

CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
MW167S	SIGMA TRANSWAB® - 2 Standard Plastic Foam Printed Breakpoint - 12x80 Vial - 1.5ml Amies Liquid Medium	Wound, skin, throat. MRSA Screening.
MW176S	SIGMA TRANSWAB® - Standard Plastic Foam Printed Breakpoint - 12x80 Vial - 1ml Liquid Amies Medium	Wound, skin, throat.
MW177S	SIGMA TRANSWAB® - ENT Minitip Foam Printed Breakpoint - 12x80 Vial - 1ml Liquid Amies Medium	Nasopharyngeal, paediatric and urogenital.
MW176S2ml	SIGMA TRANSWAB® - Standard Plastic Foam Printed Breakpoint - 12x80 Tube - 2ml Liquid Amies Medium	Wound, skin, throat.
MW176S3	SIGMA TRANSWAB® - 1 Standard Plastic Foam Printed Breakpoint 2 Red Plastic Foam - 12x80 Vial - 1.5ml Liquid Amies Medium	Wound, skin, throat. MRSA screening.
MW176SE2	SIGMA TRANSWAB® - 1 Standard Foam + 1 ENT Foam Printed Breakpoint - 12x80 Vial - 1.5ml Liquid Amies Medium	Wound, skin, ear, nose, throat.
MW179SF	SIGMA TRANSWAB® - Naso Ultrafine Flockswab - 12x80 Vial - 1ml Liquid Amies Medium	Skin, throat, nasopharyngeal, paediatric.
MW176SE23ML	SIGMA TRANSWAB® - 1 Standard Foam + 1 ENT Foam Printed Breakpoint - 12x80 Vial - 3ml Liquid Amies Medium	Wound, skin, ear, nose, throat.
MW176M*	SIGMA TRANSTUBE® - 12x80 Vial - 1ml Liquid Amies Medium	N/A
501001	SIGMA TRANSWAB® - Standard Plastic Foam Printed Breakpoint - 12x80 RB Vial - 1ml Liquid Amies Medium	Wound, skin, throat.
501005	SIGMA TRANSWAB® - ENT Minitip Foam Printed Breakpoint - 12x80 RB Vial - 1ml Liquid Amies Medium	Nasopharyngeal, paediatric and urogenital.
501007	SIGMA TRANSWAB® - Ultrafine Flexible Minitip Flockswab Printed Breakpoint - 12x80 RB Vial - 1ml Liquid Amies Medium	Nasopharyngeal, paediatric
350022	SIGMA TRANSWAB® - Standard Flockswab Breakpoint - 12x80 Vial - 2ml Liquid Amies Medium	Skin, throat, nasal
MW176SO	SIGMA TRANSWAB® - Standard Plastic Foam Printed Breakpoint - 12x80 Vial ORANGE Cap - 2ml Liquid Amies Medium	Wound, skin, throat.
MW177S2ML	SIGMA TRANSWAB® - ENT Minitip Foam Printed Breakpoint - 12x80 Vial - 2ml Liquid Amies Medium	Nasopharyngeal, paediatric and urogenital.
MW176S3ML	SIGMA TRANSWAB® - Standard Plastic Foam Printed Breakpoint - 12x80 Vial - 3ml Liquid Amies	Wound, skin, throat.
MW176PF	SIGMA TRANSWAB® - Standard Flockswab Printed Breakpoint - 12x80 Vial - 1ml Liquid Amies Medium	Wound, skin, throat
MW177PF	SIGMA TRANSWAB® - ENT Minitip Flockswab Printed Breakpoint - 12x80 Vial - 1ml Liquid Amies Medium	Nasopharyngeal, paediatric and urogenital
MW178PF	SIGMA TRANSWAB® - Ultrafine Flexible Minitip Flockswab Printed Breakpoint - 12x80 Vial - 1ml Liquid Amies Medium	Nasopharyngeal, paediatric
MW860*	SIGMA TRANSTUBE® - 16x100 Vial - 3ml Liquid Amies Medium	N/A
501002	SIGMA TRANSWAB® - Standard Flockswab Printed Breakpoint - 12x80 RB Vial - 1ml Liquid Amies Medium	Wound, skin, throat
501006	SIGMA TRANSWAB® - ENT Minitip Flockswab Printed Breakpoint - 12x80 RB Vial - 1ml Liquid Amies	Nasopharyngeal, paediatric and urogenital

## WITH LIQUID AMIES MEDIUM

MW167SF	SIGMA TRANSWAB® - 1 standard Flock Swab - 1 Red Flock Swab - 12x80 Vial - 1.5ml Liquid Amies Medium	Wound, skin, throat
MW176SF3	SIGMA TRANSWAB® - 1 Standard Flockswab Printed Breakpoint + 2 Red FlockSwab - 12x80 vial - 1.5ml Liquid Amies Medium	Wound, skin, throat
MW176T3	SIGMA TRANSTUBE® - 12x80 Vial - 3ml Liquid Amies Medium	N/A

**\*\* 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.**

MDD: European Medical Devices Directive 93/42/EEC

IVD: European In Vitro Diagnostic Medical Devices 98/79/EC

\*For Tube Only IVD's, the Notified Body number for CE, and Approved Body number for UKCA do not appear on the markings.

## INTENDED USE

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 via traditional or molecular processes.

## 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. 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

## INSTRUCTIONS FOR USE plus picture



WITH LIQUID AMIES MEDIUM

Rev. 17.4



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## 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**

## 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

## QUALITY CONTROL

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

## WITH LIQUID AMIES MEDIUM

<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.

## LIMITATIONS

The survival of bacteria within a transport medium depends on several 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.

## 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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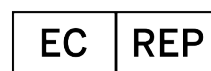
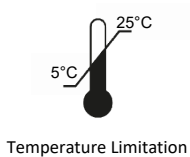
## REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP



**EC REP** Advena Ltd, Tower Business Centre, 2nd Fl.,  
Tower Street, Swatar, BKR 4013, Malta

**CH REP** Swiss AR Services AG Industriestrasse 47  
CH-6300 / Zug

## SYMBOLS &amp; DEFINITIONS



In Vitro Diagnostic Medical  
Device



Use By (YYYY/MM)



Consult Instructions for Use

Medical Device



Date of Manufacture



Peel Here

Method of Sterilisation Using  
Irradiation



UKCA Mark



Contains Sufficient for <n> Tests

Authorised Representative in the  
European Community



Catalogue Number



Swiss Representative

SGS Approval Mark



Batch Code

