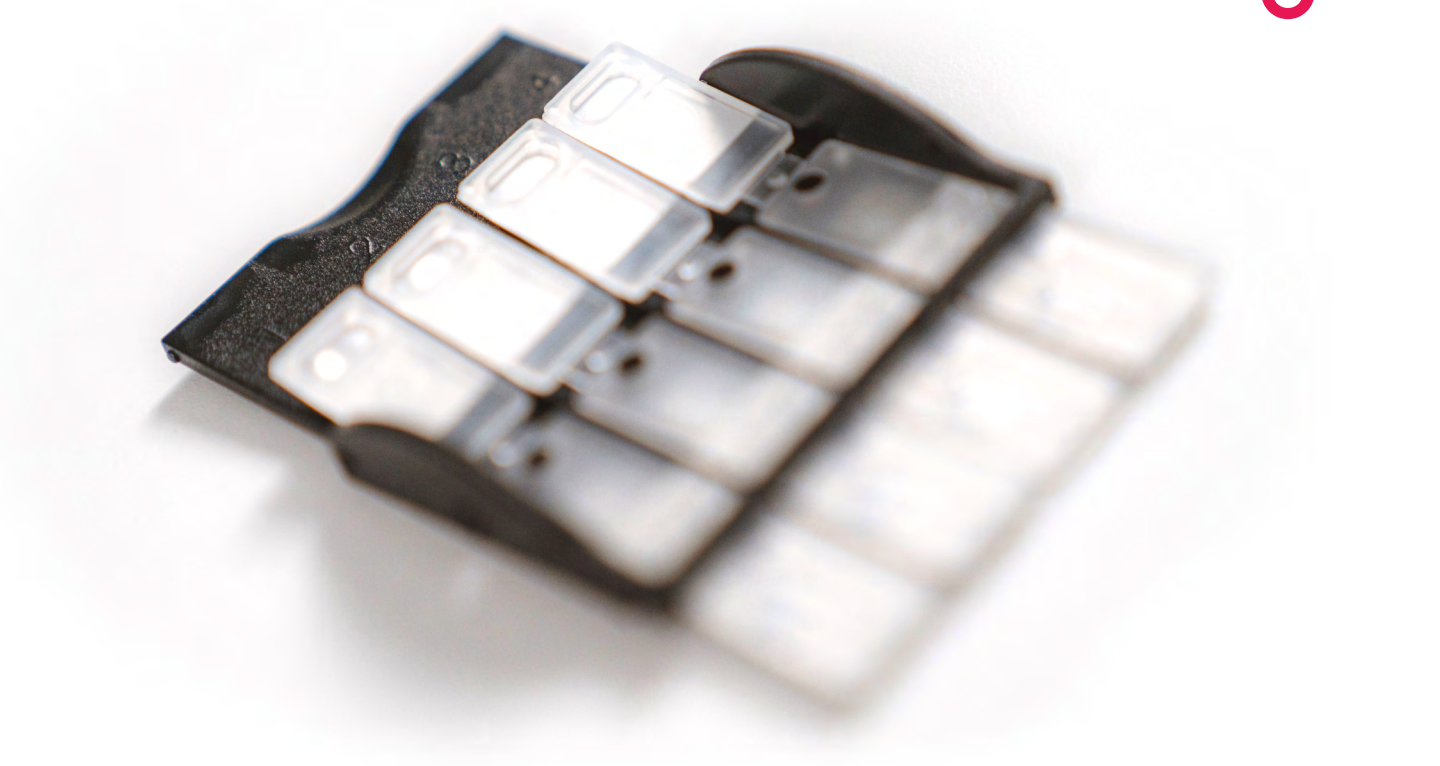
2. Pipette 35 µL of sample per Test Chip (reverse pipetting technique).

Clinical performance

The GenomEra MRSA/SA AC Assay was shown to have an unrivaled clinical performance in blood cultures in a study consisting of 232 samples from a Finnish university hospital (Table 1). The reference methods used were MALDI-TOF for species identification, minimum inhibitory concentration (MIC) tests for oxacillin (E-tests), standardized single disk tests for other antibiotics, and/or resistance STAM-panel by VITEK 2 for antibiotic susceptibility testing.

Sample size (n)	Sensitivity (%) (CI 95%)	Specificity (%) (CI 95%)	PPV (%)	NPV (%)
232	100 (96.34–100)	100 (97.11 –100)	100	100

Table 1. The GenomEra MRSA/SA AC Assay showed exceptional sensitivity and specificity in a clinical study at a Finnish university hospital.



Ordering information

To place an order, please contact your local distributor at uniogen.com/distributors/

Product name	Product code
GenomEra MRSA/SA AC Assay Kit, 20 tests	CDX-30-05-20
GenomEra MRSA/SA AC Assay Kit, 40 tests	CDX-30-05-40
GenomEra CDX System	CDX-10-020

Manufacturer
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Distributor

GenomEra® products carry the Finnish Key Flag Symbol, a valued and trusted symbol of Finnish origin.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen Oy.

The GenomEra® MRSA/SA AC Assay Kit 1.0, January 2024