FECAL TRANSWAB®

WITH LIQUID CARY BLAIR MEDIUM

CODE	DESCRIPTION	SPECIMEN	MEDICAL DEVICE CLASSIFICATION
MW168S	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.	MDD Class 1s
MW168PF	Fecal Transwab®, 2ml Liquid Cary Blair Medium, 1 standard plastic shaft, PurFlock®-tipped rectal swab, blue colour coded cap	Recovery of faecal specimens directly from patients as rectal specimens, or from faecal stool specimens.	MDD Class 1s
MW168T	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.	IVD
MW268T	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.	IVD

MDD: European Medical Devices Directive 93/42/EEC
IVD: European In Vitro Diagnostic Medical Devices 98/79/EC

Intended Use

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 & Blair1) 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.

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Reagents

Fecal Transwab® includes a tube of Liquid Cary Blair Medium

Formulation

Phosphate buffer

Sodium Thioglycollate

Sodium Chloride

Calcium Chloride

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 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 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.

When collecting a rectal swab specimen do not insert swab more than 4cm beyond anus.

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

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

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.

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*There is no swab with MW168T, MW268T

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 for MW168S & MW168PF

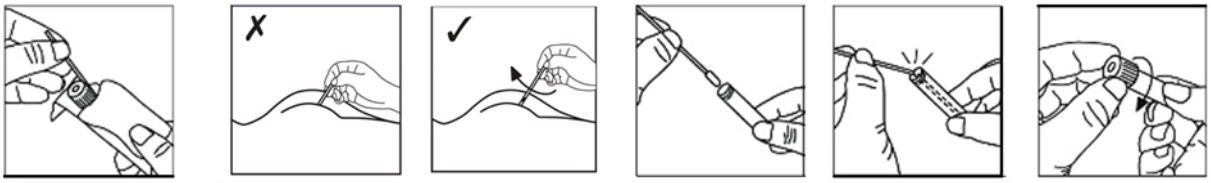
1. Peel back pouch, remove vial and place on a flat surface. Loosen cap.
2. Withdraw swab and use to take specimen.

   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.

   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. The swab will become attached to the cap.
5. Fill in patients 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. Fecal Transwab® will maintain many microorganisms for a period of 24-48hrs at room temperature storage. For fastidious species such as Campylobacter 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 25OC for

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Pseudomonas aeruginosa	NCTC 10332
Salmonella typhimurium	NCTC 0074
Escherichia coli	NCTC 9001

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

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