GENOMERA™ MRSA/SA PRODUCTS

A NEW ERA IN DIRECT MRSA DNA TESTING

ABACUS Diagnostica

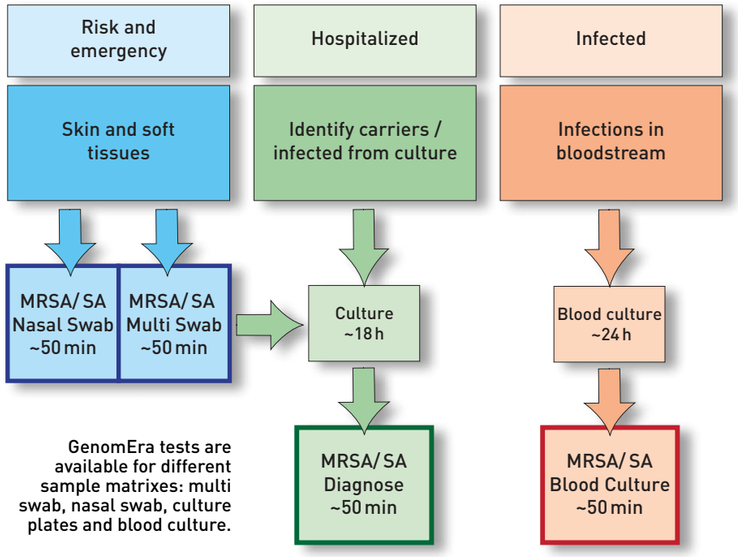
IMPROVING PATIENT CARE THROUGH EARLIER DETECTION OF **MRSA** AND **SA**

Methicillin-resistant *Staphylococcus aureus* (MRSA) has become the most commonly identified antibiotic-resistant pathogen in the world. It is a significant cause of morbidity, mortality and increased healthcare costs. *Staphylococcus aureus* infections range from mild to life threatening. The bacteria can spread through the bloodstream and infect almost any site in the body.

Along with hospital-acquired MRSA, which is a particular hazard for elderly and fragile persons, there are community-acquired MRSA infections which usually affects younger people without prior illnesses and who generally contract recurrent skin and soft tissue infections – often without a recognizable point of entry. These are also transmitted independently of medical facilities within the population itself

The goals for infection-free hospitals and improved patient care are:

- **Prevent infection of the patient**
- **Prevent MRSA spread to other patients**
- **Start early optimal antibiotic therapy**



GenomEra tests are available for different sample matrixes: multi swab, nasal swab, culture plates and blood culture.

Due to the evolution of MRSA, it is increasingly important that genetic tests cope with the different strains and manifestations of novel genotypes. Due to the accuracy that mecA gene allows, detection of it is regarded as the gold standard in determining methicillin resistance.

GenomEra CDX™ dual-target strategy combines the specific detection of *S. aureus* (SA) with the detection of the mecA gene. This strategy enables sensitive and comprehensive coverage of MRSA and SA.

GenomEra CDX™, the reliable automated end point PCR-system for homogenous MRSA and SA identification:

- Maximized cost efficiency
- Tests available for different sample matrixes: multi swab, nasal swab, culture plates, blood culture
- High performance, quality and reliability
  - A comprehensive MRSA and SA strain coverage
  - Accurate background-corrected results through proprietary dual measurement detection
- Rapid
  - 4 patients in 50 minutes
- Easy to use & contamination free system
  - All PCR reagents readily dried in test chips
  - No DNA extraction or handling of PCR reagents, no need for specialized premises or expertise for result interpretation
  - Permanently sealed test chips

The Abacus Genomera MRSA detection solution consists of consumables, automated analyzer and easy-to-use software.

FAST MRSA AND SA DETECTION FROM GENOMERA™ **MULTI SWAB** OR **NASAL SWAB**

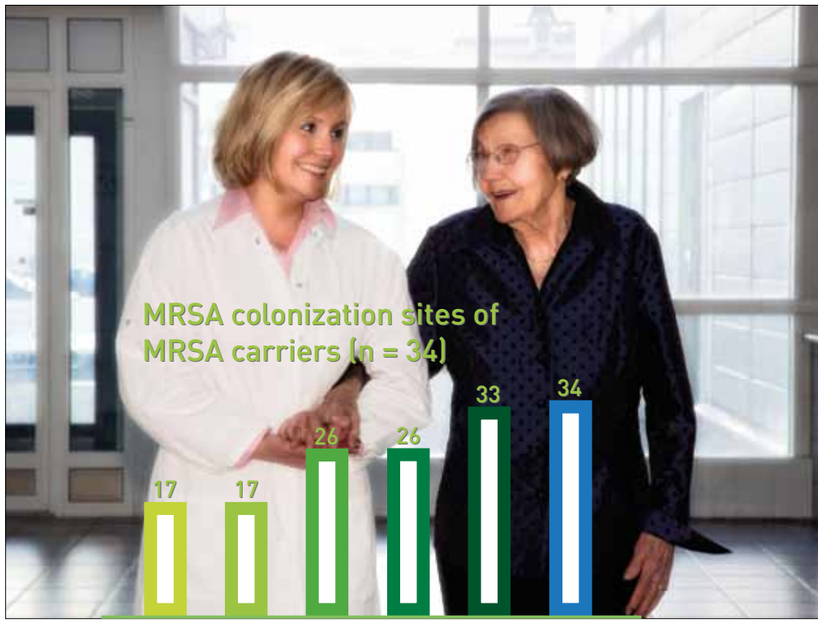
GenomEra MRSA Multi and Nasal Swab assay kits are designed for direct MRSA and SA detection and screening from clinical swab samples. The Multi Swab assay involves taking and combining swabs from more than one body site, from the sites where the carriage is most likely, such as the nose, throat, groin, and perineum. Swabs can also be taken from wounds or different infection foci if present. The clinical sensitivity of MRSA testing is significantly improved by expanding the screening to extra-nasal sites.

Pooling of swab samples prior to assay

Collecting samples from multiple colonization sites to increase the clinical sensitivity of MRSA screening has become a common practice in culture-based applications.

For the first time in PCR applications, the GenomEra MRSA Multi Swab assay directly accepts swab specimens pooled in liquid medium (eSwab MRSA Collection System, Copan). The same medium can be used for confirmation by culture so that separate samples need not be collected. Furthermore, the cost and laboratory workload can be markedly reduced by the simultaneous processing of all the swabs from one person.

Clinical findings suggest that MRSA screening programs that only test for nasal MRSA colonization of high-risk patients may be missing a large number of patients colonized with MRSA.

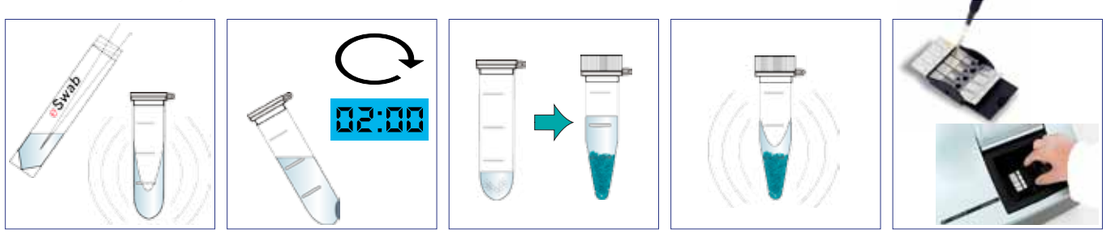


The GenomEra MRSA/SA Multi Swab assay yielded positive results for all the 34 pooled samples.

The goal of MRSA Multi and Nasal Swab screening:

- Identify patients that are potentially infected with MRSA
- Isolate the potential MRSA carriers and reduce the risk of MRSA transmission to other individuals
- Reduce the incidence and associated morbidity and mortality of MRSA and SA infections

Assay steps for the direct Multi and Nasal Swab assays:



Take a sample; vortex | **Centrifuge 2 minutes and remove the supernatant** | **Re-suspense the pellet, transfer to tube B** | **Vortex for 2 minutes, spin briefly** | **Pipette to test chips and start the GenomEra CDX assay run**

RAPID GENOMERA™ DIAGNOSIS FROM ANY POSITIVE **CULTURE PLATE**

Culture-based methods are widely used for primary routine screening of MRSA and form the foundation for cost-effective MRSA detection in non-urgent settings. The most cost-efficient way for culture-based screening is to use multi swab samples from the same patient.

For an early diagnosis, the genetic identification of the grown colonies is a vital process in the reliable detection of MRSA.

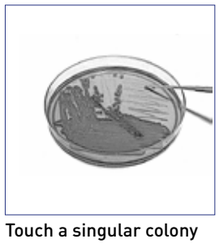
The automated GenomEra MRSA/SA PCR test allows rapid and sensitive detection of MRSA or SA in bacterial colonies picked from any culture plate suspected positive for MRSA or SA. The test does not require sample preparation such as cell lysis or DNA extraction. Accordingly, the test enables a definitive genetic diagnosis of MRSA or SA in less than one hour compared to hours or even days spent with conventional identification methods.

Definitive results for 4 patients are obtained in 50 minutes.

GenomEra MRSA/SA \ Culture	*MRSA+*	*SA+*	*Negat.*	
MRSA+	415	-	-	Sensitivity for MRSA (415/415) = 100%
SA+	-	100	1*	Sensitivity for SA (100/100) = 100%
Negative	-	-	81	Specificity (81/82) = 98.8 %

* Morphologically S. aureus -like S. pasteuri / S. warneri. The PCR-inhibition rate was 0.17% (1/597).

Assay steps for culture plates:



Touch a singular colony

Shake the cells int o buffer

Pipette to test chips and start the GenomEra CDX assay run

GENOMERA™ MRSA/SA DETECTION FROM **BLOOD CULTURE**

When the infection has spread to the bloodstream, reliable results are needed fast. The immune response to bacteraemia can cause sepsis and septic shock, which result in a high rate of mortality despite intensive care. The bacteria can also invade other sites of the body via the bloodstream, causing other life threatening infections.

The current microbe identification methods may take from 1-2 additional days after receiving a positive signal from blood culture. In the meantime clinicians often employ empiric treatment approaches, that can be costly, ineffective and contribute to the emergence of antibiotic resistant bacteria.

The GenomEra MRSA/SA Blood Culture test detects the presence of MRSA and SA in positive blood culture bottles in 50 minutes and enables immediate start of targeted antimicrobial therapy. It has been reported that each hour of delay in the administration of an effective antimicrobial therapy results in mean decrease of 8 % in patient survival (Kumar A et al. Crit Care Med 2006;34:1589–1596). A rapid and direct nucleic acid based test thus brings significant improvements to the care of critically ill patients.

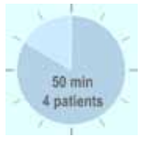
Results for 4 patients are obtained in 50 minutes.

GenomEra MRSA/SA Blood Culture \ Routine microbe identification	*MRSA+*	*SA+*	*Negat.*	
MRSA+	2	-	-	Sensitivity for MRSA (2/2) = 100%
SA+	-	35	-	Sensitivity for SA (35/35) = 100%
Negative	-	-	54	Specificity (54/54) = 100 %

Assay steps for the GenomEra MRSA/SA Blood Culture test:

Mix the positive blood culture sample with buffer

Pipette to test chips and start the GenomEra CDX assay run



GENOMERA CDX™ TAKES **YOUR DNA TESTING** TO **A NEW LEVEL** OF EASINESS AND CONVENIENCE!

The GenomEra CDX™ system offers a simple-to-use and cost-efficient solution for routine DNA testing, with the high performance, quality of results and reliability.

GenomEra CDX™ brings Speed, Simplicity and Safety to DNA testing:

- A proprietary test chip concept
- An automated PCR analyzer
- A software interface with robust result interpretation technology.

Top class sensitivity

The unique combination of highly fluorescent, proprietary lanthanide labels and the robust time-resolved detection technology enables a high detection sensitivity with no signal interference from the clinical samples. The proprietary two-point detection technique ensures background-corrected results with no late-cycle obscurities.

Simplicity at its extreme

All PCR reagents are readily dried and preloaded in the patented, ready-to-use test chips. There is thus no need to resuspend or handle PCR reagents. No troublesome DNA extraction is required either.

Robustness and reliability

The easy-to-use graphical software interface provides a powerful tool for automated and reliable result interpretation. Traceability is ensured by using barcodes, which are automatically read by the analyzer at the start of each test run.

High Speed Results

The patented multi-block thermal cycling technology enables rapid PCR amplification with 45 thermal cycles. The run time for 4 patient samples is 50 minutes. The sample preparation of the 4 samples takes 5-10 min depending on the assay kit.

Decreased contamination risk

The preloaded test chip design and the automated, permanent sealing of the test chips enable easy disposal of the low-volume waste with no risk of cross-contamination. There is no need for dedicated laboratory premises or for expertise or previous experience in PCR testing.

ABACUS DIAGNOSTICA – FOR **RAPID** AND **EASY** DNA TESTING

Abacus Diagnostica Oy, located in the Science Park of Turku Finland, develops and manufactures rapid and simple solutions for high performance IVD DNA detection.

The company's proprietary, fully automated testing platform GenomEra CDX™ takes DNA testing to a new level of convenience and simplicity. The company's IVD MRSA product family makes it possible to perform high-performance genetic testing even outside a specialized laboratory environment and by personnel without experience in molecular biology.

Strong scientific background, patent families for:

- All-in-one PCR assay chemistry
- Enhanced competitive hybridization probe technology
- Time-resolved lanthanide -labels
- Robust two-step end point detection technology
- Thermal cycling principle using pre-heated blocks and flat test chips
- Simple sample preparation

The company is ISO 9001 and ISO 13485 certified.

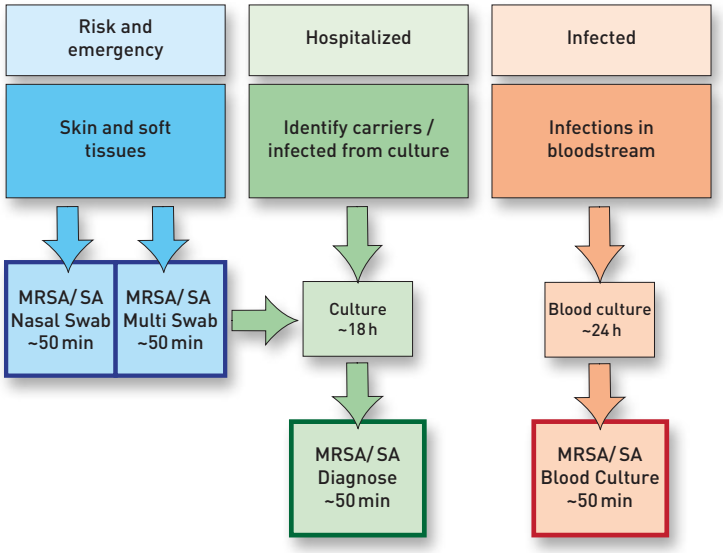
Proprietary technology platform of Abacus Diagnostica is covered by several patent families.

GENOMERA MRSA/SA PRODUCTS
ORDERING INFORMATION

GenomEra MRSA/SA Diagnose	CDX-30-01-40
GenomEra MRSA/SA Multi Swab*	CDX-30-02-20
GenomEra MRSA/SA Nasal Swab*	CDX-30-04-20
GenomEra MRSA/SA Blood Culture	CDX-30-03-40
GenomEra CDX System	CDX-10-020

* Available in June 2011

GenomEra MRSA/SA Product Family



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