GENSPEED
BIOTECH

GENSPEED® HAI Portfolio

Test panel for the
molecular identification of
nosocomial pathogens

www.genspeed-biotech.com

GENSPEED® MRSA test system

Full Speed – just a few steps to reliable test results

The key advantages of the GENSPEED® test system

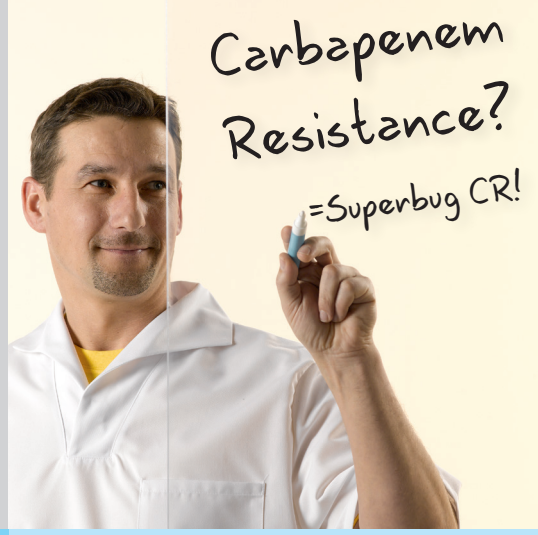
MRSA, **C.diff OneStep**, **Superbug CR** and **VanABC plus**

GENSPEED® C.diff OneStep

The new molecular way of detecting *C. difficile*

GENSPEED® Superbug CR

Tracking down carbapenem-resistance



THE GENSPEED® HAI* ASSAY PORTFOLIO

- Genspeed covers all relevant nosocomial pathogens and their common resistances
- Smart sample preparation and ready-to-use reagents
- Each assay type delivers detailed results on several parameters

* Hospital Acquired Infections

THE GENSPEED® EQUIPMENT

- Low inititial costs, small footprint for minimum space requirement, integrated calibration
- Automated assay procedure for minimum hands-on-time
- Detailed individual reports and statistical analysis

THE GENSPEED® ADVANCE

- State-of-the-art molecular analysis
- Individual assays at any time
- From sample to result in under 100 minutes
- Integrated process controls

GENSPEED® VanABC plus

Molecular multiplex assay
for maximum information

GENSPEED® MRSA test system

*mec*A und *mec*C detection in less than 100 min*

GENSPEED® MRSA is a diagnostic tool for the qualitative detection of methicillin resistant *Staphylococcus aureus* (MRSA) in human nasal and pharyngeal smears, inguinal swabs or bacterial culture.

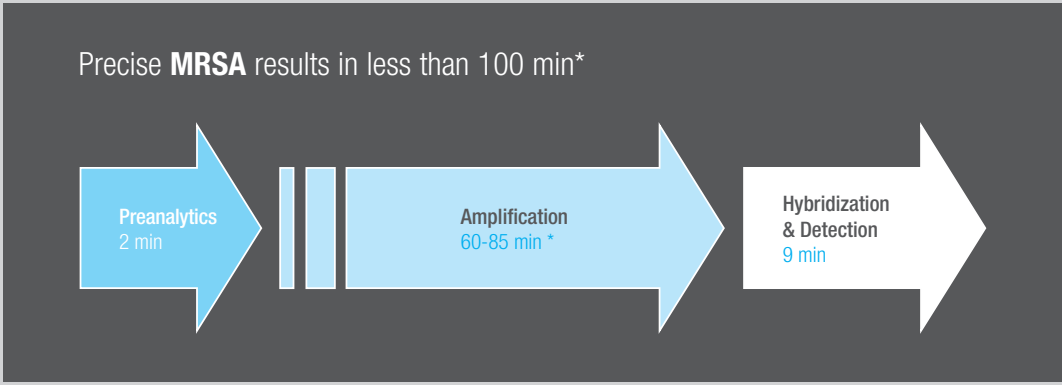
S. aureus is recognized worldwide as the most significant cause of nosocomial infections.

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 with a short turnaround time.

An efficient MRSA screening policy not only ensures the well-being of your patients but is also an important economic consideration. The early detection is key to prevent MRSA-associated complications, prolonged hospital stays and the resulting additional expenses of 1,600.- € per patient per day.

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. Those systems require sample batching in order to be economically efficient. Consequently, there are even more delays to obtain the results for an individual patient sample.



GENSPEED® MRSA is particulary suitable for low throughput applications and allows *mec*A and *mec*C detection in less than 100 min.*.

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

GENSPEED® MRSA detects both methicillin resistance genes – *mec*A and *mec*C.

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

No false positive results due to »Empty Cassette Variants« and no false negative results due to the neglect of the new resistance gene *mec*C.

GENSPEED® C.diff OneStep test system

All important parameters in one assay

GENSPEED® C.diff OneStep is a rapid diagnostic test for the qualitative detection of toxigenic *Clostridium difficile* in stool samples using the **GENSPEED®** technology.

GENSPEED® C.diff OneStep combines ease of use, generation of comprehensive high quality results with a fast time to result featuring:

- OneStep diagnostic algorithm
- One single multiplexed test for four Clostridium-specific genes
- High specificity and sensitivity
- Fast turnaround time – results in under 100 min*
- Detection of predictive marker for recurring *C. difficile* colitis[3]
- Attractive cost-benefit ratio

CLOSTRIDIUM DIFFICILE

Clostridium difficile is an anaerobic gram positive, rodshaped, spore-building bacterium. *C. difficile* infection (CDI) is the most common healthcare-associated infection, causing antibiotic-associated diarrhoea (AAD) that may lead to pseudomembranous colitis and even death. CDI has an enormous impact on healthcare systems worldwide and it is estimated that *C. difficile*-associated diseases cause additional costs of up to EUR 3 billion per year in Europe[1]. It is believed that CDI causes 14.000 deaths per year in the United States of America alone.

GENSPEED® C.diff OneStep integrates the two-step method into a single assay and offers fast, sensitive and conclusive results.

- One-Step assay
- One assay principle
- Better Lab-to-Lab comparability of test results

Sequential two-step methods are using different combinations of different test principles:

The **GENSPEED® C.diff OneStep** alternative offers fast, specific and conclusive results due to its unique multi-parameter based identification algorithm:

The **GENSPEED® C.diff OneStep** test combines the detection of GDH, toxin A and B as well as the binary toxin in a single simple molecular diagnostic test.

Simple preanalytics, ready-to-use reagents and sensitive, multiplex PCR for fast and accurate results. A ready-to-use system with a short time to result.

GENSPEED® Superbug CR test system

Tracking down carbapenem-resistance

GENSPEED® Superbug CR is a rapid diagnostic test for the qualitative detection of the most relevant bacterial carbapenemase genes in stool and rectal swab samples using the **GENSPEED®** technology.

The **GENSPEED® Superbug CR** test combines ease of use with the generation of comprehensive high quality results featuring:

- Simple preanalytics and integrated controls
- One single multiplexed test for the detection of more than 70 carbapenemase-variants
- High specificity and sensitivity
- Short turnaround time – results in under 100 min*
- Attractive cost-benefit ratio

CARBAPENEM-RESISTANCE

Due to the soaring prevalence of antibiotic resistant bacteria in health-care facilities, carbapenems very often represent the last remaining treatment option for numerous life-threatening infections.

CONVENTIONAL METHODS TO DETECT CARBAPENEM-RESISTANT BACTERIA – A QUESTION OF EXPERIENCE AND INTERPRETATION

Microbiological culture methods to characterize antibiotic resistance of bacterial isolates require incubation periods of at least 24 to 48 hours. The obtained phenotypes have to evaluated on the basis of subjective parameters (for example, measurements for the determination of the minimum inhibitory concentrations (MIC), color changes, ...). The experience of the person performing the tests is critical and can lead to increased variations during assessment of the results.

THE ALTERNATIVE – GENSPEED® Superbug CR

GENSPEED® Superbug CR offers fast, specific and conclusive results.

- One-Step assay
- Objective, reproducible reports
- Better lab-to-lab comparability of test results

The **GENSPEED® Superbug CR** test allows for the detection of the most relevant carbapenemase genes in stool and rectal swab material in a single simple molecular diagnostic test.

Simple preanalytics, ready-to-use reagents and sensitive, multiplex PCR for fast and accurate results. A ready-to-use system with a short time to result.

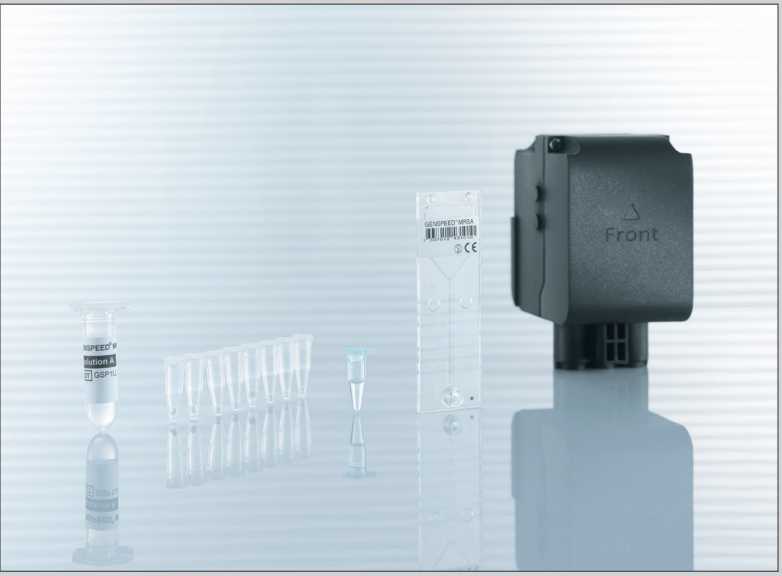
GENSPEED® VanABC plus test system

Complete information on Vancomycin-resistance

GENSPEED® VanABC plus is a rapid diagnostic test for the qualitative detection of genes associated with vancomycin-resistance in bacteria obtained from rectal swabs, stool or bacterial culture.

GENSPEED® VanABC plus plus combines ease of use with the generation of comprehensive high quality results featuring:

- Detection of transmissible and non-transmissible vancomycin resistance genes
- Single-tube multiplex assay for resistance and marker genes
- High specificity and sensitivity
- Fast turnaround time – results in under 100 min*
- Attractive cost-benefit ratio



VANCOMYCIN RESISTANT BACTERIA

Vancomycin-resistance is most often encountered in bacteria belonging to the genus enterococcus hence their name vancomycin resistant enterococci (VRE). Most enterococcal infections are due to *E. faecalis* and *E. faecium*. While in the US 75 % of all clinical *E. faecium* isolates are vancomycin resistant, the resistance rates within Europe vary between 1 % and 31 %.

Early detection of VRE, particularly those carrying the transferable vanA and vanB gene clusters, is important for nosocomial prevention measures, infectious disease control, and the prevention of the emergence of other vancomycin-resistant bacteria.

THE ALTERNATIVE – GENSPEED® VanABC plus

GENSPEED® VanABC plus offers fast, specific and conclusive results:

- One-Step assay
- Objective, reproducible reports
- Better lab-to-lab comparability of test results

GENSPEED® VanABC plus is a molecular multiplex assay to differentiate the two main types i.e. acquired or intrinsic vancomycin-resistance.

* Time can vary with validated PCR-cycler used.

ARTICLE OVERVIEW GENSPEED® HAI PORTFOLIO

Art. Nr.	Beschreibung	Verpackung
GSHW103EN*	**GENSPEED®** Starter Package (**GENSPEED®** R2, PCR-Cycler, Notebook, Accessories)	1 pc.
GSHW001	**GENSPEED®** R2 Analyzer	1 pc.
GSTK101	**GENSPEED® MRSA** Test Kit	48 rxn.
GSTK102	**GENSPEED® C.diff OneStep** Test Kit (incl. Preanalytics Kit)	48 rxn.
GSTK103	**GENSPEED® Superbug CR** Test Kit (incl. Preanalytics Kit)	48 rxn.
GSTK104	**GENSPEED® VanABC plus** Test Kit (incl. Preanalytics Kit)	48 rxn.

* GSHW103EN contains peqSTAR Thermocycler (other cycler on request)

For further information please visit our website **www.genspeed-biotech.com**

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