

## Σ-TSB™ (SIGMA-TSB™)

WITH TRYPTONE SOYA BROTH AND 6.5% NACL

CODE	DESCRIPTION	SPECIMEN
MWTSB65	Sigma TSB with 6.5% NaCl, with 2ml medium, with standard Sigma swab	Nose, throat, axilla, groin, perineum
MWTSB65R	Sigma TSB with 6.5% NaCl, with 2ml medium, with Sigma rectal swab	Rectum
MWTSB65T	Sigma TSB with 6.5% NaCl, with 2ml medium. Tube only.	

*\*Product with (Tube Only\*\*) in the description is registered as IVD only (EU Directives and Regulations). All other product codes are class 1s MDD's.*

### Intended Use

MWE Sigma-TSB™ is a swab-based device for the direct collection and rapid processing of MRSA screening specimens. Sigma-TSB™ specimens are processed using standard clinical laboratory procedures for specimens which are to be tested for methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-sensitive *Staphylococcus aureus* (MSSA) by culture or molecular methods.

The product includes a vial of TSB enrichment broth and a swab which can be snapped into the vial. After collecting the specimen, the vial can be incubated for a few hours before inoculation onto a chromogenic agar medium for the direct detection and identification of MRSA. The vial is compatible with all current automated processing platforms.

### Summary and Principles

One of the routine procedures in the diagnosis of infections involves the collection and transportation of a clinical swab specimen from the patient to the laboratory. For swab specimens which are to be tested for MRSA, the first stage of processing in the laboratory is often to transfer the swab to an enrichment broth containing sodium chloride (NaCl). Most strains of *Staphylococcus aureus* will grow in the presence of NaCl, while other organisms commonly picked up on swabs will be inhibited. In the Dutch guideline on the laboratory detection of methicillin-resistant *Staphylococcus aureus* an NaCl concentration of 6.5% (w/v) in an otherwise non-inhibitory broth such as tryptic soy broth (TSB) is recommended. In MWE Sigma-TSB with 6.5% NaCl, those two stages are combined, so that for those specimens which are only intended to be tested for MRSA, the swab specimen is collected directly into the transport tube containing TSB with 6.5% NaCl. The tube can be incubated immediately on arrival at the laboratory, and even during transport at ambient temperatures over a few hours there can already be growth of *Staphylococcus aureus*. Following incubation, the broth is inoculated on to a suitable chromogenic agar, and any MRSA or MSSA colonies readily observed. Thus, MRSA is rapidly detected, and appropriate action taken regarding the patient.

### Reagents

MWE Sigma-TSB with 6.5% NaCl liquid medium is a nutrient medium containing tryptone, soy peptone and dextrose, buffered with dipotassium phosphate, and with 6.5% (w/v) sodium chloride as a selective agent.

### Precautions

For professional use only.

For *Staphylococcus* specimens only

For in vitro diagnostic use only



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Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. Prior to discarding, swabs and other contaminated materials must be sterilised by autoclaving. Once a swab sample is collected, it should be placed immediately into the transport tube where it comes into contact with the TSB enrichment broth. Swab specimens for microorganism isolation and / or detection should be submitted to the laboratory as quickly as possible after collection.

Do not use if package seal is broken.

Do not use if swab shaft is broken.

### Important Note

When collecting specimen from patient.

Do not use excessive force, pressure or bending while using the swab to collect a specimen from the patient, as this could cause accidental breakage of the swab shaft. Some swab shafts do have a defined breakpoint to allow the swab to be snapped off into the transport tube, but in all cases, excessive force must never be used while collecting the specimen.

Swabs with breakpoints are not suitable for collecting specimens via tracheotomy tube.

### Material Safety Information

Σ-TSB™ plastic components do not contain latex or PVC.

### Storage

Σ-TSB™ with 6.5% NaCl should be stored in a dry place at temperatures between + 5°C to 25°C.

DO NOT FREEZE

### Expiry Date

12 months from the date of manufacture. The expiration date is shown on the tube label, peel pouch, and box label.

### Specimen Collection and Handling

Materials Provided

Each device includes:

One white shaft swab alone, or one white shaft swab with a printed line at the insertion point for the collection of fecal specimens. (MWTSB65R) \*

Transport tube with TSB medium with 6.5% NaCl.

\*There is no swab with MWTSB65T

Materials required but not provided

External transport container compliant with local regulations

Microbiology facilities for processing specimens, including equipment and consumables for culture or molecular processing

37°C incubator

Chromogenic agar or another growth medium as required for processing specimens

### Instructions for Use

Before use, always check that the immediate packaging (peel pouch) is intact, that the tube contains medium and there are no signs of leakage. In case of a defect do not use the device. Appropriate protective clothing including



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sterile gloves should be worn when collecting and handling potentially infectious specimens. Care should be taken to avoid splashes and aerosols when snapping the swab shaft against the tube.

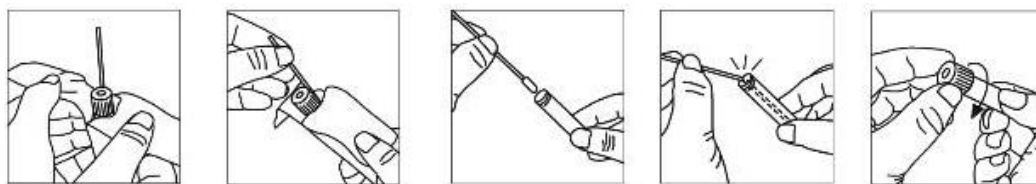
#### Instructions for taking specimen

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap by partially unscrewing.
2. Withdraw swab and use to take specimen
3. Remove cap from vial, insert swab into vial and snap off the non-bud end so that the remaining shaft fits within the vial.
4. Replace cap and tighten until secure
5. Complete patient and specimen details on label, and transport unto laboratory immediately.

#### Processing Specimens (Culture method)

1. Upon receipt at laboratory, or as soon thereafter as possible, place tube in 37°C incubator.
2. Incubate for 24 hours.
3. After incubation withdraw.
4. Vortex, or agitate manually
5. Using pipette or inoculating loop withdraw some of the broth and inoculate onto a suitable chromogenic agar that can distinguish MRSA and MSSA.
6. Incubate plates overnight (18 – 24 hours)
7. After incubation withdraw plates from incubator and observe carefully for any positive MRSA colonies.
8. If any MRSA colonies are observed the result should immediately be communicated to the ward or clinic where the patient is being held, or had attended, so that appropriate isolation and treatment can commence.

#### Instructions for Use (*continued*)



#### Automated Processing

MWE Sigma-TSB with 6.5% NaCl is suitable for use with most automated processing platforms, including those with automatic decapping of tubes. Please refer to the automated platform manufacturers' instruction manuals for specific information.

#### Performance Tests

Each batch of MWE Sigma-TSB with 6.5% NaCl is tested for sterility, pH, and non-toxicity. It is also tested for the ability to increase numbers of MRSA or MSSA, and the inhibition of Escherichia coli.

#### Limitations

1. When collecting and processing specimens follow relevant safety guidance for the handling of potentially



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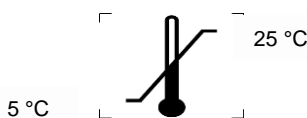
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infectious material, and for the maintenance of the biological integrity of the specimen.

2. The condition, time of collection, and volume of specimen are all significant factors in obtaining accurate and reliable results, whether using culture or molecular techniques. Always follow the recommended guidelines for specimen collection.
3. MWE Sigma-TSB with 6.5% NaCl is intended for use with the medium and swabs provided. Medium and swabs from other sources are not validated (unless specifically stated by the manufacturer and confirmed by Medical Wire), and using such could affect the performance of any tests.

### Warnings

- This product is for Single Use Only. Attempted reuse may cause a serious risk of infection and inaccurate results.
- Do not resterilise unused swabs
- Do not repack components
- Not suitable for other uses other than the stated intended use.
- The use of this product with any rapid diagnostic kit or with diagnostic instrumentation should be validated by the user.
- Do not use this product if the swab is visibly damaged
- Do not use excessive force or pressure when collecting swab samples as this may cause the swab shaft to break
- MWE Sigma-TSB with 6.5% NaCl a Class IIA Medical Device in accordance with the European Medical Devices Directive 93/42/EEC and as such can be used for sampling all body surfaces, orifices, and surgical wounds.
- Follow directions for use. The manufacturer cannot be held responsible for unauthorised or unqualified use of the product.
- Specimen collection and processing should only be conducted by trained personnel.
- All specimens are to be considered infectious, and must be handled with appropriate precautions, and disposed of as clinical infectious waste.
- MWE Sigma-TSB with 6.5% NaCl medium is not to be used for premoistening the swab prior to specimen collection, or for premoistening in any way the sampling site.



**STERILE R**



**MD**

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