About ELITechGroup Molecular Diagnostics...

our mission

ELITechGroup Molecular Diagnostics has established its position as a leading PCR innovator with its revolutionary MGB Technology. Guided by over 45 years of industry experience in diagnosing the human condition, ELITechGroup is dedicated to providing the highest quality Real-Time PCR solutions to improve patient outcomes for infectious, respiratory and sexually transmitted diseases, stem-cell and solid organ transplantation, cancer and human genetics.

ELITechGroup Molecular Diagnostics' suite of Real-Time PCR solutions enable healthcare providers to make better medical decisions, improve patient outcomes and deliver a superior level of service and patient care.

MRSA/SA ELITe MGB® Kit

better **detection,** effective **control** and **prevention, lowest cost** overall

Proven Technology

- ✓ Industry-leading MGB Real-Time PCR technology on a flexible system solution
- ✓ MGB Real-Time solutions proven in thousands of laboratories worldwide

Innovative Design

- ✓ Exclusive detection of the *mecC* gene
- ✓ Unique multiplex biomarker design reduces false negative and false positives results (patent applied)
- ✓ Assay designed to amplify both gene targets equally to confirm true MRSA infection

Trusted Results

- ✓ Accurate MRSA and *S. aureus* results for improved outcomes
- ✓ Effectively manage limited resources to improve bottom line

Ordering Information

Reference	Description	Quantity
M800351	MRSA/SA ELITe MGB® Kit	100 reactions
M800356	MRSA/SA ELITe Positive Control	24 reactions

For *in vitro* Diagnostic use

Over the past decade, the ELITechGroup Companies have established global scientific and technical leadership with a solid world-wide distribution network. Through our products and licensing, thousands of customers have experienced ELITech quality, convenience and reliability in over 100 countries. Local support is provided by dedicated and well trained sales and service representatives.

Limited License

Please visit http://www.elitechgroup.com/corporate/elitemgb-legalnotice for complete licensing and warranty information

Product available outside the US

EMD MRSA-490-2013/00EN

Please contact your sales representative for product availability in your country.

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MOLECULAR DIAGNOSTICS

MRSA MANAGEMENT

MRSA/SA ELITe MGB® Kit

Exclusive ***mecC gene*** *detection*

EXCLUSIVE *Next Generation* MRSA/SA Real-Time PCR assay detecting the ***mecC*** (***mecA*** $_{LGA251}$ **gene)**

UNIQUE multiplex biomarker design (patent applied)

BETTER detection with industry-leading MGB technology

IMPROVED resource management for healthier bottom-lines

ELITechGroup
MOLECULAR DIAGNOSTICS

Better detection, effective control & prevention

answering a critical unmet need

A **NEXT GENERATION** MRSA and *S. aureus* test that accurately detects emerging, clinically important MRSA variants with fewer false negative and false positive results.

In clinical studies, the *mecC* homologue, as known as *mecA* $_{LGA\ 251}$, has been shown to be a clinically important MRSA variant present in as many as **4 to 6% of all MRSA** infections [1,2]. Sharing only 70% nucleotide homology[3] with the conventional *mecA*, this variant is not detected by other commercial MRSA tests.

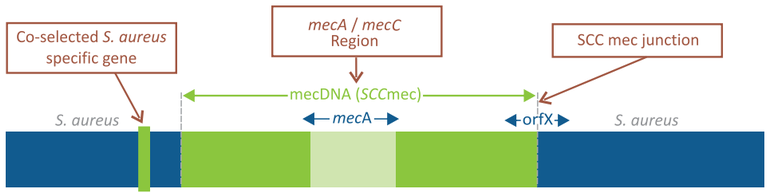
MRSA/SA ELITe MGB Kit® is a multiplex assay targeting:

- *S. aureus* specific gene: A highly conserved *S.aureus* specific target that is co-selected with mecA gene in MRSA positive samples.
- *mecA* gene: Detects methicillin restant organisms. Indicates the presence of a true MRSA positive result when co-detected with *S. aureus* specific gene.
- *mecC* gene: Detects the clinically important MRSA *mecC* variant further reducing false negative MRSA results.

EXCLUSIVE!

FIGURE 1

S. aureus gene map including *SCCmec* element



Improved outcomes & significantly lower overall cost

impact

False negative and false positive MRSA and *S. aureus* results present serious medical and economic challenges for healthcare providers impacting patient outcomes and satisfaction, staff safety, quality of care and overall costs.

TABLE 1

Comparison of MRSA and SA performance among leading amplification methods and culture.

Performance	ELITech	Company A	Company B	Company C	Company D	Culture
MRSA Sensitivity	100%	91.9%	92%	91.1%	90.4%	85%[5]
MRSA Specificity	97.5%	97.9%	94.6%	96.8%	96.9%	
SA Sensitivity	98%	93,3%	*No SA differentiation*			
SA Specificity	100%	90.5%				

Each missed MRSA infection may result in additional costs of €10,000 to €26,000 per patient.

solution

MRSA/SA ELITe MGB® Kit – The unique multiplex MGB Probe design detects the recently identified MRSA *mecC* variant and reduces the number of false negative and false positive results.

feature

- Industry-leading MGB Real-time PCR technology
- Exclusive detection of the recently identified *mecC*
- Unique multiplex MGB design targets conserved regions of *mecA* and *S. aureus* specific genes
- Assay designed to amplify both gene targets equally to confirm true MRSA infection

benefit

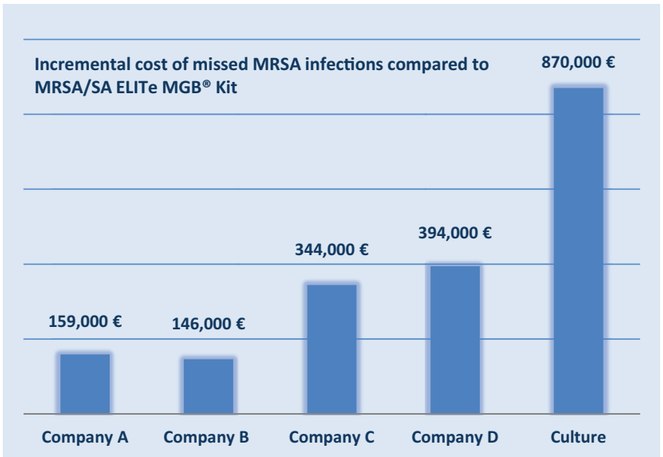
- Allows assay to be designed with short and specific DNA probes
- Avoids false negatives inherent in other Real-Time PCR assays due to misidentification of newly identified *mecA* gene variant
- Avoids primer-probe sequence mismatch due to *SSCmec* and spa and heterogeneity inherent in other Real-Time PCR assays
- Quantitatively compares *mecA* and *S. aureus* gene targets to reduce false negative and false positive results

result

MRSA/SA ELITe MGB was designed to have one of the lowest false negative rates enabling healthcare providers to make better medical decisions, improve patient outcomes and significantly reduce costs.

FIGURE 2

The incremental cost of missed MRSA infections among leading amplification methods and culture compared to MRSA/SA ELITe MGB® Kit (see references 6 - 9).



References

1. Larsen et al. "Nationwide survey of methicillin-resistant *Staphylococcus aureus* harboring mecA_{LGA251} *(mecC)* reveals a reservoir in ruminants". Poster presentation(P1317);ECCMID 2012
2. Stegger et al. "Rapid detection, differentiation and typing of methicillin-resistant *Staphyloccus aureus* harboring either *mecA* or the new *mecA* homologue *mecA*$_{LGA251}$", Clin Microbiol Infect. 2012 Apr;18(4):395-400
3. Garcia-Alvarez et al. "Methicillin-resistant *Staphyloccou aureus* with a novel *mecA* homologue in human and bovine populations in th UK and denmark: a descriptive study", Lancet Infect Dis.Aug 2011:11(8):595-603
4. Clinical data values used in this table excerpted from the "Expected Results" section of each manufacturers' package insert.
5. Ito et al. on behalf of the International Working Group on the Classification of Staphylococcal Cassette Chromosome Elements (IWG-SCC) "*Guidelines for Reporting Novel mecA Gene Homologues*", Antimicrobial Agents and Chemotherapy; 2012 Oct; Vol.56 No.10:4997–4999

References

6. Based on results published and summarized in "The impact of incorrect MRSA diagnoses", MLO, January 2012, pp 26-27.
7. Assumptions: MRSA incidence rate of 7.58% (combined observed MRSA rate for all manufacturer methods); hospitals testing an average of 6,300 patients/year identifying 478 MRSA positive patients. An average value of 1800€ in additional patient care coasts per missed MRSA infection was used in the above example.
8. Vriens MR et al., *Infect control hosp Epidemiol* Epidemiol. 2002 Sept.; 23(9):491-494
9. Kim Tet al., *Infect control hosp Epidemiol.* 2001 Feb.;22(2):99-104