GENSPEED® MRSA Test System

Setting the pace - Precise MRSA results within 75 minutes
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Setting the pace!

The new, revolutionary GENSPEED® MRSA Test System from Greiner Bio-One is an in vitro diagnostic tool for qualitative detection of methicillin resistant staphylococcus aureus (MRSA) in human nasal and pharyngeal smears. This bacterium is recognized worldwide as the most significant cause of nosocomial infections.

GENSPEED® MRSA was developed as a time and cost saving rapid test for low throughput testing applications in hospitals and laboratories. The main advantage of the product lies in the acceleration of the analysis, providing reliable results within merely 75 minutes.

Sensitivity owing to PCR technology, combined with the speed and specificity of the GENSPEED® Test System - ready to use with a short turnaround time!

With an average 7-day prolongation and additional expenses of 1,600.- Euro per patient / day,¹ the question is no longer whether an MRSA screening should be carried out nor not, but rather, which test system should be used.

Conventional culture for MRSA analysis takes up to 48 hours, leading to additional care and treatment costs for the necessary quarantine days.

Other molecular biological systems have been developed for high throughput application. Since due to economic reasons it is often necessary to wait for a certain number of patient samples before testing, the results for one patient are often not available until the next day.

The GENSPEED® MRSA Test System is particularly suitable for low throughput applications with a turnaround time (TAT) of only 75 minutes!

Precise MRSA results within 75 minutes

1. Lysis & DNA amplification
2. Denaturation & Hybridization
3. Detection & Reporting

¹The average 7-day prolongation and additional expenses of 1,600.- Euro per patient / day is an estimate based on typical medical and economic circumstances. The actual expenses may vary depending on specific local conditions and patient care practices.
The advantages of the GENSPEED® MRSA Test System

Fast turnaround time (TAT)

Speed

The speed of the test speaks for itself. With only 75 minutes from sample collection to result, GENSPEED® MRSA is among the fastest test systems on the market.

Individual sample analysis at any time

Each sample can be analyzed immediately. No batching required.

Unique detection of the new resistance gene mecC

GENSPEED® MRSA was the first test system in the world for the detection of mecC. Preliminary studies have demanded new detection methods for mecC, to ensure identification of MRSA in the future. 1,2,3,4,5,6

Differential diagnostics

GENSPEED® MRSA distinguishes MRSA from MRSE or mecA/C positive S.haemolyticus using its ability to simultaneously detect multiple analytes (multiplexing).

High degree of accuracy

Three controls (Negative control, PCR control, and implementation control) ensure the accuracy of the results.

One swab for everything

One and the same swab for GENSPEED® MRSA and bacterial culture.

No false positive results due to “Empty Cassette Variants” and no false negative results due to the neglect of the new resistance gene mecC

The resistance behaviour to methicillin is encoded by the Staphylococcus Cassette Chromosome mec (SCCmec). 7

So-called “Empty Cassette Variants” are a problem for many MRSA test systems on the market. These are S.aureus strains whose gene cassette does not contain the resistance gene mecA (deletion) therefore they are sensitive to methicillin (treatment with antibiotics possible). Test systems which target the cassette as an entity, disregard the mecA gene and yield false positive results.

Moreover, in 2011 the new gene variant mecC was discovered in England and has since then been detected in six more countries: DE, DK, FR, IE, NL, PT. 2 Although the examined strains show phenotypical methicillin resistance, it could not be detected with PCR tests currently on the market. 3,4,5,8

GENSPEED® MRSA is the first commercially available test, which detects both methicillin resistance genes – mecA and mecC.

Technical advantages at a glance

Easy handling

Objective results

Optional interfacing with your LIMS*

Up to four devices can be used in parallel

Electronic evaluation of measurement data guarantees objective results. The test system can be individually connected to your LIMS* if needed.

* laboratory information management system
Components of the GENSPEED® MRSA Test System

The GENSPEED® MRSA Test-Chip
- facilitates rapid testing by special microfluidics for accelerated hybridization
- contains DNA probes for
  - S.aureus
  - S.epidermidis/haemolyticus
  - the resistance genes mecA and mecC
- as well as three on-chip controls to assure the MRSA test results.

The GENSPEED® R2
In order to offer optimal ease of use, the analyzer features:
- power supply and control via USB
- integrated microliter-dispensing unit for automated injection of reagents from an exchangeable cartridge (48 tests)
- an integrated calibrator
- an integrated barcode module for identifying the Test-Chip
- patented optoelectronics for highly sensitive detection

The Notebook with integrated GENSPEED® Report Software
- controls the GENSPEED® R2 (up to 4 units in parallel)
- offers intuitive user guidance through test procedure
- analyses measurement data
- creates individualised reports
- allows optional connection to the LIMS

The PCR-Cycler
- 2 fixed volume pipettes
- 1 tube rack
- 2 boxes GBO filter tips

Swabs are not provided by Greiner Bio-One as a system component. We recommend "108C Amies Agar Gel - Single plastic swab - blue cap". These swabs can be used additionally after PCR for bacterial culture. www.copaninnovation.com

Full Speed - just a view steps to a reliable test result

1 DNA amplification
Native specimens are prepared by simplest preanalytics and DNA is amplified by robust multiplex PCR.

2 Sample Addition and Analysis
After application to the chip the PCR product is automatically analysed in the GENSPEED® R2.

3 Reporting
The GENSPEED® Report Software analyses the data and generates a report.

References
1 Medizinische Wirksamkeit und Kosten-Effektivität von Präventions- und Kontrollmaßnahmen gegen Methicillin-resistente Staphylococcus aureus (MRSA) – Infektionen im Krankenhaus, HTA Bericht 100; DIMDI (Deutsches Institut für Medizinische Dokumentation und Information)
2 November 2011 EURL course DTU Food, Technical University of Denmark (EURL=European Union/Reference Laboratory) - Antimicrobial Resistance National Food Institute
6 The Lancet Infectious Diseases, Volume 11, Issue 8, Pages 596 - 803, August 2011 Background
7 http://www.fennerlabor.de/uploads/media/MRSA.pdf

Item Nº Description Packaging
453227 GENSPEED® Starter Package (GENSPEED® R2, PCR-Cycler, Notebook, Accessories) 1 pc.
453224 GENSPEED® R2 Analyzer 1 pc.
453225 GENSPEED® MRSA Test-Kit (for use with GENSPEED® R2) 48 rxn.
453226 GENSPEED® MRSA Test-Kit (for use with GENSPEED® R2) 16 rxn.
MRSA?
= 75 min