

## Σ-TRANSWAB® (SIGMA-TRANSWAB®)

WITH LIQUID AMIES MEDIUM

CODE	DESCRIPTION	SPECIMEN	CODE	DESCRIPTION	SPECIMEN
MW167S	Small vial, 1.0ml of liquid Amies medium 2 Sigma swabs (1 white with breakpoint, 1 red without breakpoint)	Wound, skin, throat. MRSA Screening.	MW177S2ML	Small vial, 2.0ml of liquid Amies medium 1 Sigma swab (mini-tip with breakpoint)	Nasopharyngeal, paediatric and urogenital.
MW176S	Small vial, 1.0ml of liquid Amies medium 1 Sigma swab (white with breakpoint)	Wound, skin, throat.	MW176S3ML	Sigma Transwab® 1 x Sigma Swab, 3ml Liquid Amies & Cap Capture.	Wound, skin, throat.
MW177S	Small vial, 1.0ml of liquid Amies medium 1 Sigma swab (mini-tip with breakpoint)	Nasopharyngeal, paediatric and urogenital.	MW176HF	Small vial, 1.0ml of liquid Amies medium 1 HydraFlock® swab (white with breakpoint)	Wound, skin, throat.
MW176S2ml	Small vial, 2.0ml of liquid Amies medium 1 Sigma swab (white with breakpoint)	Wound, skin, throat.	MW177HF	Small vial, 1.0ml of liquid Amies medium 1 HydraFlock® swab (mini-tip with breakpoint)	Nasopharyngeal, paediatric and urogenital
MW176S3	Small vial, 1.0ml of liquid Amies medium 3 Sigma swabs (1 white with breakpoint, 2 red without breakpoint)	MRSA Screening and multiple body sites.	MW178HF	Small vial, 1.0ml of liquid Amies medium 1 Hydraflock® swab (micro-ultrafine with breakpoint)	Nasopharyngeal, paediatric
MW176SE2	Small vial, 1.0ml of liquid Amies medium 2 Sigma swabs (1 white with breakpoint, 1 mini-tip with breakpoint)	Wound, skin, ear, nose, throat.	MW176PF	Small vial, 1.0ml of liquid Amies medium 1 PurFlock® swab (white with breakpoint)	Wound, skin, throat
MW176SB2ML	Small vial, 2.0ml of liquid Amies medium 1 Sigma swab (white with breakpoint), Blue cap	Wound, skin, throat.	MW177PF	Small vial, 1.0ml of liquid Amies medium 1 PurFlock® swab (mini-tip with breakpoint)	Nasopharyngeal, paediatric and urogenital
MW176SE23ML	Small vial, 3.0ml of liquid Amies medium 2 Sigma swabs (1 white with breakpoint, 1 mini-tip with breakpoint)	Wound, skin, ear, nose, throat.	MW178PF	Small vial, 1.0ml of liquid Amies medium 1 PurFlock® swab (micro-ultrafine with breakpoint)	Nasopharyngeal, paediatric
MW176M	Small vial 1.0ml of liquid Amies medium, no swab		MW860*	Large vial 3.0ml of liquid Amies medium, (Tube only)	

\*\* Products with (Tube Only\*\*) in the description are products which are registered as IVD's only (EU Directives and Regulations) . MW177 and MW178 product codes are class 1s MDD's, all other product codes are class 11a MDD's.

### Intended Use

Σ-Transwab® (Sigma-Transwab®) Specimen Collection and Transport System is intended to preserve the viability and infectivity of microbiological specimens after their collection and during transport from the collection site to the testing laboratory. Σ-Transwab® specimens are processed using standard clinical laboratory procedures for microbiological specimens.

### Summary and Principles

One of the routine procedures in the diagnosis of infections involves the collection and transportation of a clinical



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swab specimen from the patient to the laboratory. Specimens containing live microorganisms may be submitted to a laboratory for diagnosis or confirmation of the patient's illness. Σ-Transwab® devices include one, two or three swabs with cellular foam, or flocked polyester bud, and a tube of liquid medium to keep the specimen moist, and to maintain any microorganisms in a viable condition until they can be investigated at the laboratory. The liquid medium consists of an inorganic buffer to stabilize the pH of the medium and a reducing agent to remove dissolved oxygen from the medium.

For specific recommendations about the collection of specimens for microorganisms and primary isolation techniques, consult publications such as Cumitech (various)<sup>1</sup>, Clinical Microbiology Procedures Handbook<sup>2</sup>, or Manual of Clinical Microbiology<sup>3</sup>.

### Reagents

Σ-Transwab® includes a tube of Liquid Amies Medium

Formulation

Deionised water

Sodium chloride

Potassium chloride

Magnesium chloride

Calcium chloride

Potassium di-hydrogen phosphate

Di-sodium hydrogen phosphate

Sodium thioglycollate

### Precautions

For professional use only.

For in vitro diagnostic use only

This device is a Single Use Device and therefore cannot be reused, it must be assumed that all used devices contain infectious organisms and therefore should be handled accordingly. After use all devices must be disposed of according to laboratory regulations for infectious waste.

**Do Not Use If Package Seal 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-Transwab® plastic components do not contain latex or PVC.

### Storage

Σ-Transwab® should be stored in a dry place at temperatures between + 5°C to 25°C.

DO NOT FREEZE



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### Expiry Date

24 months from date of manufacture, 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 with one or two red shaft swabs for collection of specimens. \*

Transport tube with liquid Amies medium

\*There is no swab with MW176M, MW860

Materials required but not provided

External transport container compliant with local regulations

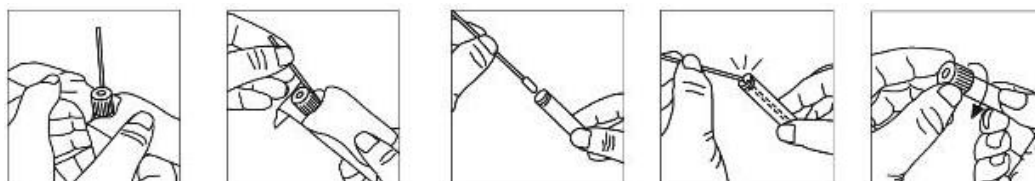
Microbiology facilities for processing specimens, including equipment and consumables for culture or molecular processing

### Instructions for Use

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

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap.
2. Withdraw the white 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. The swabs have a scored breakpoint or moulded breakpoint to assist this process.
4. If there are red shaft swabs, use one swab to take a further specimen, insert swab into vial, agitate in the medium, then withdraw the swab carefully by pressing and rotating against the side of the vial to express as much liquid as possible.
5. The red swab is now discarded as clinical waste.
6. If there is a second red shaft swab, repeat steps 4 and 5. Each swab can be used to sample a different body site from the same patient.
7. Replace cap and turn until secure. The white swab will become attached to the cap, except for MW177PF, MW177HF, MW178HF, MW178PF, MW177S and MW177S2ML.
8. Fill in patient's details.
9. Transport to the laboratory immediately.

### Instructions for Use (continued)



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### Expected Results

The survival of bacteria within a transport medium depends on a number of factors, such as storage temperature, type of bacteria, concentration of bacteria, duration of transport. Σ-Transwab® will maintain many microorganisms for a period of 24-48hrs at room temperature storage. For fastidious species such as *Neisseria gonorrhoeae* we recommend that the device is transported to the testing laboratory as quickly as possible for direct culture to guarantee adequate survival, if this is not feasible we recommend a storage temperature of 2-8°C and the device to reach the testing laboratory within 24hrs.

### Performance Tests

Recovery within specification at 4°C and 25°C tested with a selection of organisms from the following panel, in accordance with CLSI M40-A2

<i>Pseudomonas aeruginosa</i>	ATCC®BAA-427
<i>Streptococcus pyogenes</i>	ATCC®19615
<i>Haemophilus influenzae</i>	ATCC® 10211
<i>Streptococcus pneumoniae</i>	ATCC® 6305
<i>Bacteroides fragilis</i>	ATCC® 25285
<i>Peptostreptococcus anaerobius</i>	ATCC®27337
<i>Fusobacterium nucleatum</i>	ATCC®25586
<i>Prevotella melaninogenica</i>	ATCC®25845
<i>Propionibacterium acnes</i>	ATCC®6915
<i>Neisseria gonorrhoeae</i>	ATCC® 43069
<i>Bordetella pertussis*</i>	ATCC® 9797

\**Bordetella pertussis* is included for the following products MW177S, MW177S2ML, MW177PF, MW178PF, MW177HF and MW178HF.

### References

1. Cumitech - Various American Society for Microbiology, Washington D.C., various dates. [www.asm.org](http://www.asm.org)
2. Garcia, L., (3 ed.), Clinical Microbiology Procedures Handbook. American Society for Microbiology, Washington, D.C., 2010
3. Manual of Clinical Microbiology, 11th Edition, ASM Press, Washington D.C., 2015
4. CLSI. 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A. CLSI document M40-A2. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003. And revised edition M40-A2 published 2014.

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