

CODE	DESCRIPTION	SPECIMEN	MEDICAL DEVICE CLASSIFICATION	UDI-DI
MW168	Transwab®, Semi solid Cary Blair Medium, 1 standard plastic shaft, rayon-tipped swab, red colour coded cap	Recovery of faecal specimens directly from patients as rectal specimens, or from faecal stool specimens.	MDD Class 1s	05060259070310

MDD: European Medical Devices Directive 93/42/EEC
 Medical Devices Regulations 2002, UK Statutory Instrument No. 618

Intended Use

Cary Blair Transwab® is a unique transport system for the safe and efficient transport of enteric bacteria.

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. Cary Blair Transwab® contains a semi-solid 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.

Cary Blair Transwab® is supplied sterile. The unit consists of a sterile peel pack containing a swab stick with rayon tip with colour-coded cap which is used to collect the sample and a pre-labelled transport tube containing transport medium. The swab needs to be placed in the transport medium after the sample has been collected.

Reagents

Transwab® includes a tube of Semi Solid Cary Blair Medium

Formulation;

- Disodium hydrogen phosphate
- Sodium Thioglycollate
- Sodium Chloride
- Calcium Chloride
- Agar

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. In all cases, excessive force must never be used while collecting the specimen.



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

Material Safety Information

DO NOT USE IF PACKAGE SEAL IS BROKEN

Cary Blair Transwab® plastic components do not contain latex or PVC

Storage

Cary Blair 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 swab (plastic shaft with rayon bud) mounted in a plastic bell cap.

Transport tube with semi solid Cary Blair medium

125 devices are included in each box.

Materials required but not provided;

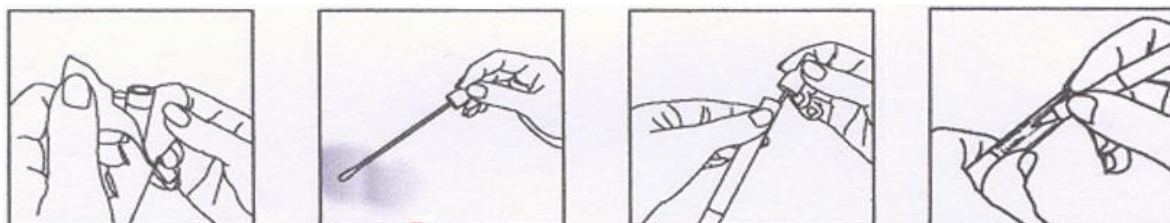
External transport container compliant with local regulations

Microbiology facilities for processing specimens, including equipment and consumables for culture or molecular processing, incubating systems, anaerobic workstations or gas jars.

Instructions for Use for MW168

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 clear plug to break seal, remove and discard.
3. Withdraw swab and use to take specimen.

(a) Procedure for sampling from a stool specimen

According to consistency of material dip swab into specimen, or rub swab over specimen to collect as much material as possible.

(b) Procedure for rectal specimen collection

Gently insert the swab beyond the anal sphincter. Do not insert further than 4cm. Rotate the



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swab and remove. The swab should show faeces.

4. Insert swab into the tube of medium, pushing down firmly until the bell cap reaches marker line.
5. Fill in patient's 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, and duration of transport. Transwab® with semi solid Cary Blair medium 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.

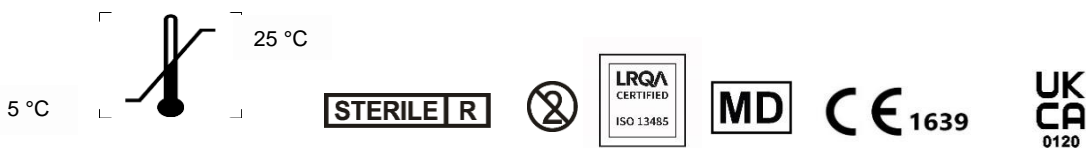
Performance Tests

Recovery within specification at 25°C

Pseudomonas aeruginosa	NCTC 10332 (24 hours)
Salmonella typhimurium	NCTC 0074 (24 hours)
Escherichia coli	NCTC 9001 (24 hours)

References

1. Cary S. G. and Blair E. B. (1964) J. Bact. 88. 96-98.



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