TRANSWAB®

WITH AMIES GEL MEDIUM

CODE	DESCRIPTION	SPECIMEN
MW169P	Transwab® Duo, Standard plastic shaft swabs with rayon bud, Amies Clear	Wound, Skin, throat
MW169C	Transwab® Duo, Standard plastic shaft swabs with rayon bud, Amies Charcoal	Wound, Skin, throat
MW170	Transwab® Standard plastic shaft swab with rayon bud, Amies Clear	Wound, Skin, Urogenital throat, MRSA screening.
MW171	Transwab®. Standard plastic shaft swab with rayon bud, Amies Charcoal	Wound, Skin, Urogenital throat, Vagina
MW172P	Transwab® ENT, Aluminium wire shaft swab with rayon bud, Amies Clear	Urethral, Ear, nose, throat
MW172C	Transwab® ENT, Aluminium wire shaft swab with rayon bud, Amies Charcoal	Urethral, Ear, nose, throat
MW173P	Transwab® Pernasal, Ultrafine twisted nichrome wire shaft swab with rayon bud, Amies Clear	Nasopharyngeal, paediatric,
MW173C	Transwab®, Pernasal, Ultrafine twisted nichrome wire shaft swab with rayon bud, Amies Charcoal	Nasopharyngeal, paediatric,
MW175P	Transwab® Theatre Pack, Standard plastic shaft swab with rayon bud, Amies Clear, Triple wrapped	As MW170 for use in theatre
MW175C	Transwab® Theatre Pack, Standard plastic shaft swab with rayon bud, Amies Charcoal, Triple wrapped	As MW171 for use in theatre

Intended Use

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. 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 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. Transwab® devices include one or two swabs with rayon bud, mounted into the plastic bell cap and a tube of semi-solid medium to keep the specimen moist, and to maintain any microorganisms in a viable condition until they can be investigated at the laboratory. The medium consists of an inorganic buffer to stabilize the pH of the medium, agar to reduce the diffusion of air, and a reducing agent to remove dissolved oxygen from the medium. Where stated the medium also includes charcoal as an adsorbent for anti-bacterial substances.

For specific recommendations about the collection of specimens for microorganisms and primary isolation techniques, consult publications such as Cumitech (various)[1], Clinical Microbiology Procedures Handbook[2], or Manual

Medical Wire & Equipment Co (Bath) Ltd
Potley Lane, Corsham, Wiltshire, England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

of Clinical Microbiology[3].

Reagents

Transwab® includes a tube of Amies Gel Medium

Formulation

Deionised water .

Sodium chloride

Potassium chloride

Magnesium chloride

Calcium Chloride Activated

Agar

Di-sodium hydrogen phosphate

Potassium di-hydrogen phosphate

Sodium thioglycolate

Charcoal*

**Charcoal is included if stated in the product description*

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

MATERIAL SAFETY INFORMATION

Transwab® plastic components do not contain latex or PVC.

Storage

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

A single or double swab (plastic shaft with rayon bud) mounted in a plastic bell cap. (For MW170SH and MW171SH a separate foam tipped plastic shaft swab with breakpoint is provided to enable it to fit into the shorter screw cap transport vial)

Transport tube with semi-solid Amies medium

125 or 100 devices are included in each box.

Materials required but not provided

Medical Wire & Equipment Co (Bath) Ltd
Potley Lane, Corsham, Wiltshire, England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

TRANSWAB®

WITH AMIES GEL MEDIUM

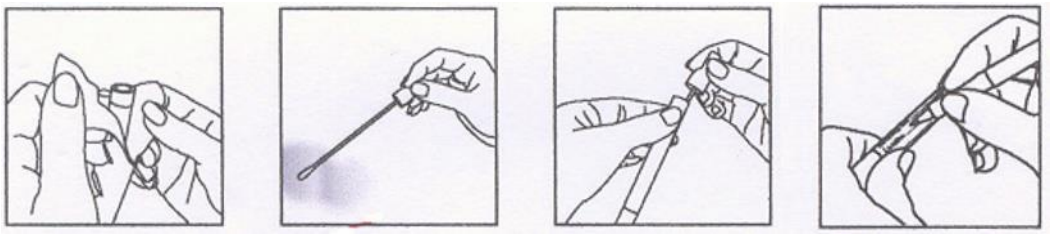
External transport container compliant with local regulations

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

Instructions for Use (except for MW170SH & MW171SH)

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

1. Peel back pouch at “Peel Here” arrow until bell cap and tube plug are exposed.



2. Twist tube plug to break seal, remove and discard.
3. Withdraw swab from peel pouch, holding with bell cap, and use to collect specimen.
4. Insert swab into the tube of medium, pushing down firmly until the bell cap reaches marker line.
5. ill in patient’s details.
6. Transport to laboratory immediately.

Instructions for Use for MW170SH & MW171SH

N.B. MW170SH and MW171SH are intended for the transport of samples to reference laboratories. The organisms will have already been grown on agar plates from which they are harvested by the swab. The shortened design allows them to fit in the safety containers used for inter-laboratory transport.

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap.
2. Withdraw the 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 swab has a scored breakpoint or moulded breakpoint to assist this process.
4. Replace cap and turn until secure. The swab will become attached to the cap.
5. Fill in specimen details.
6. Transport to the laboratory immediately

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. 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^{o}C and the device to reach the testing laboratory within 24hrs.

Performance Tests

Recovery within specification at 4^{O}C and 25^{O}C tested with a selection of organisms from the following panel, in

Medical Wire & Equipment Co (Bath) Ltd
Potley Lane, Corsham, Wiltshire, England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

TRANSWAB®

WITH AMIES GEL MEDIUM

accordance with CLSI M40-A2

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

** Bordetella pertussis* is included for the following products MW172C, MW172P, MW173C, MW173P

References

1. Cumitech - Various American Society for Microbiology, Washington D.C., various dates. 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.

5 °C 25 °C STERILE R LRQA CERTIFIED ISO 13485 MD CE 1639 UK CA 0120

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

CH REP Swiss AR Services GmbH Industriestrasse 47 CH-6300 / Zug

Medical Wire & Equipment Co (Bath) Ltd
Potley Lane, Corsham, Wiltshire, England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk