

NOTICE of CHANGE dated 05/07/18

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«MRSA / SA - ELITe Positive Control»

Ref. M800356







This new revision of the Instruction for Use (IFU) contains the following changes:

- *The number of tubes and the volume of Positive Control has been modified from 4 x 65 µL to 2 x 160 µL.*

All the changes introduced are detailed in the Instruction for Use Manual (IFU).

Composition, use and performance of the product remain unchanged.

PLEASE NOTE

	LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT
	LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT



MRSA/SA - ELITE Positive Control

plasmid DNA control for qualitative assay

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INTENDED USE

The product «MRSA/SA - ELITE Positive Control» is intended for use as a positive control in qualitative nucleic acids amplification assays for the **detection of the DNA of *Staphylococcus aureus* (SA)** and **methicillin-resistant *Staphylococcus aureus* (MRSA)**, including the LGA251 strain) with «MRSA/SA ELITE MGB® Kit» product manufactured by ELITechGroup S.p.A.

PRODUCT DESCRIPTION

The product supplies the **Positive Control**, which consists of two stabilized solutions of plasmids. Each solution is aliquoted into **two ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for **5 sessions** in association with «ELITE InGenius®» and **12 sessions** in association with other systems.

One plasmid solution contains a region of a *Staphylococcus aureus*-specific gene and a region of the *mecA* gene; the other plasmid solution contains the same region of a *Staphylococcus aureus*-specific gene and a region of *mecC* gene. Both *mecA* and *mecC* genes (*mecA*_{LGA251}) confer resistance to methicillin and to other beta-lactam antibiotics. These plasmids are detected by the real time amplification reaction, attesting the assay's ability to detect the SA and MRSA DNA, including LGA251 strain.

The product is sufficient for **10 separate analytic sessions** in association with «ELITE InGenius» and **24 separate analytic sessions** in association with other systems, by using 10 µL per reaction.

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MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification and Labelling
MRSA/SA Positive Control	plasmid DNA solution	2 x 160 µL	-
LGA251/SA Positive Control	plasmid DNA solution	2 x 160 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile or similar material gloves.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (2-20 µL, 5-50 µL, 50-200 µL).
- Molecular biology grade water.

OTHER PRODUCTS REQUIRED

The reagents for real time amplification and the consumables **are not** included in this product.

To perform the Real Time amplification, the product «MRSA/SA ELITE MGB® Kit » (ELITechGroup S.p.A. ref. M800351) it is required. This is a complete and ready for use reaction mixture for real time amplification in a stabilising solution.

In association with «ELITE InGenius» (ELITechGroup S.p.A. ref. INT030), it is required the use of generic product «ELITE InGenius® PCR Cassette» (ELITechGroup S.p.A. ref. INT035PCR). These are dedicated consumables for Real Time PCR reactions.

When a 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems®) is used, it is required the use of generic product: «Q - PCR Microplates Fast» (ELITechGroup S.p.A., code RTSACC02), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

WARNINGS AND PRECAUTIONS

This product is exclusively for *in vitro* use.

Warnings and general precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards. Disposable combustible material must be incinerated. Liquid waste containing acids or bases must be neutralised before disposal.

Wear suitable protective clothes and gloves and protect eyes and face.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Carefully wash hands after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with the regulations in force.

Carefully read all the instructions provided in the product before running the assay.

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While running the assay, follow the instructions provided in the product.
Do not use the product after the indicated expiry date.
Only use the reagents provided in the product and those recommended by the manufacturer.
Do not use reagents from different batches.
Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acids extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

When amplification session is manually setup, it is necessary to have available separate areas for the extraction / preparation of amplification reactions and for the amplification / detection of amplification products. Never introduce an amplification product in the area designated for extraction / preparation of amplification reactions.

When amplification session is manually setup, it is necessary to have available lab coats, gloves and tools which are exclusively used for the extraction / preparation of the amplification reactions and for the amplification / detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification / detection of amplification products to the area designated for the extraction / preparation of the amplification reactions.

The samples must be exclusively used for this type of analysis. Samples must be handled under a laminar airflow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be sterile, free from DNases and RNases, free from DNA and RNA.

The reagents must be handled under a laminar airflow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. The pipettes used to handle the reagents must be exclusively used for this purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be sterile, free from DNases and RNases, free from DNA and RNA.

Amplification products must be handled in such a way as to reduce as much as possible dispersion into the environment in order to avoid the possibility of contamination. The pipettes used to handle amplification products must be exclusively used for this purpose.

Warnings and precautions specific for the components

The **MRSA/SA Positive Control** and the **LGA251/SA Positive Control** must be stored at -20°C.

The **MRSA/SA Positive Control** and the **LGA251/SA Positive Control** can be frozen and thawed for no more than **twelve times**.

PROCEDURE

The «**MRSA/SA ELiTe Positive Control**» products must be used with the complete reaction mixture of the «**MRSA/SA ELiTe MGB® Kit**» product.

Before use, take and thaw the **MRSA/SA Positive Control** tubes and the **LGA251/SA Positive Control** tubes. Mix gently, spin down the contents for 5 seconds and keep them on ice for a maximum of four hours.

The two **Positive Control solutions** are ready for use: **10 µL** is directly added to the reaction mixture. A single separate reaction mixture must be used for each plasmid solution.

The complete procedure involves setup and carrying out of a real time amplification reaction and is described in detail in the instructions for use enclosed with the «**MRSA/SA ELiTe MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the SA and MRSA DNA, are described in details in the instructions for use enclosed in the «**MRSA/SA ELiTe MGB® Kit**» product.

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N.B.: The results of the Positive Control amplification will be stored by the instrument «**ELiTe InGenius**» and used to create a control chart. For each batch of product «**MRSA/SA ELiTe MGB® Kit**» the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire after 15 days.







N.B.: The **Positive Control solutions** can be frozen and thawed for a maximum of **twelve times**.

REFERENCES

Garcia-Alvarez, L. et al. Methicillin-resistant *Staphylococcus aureus* with a novel *mecA* homologue in human and bovine populations in the UK and Denmark: a descriptive study. *Lancet Infect Dis* 2011, 11:595-603

Ito T. et al. Guidelines for reporting novel *mecA* gene homologues. *Antimicrob Agents Chemother.* 2012 October; 56(10): 4997-4999.

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	<i>in vitro</i> diagnostic medical device.
	Fulfilling the requirements of the European Directive 98/79/EC for <i>in vitro</i> diagnostic medical devices.
	Contains sufficient for "N" tests.
	Attention, consult instructions for use.
CONT	Contents.
	Manufacturer.

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