

CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
M200145	U-SWAB™ FECAL – Scoop – 12x80 Vial – 2ml Cary Blair Medium	Stool (Feces)
M200146	U-SWAB™ FECAL – Scoop – 16x100 Vial - 2ml Cary Blair Liquid Medium	Stool (Feces)
M200147	U-SWAB™ FECAL TRANSTUBE – Scoop – 12x80 Vial – Dry	Stool (Feces)
M200148	U-SWAB™ FECAL TRANSTUBE – Scoop – 16x100 Vial – Dry	Stool (Feces)

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

U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE Specimen Collection and Transport System is intended to preserve the viability and infectivity of fecal specimens after their collection and during transport from the collection site to the testing laboratory. The product can be used to collect stool specimens; the scoop can be used to take material from the patient's home. The collected stool specimen is transferred into the empty container or the container with liquid transport medium, depending on the type of test required. 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 specimens 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. U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE devices include a self-capping scoop, with either an empty tube or 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)¹, Clinical Microbiology Procedures Handbook², or Manual of Clinical Microbiology³.

REAGENTS

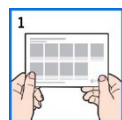
Formulation:

Disodium Phosphate
Sodium Thioglycollate
Sodium Chloride
Calcium Chloride
pH 7.5-8.5

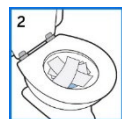
U-SWAB™ FECAL

U-SWAB™ FECAL TRANSTUBE

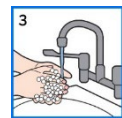
INSTRUCTIONS FOR USE



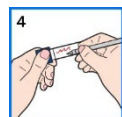
1. Make sure you read the instructions properly before starting to collect your sample.



2. Lay toilet paper in the toilet bowl to make it easier for you to collect your sample. Try to prevent the sample from touching the water.



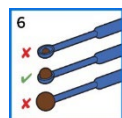
3. Ensure you wash your hands before you start taking the sample.



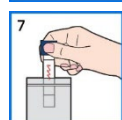
4. Fill in the required information on the U-SWAB™ FECAL tube. Take care to ensure your writing is clear.



5. Remove the cap from the tube and place on a stable, level surface. Take the blue spoon from the peel pouch, ensuring it only touches the stool sample (and nothing else). Use the blue spoon to collect your sample.



6. Collect a pea size amount of feces.



7. Put the sample spoon into the fecal collection tube and secure the cap. Place the fecal collection vial into the transport pouch and seal closed.



8. Wash your hands. Return sample to healthcare provider.

PRECAUTIONS

For self-sampling procedures on people over 13 years of age

NOT FOR USE by children under the age of 13. A parent or guardian would need to take the sample.

NOT FOR USE by disabled patients or patients requiring care a parent or carer would need to assist when taking the sample.

For in vitro diagnostic use only.

All U-SWAB™ swabs are Single Use Devices and therefore cannot be reused.

DO NOT USE IF PACKAGE SEAL IS BROKEN.

MATERIAL SAFETY INFORMATION

U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE plastic components do not contain latex or PVC.

STORAGE

U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE 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.

U-SWAB™ FECAL WITH CARY BLAIR MEDIUM
U-SWAB™ FECAL TRANSTUBE

Rev. 1



PROCESSING SPECIMENS

For specific recommendations about the processing of specimens for microorganisms and primary isolation techniques, consult national guidelines, or publications (as stated in the reference list)

When handling clinical specimens always wear protective gloves and any other protective clothing appropriate to the risk associated with the type of specimen.

If used with any other proprietary kits or test systems, reference must be made to the kit or test manufacturer to ensure that the swab is compatible, and appropriate controls included in the test protocol.

QUALITY CONTROL

Quality control can be performed using the CLSI Standard M40-A2⁵. (Cary Blair medium only)

LIMITATIONS

U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE is specifically intended for enteric specimens

U-SWAB™ FECAL & U-SWAB™ FECAL TRANSTUBE 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-A2⁵. 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°C and 4°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

U-SWAB™ FECAL U-SWAB™ FECAL TRANSTUBE

REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP



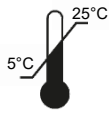
EC REP

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 & 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



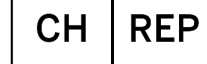
Consult Instructions for Use



Peel Here



Contains Sufficient for <n>
Tests



Swiss Representative

