SIGMA FECAL TRANSWAB®
LIQUID CARY BLAIR MEDIUM

CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
MW168S	SIGMA FECAL TRANSWAB®, 2ml Liquid Cary Blair Medium, 1 standard plastic shaft, foam-tipped rectal swab, blue colour coded cap	Recovery of faecal specimens directly from patients as rectal specimens, or from faecal stool specimens.
MW168T	SIGMA FECAL TRANSWAB®, 2ml Liquid Cary Blair Medium, no swab, blue colour coded cap	Recovery of faecal specimens directly from patients as rectal specimens, or from faecal stool specimens.
MW268T	SIGMA FECAL TRANSWAB®, 2ml Liquid Cary Blair Medium, no swab, blue colour coded cap	Recovery of faecal specimens directly from patients as rectal specimens, or from faecal stool specimens.

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 FECAL TRANSWAB® Specimen Collection and Transport System is intended to preserve the viability and infectivity of faecal specimens after their collection and during transport from the collection site to the testing laboratory. The product can be used to collect stool specimen directly from the patient, using the swab as a rectal swab. Alternatively, the swab can be used to take material from a previously collected stool specimen. ∑- FECAL TRANSWAB® specimens are processed using standard clinical laboratory operating 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. ∑-FECAL TRANSWAB® devices include a swab with cellular foam, or flocked polyester bud, and a tube of liquid medium (Cary & Blair) to keep the specimen moist, and to maintain any microorganisms in a viable condition until they can be investigated at the laboratory by standard techniques such as culture. 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 the following ASM publications: Cumitech (various), Clinical Microbiology Procedures Handbook, or Manual of Clinical Microbiology.

REAGENTS

∑- FECAL TRANSWAB® includes a tube of Liquid Cary Blair Medium
Formulation
Disodium Phosphate
Sodium Thioglycollate
Sodium Chloride
Calcium Chloride
pH 7.5-8.5

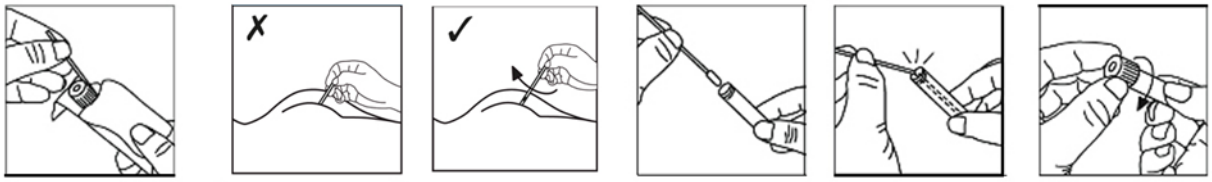
INSTRUCTIONS FOR USE(MW168S)

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap.
2. Withdraw swab and use to take specimen.
   For Sampling from Stool Specimen
   According to consistency of material dip swab into specimen or rub swab over specimen to collect as much material as possible.

Medical Wire & Equipment Co (Bath) Ltd
Leafield Industrial Estate, 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

Procedure for Rectal Swab Specimen Collection
Gently insert the swab beyond the anal sphincter. Do not insert further than 2cm. Rotate the swab and remove. The swab should show faeces.

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 shaft has a breakpoint to assist this process.
4. Replace cap and turn until secure. With MW168S the swab will become attached to the cap. With MW268S the swab does not attach to the cap.
5. Fill in patient's details.
6. Transport to the laboratory immediately



INSTRUCTIONS FOR USE (MW168T & MW268T)

∑-FECAL TRANSWAB® MW168T and MW268T are not supplied with a swab. They can be used directly with a stool specimen.

1. Place vial on a flat surface. Remove cap.
2. A small amount of stool specimen is transferred to the tube of medium using a suitable collection device such as a sterile swab, scoop, or inoculating loop.
3. Immerse specimen into the liquid medium in the tube. Swirl around to release as much material as possible into the liquid medium
4. Replace cap and turn until secure.
5. Fill in patient's details.
6. Transport to the laboratory immediately

PRECAUTIONS

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 infections 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 excessive force, pressure or bending while using the swab to collect a specimen from the patient
When collecting a rectal swab specimen do not insert swab more than 2cm beyond anus
DO NOT USE IF PACKAGE SEAL IS BROKEN.

MATERIAL SAFETY INFORMATION

∑- FECAL TRANSWAB® plastic components do not contain latex or PVC

STORAGE

∑-FECAL TRANSWAB® should be stored in a dry place at temperatures between + 5°C to 25°C.
DO NOT FREEZE

EXPIRY DATE

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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

Swab for collection of specimen*
Transport tube with Liquid Cary Blair medium.
*There is no swab with MW168T, MW268T

Materials Required But Not Provided

External transport container compliant with local regulations
Microbiology facilities for processing specimens

PROCESSING SPECIMENS

Inoculation of specimens into culture should be performed within 48 hours of specimen collection

QUALITY CONTROL

Quality control can be performed using the CLSI Standard M40-A2[5].

LIMITATIONS

1. ∑-FECAL TRANSWAB® is specifically intended for enteric specimens
2. ∑- FECAL TRANSWAB® is not validated for the transport of the following M40-A2 listed organisms: *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Streptococcus pneumoniae, Haemophilus influenzae, Bacteroides fragilis, Peptostreptococcus anaerobius, Fusobacterium nucleatum, Propionibacterium acnes, Prevotella melaninogenica* or *Neisseria gonorrhoeae.*

RECOVERY STUDIES

Three different batches of SIGMA FECAL TRANSWAB® transport swabs were tested in accordance with CLSI 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A2[5]. Test organisms used were as specified in the standard as "Quality Control Organisms for Fecal Transport Devices". Known concentrations of *Escherichia coli* ATCC 25922, *Salmonella* Typhimurium ATCC® 14028, and *Shigella flexneri* ATCC® 12022, were inoculated in triplicate onto swabs from three different lot numbers and held at 22^{O}C and 4^{O}C for up to 72 hours. Recoveries were measured at 0 hours, 24 hours, 48 hours and 72 hours. The results show that SIGMA FECAL TRANSWAB® transport swabs maintain the viability of these organisms as set out in the standard.

REFERENCES

1. Cary S. G. and Blair E. B. (1964) J. Bact. 88. 96-98.
2. Cumitech - Various American Society for Microbiology, Washington D.C., various dates. www.asm.org
3. Garcia, L., (3 ed.), Clinical Microbiology Procedures Handbook. American Society for Microbiology, Washington, D.C., 2010
4. Manual of Clinical Microbiology, 11th Edition, ASM Press, Washington D.C.
5. Clinical Laboratory Standards Institute (CLSI). 'Quality Control of Microbiological Transport Systems'; Approved Standard – Second Edition. M40-A2. CLSI document M40-A2 CLSI. (ISBN 1-56238-963-7) Clinical Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2014

REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP

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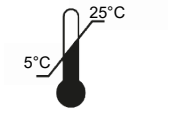
info@mwe.co.uk www.mwe.co.uk

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 & DEFINITIONS



Temperature Limitation


Do Not Reuse


Do Not Use If Package Damaged


Manufacturer

CE Mark

In Vitro Diagnostic Medical Device

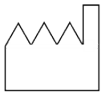
Medical Device

Method of Sterilisation Using Irradiation

Authorised Representative in the European Community

SGS Approval Mark


Use By (YYYY/MM)


Date of Manufacture

UKCA Mark

Catalogue Number

Batch Code


Consult Instructions for Use


Peel Here

Contains Sufficient for <n> Tests

Swiss Representative

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