CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
M200101	U-SWAB™ VAGINAL – Standard Flockswab – 80mm Breakpoint – Labelled Tube	Vagina
M200102	U-SWAB™ VAGINAL - Standard Flockswab – 80mm Breakpoint – Labelled Tube – Scannable Peel Barcode	Vagina

MDD: European Medical Devices Directive 93/42/EEC

INTENDED USE

U-SWAB™ VAGINAL can be used for the safe collection of clinical specimens.

SUMMARY AND PRINCIPLES

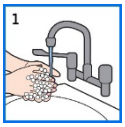
One of the routine procedures in the diagnosis of infections involves the collection of a clinical swab specimen from the patient. The swab absorbs or adsorbs biological material from the vagina. This specimen will need to be transferred to a laboratory using transportation methods appropriate to the nature of the intended tests.

If used with any proprietary kits or test systems, reference must be made to the kit or test product insert or Instructions for Use documents to ensure that the swab is compatible, and appropriate controls should be included in the test protocol.

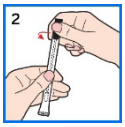
REAGENTS

N/A for this product

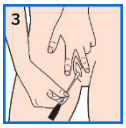
INSTRUCTIONS FOR USE



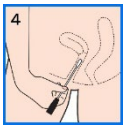
1. Thoroughly wash your hands with soap and water, then dry them.



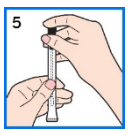
2. Twist the black cap on the tube, this will break the paper seal.



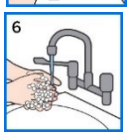
3. Remove the swab from the tube, to collect the sample, hold the swab halfway down.
   Use the other hand to open the vagina.



4. Gently insert the swab tip to about 6cm (this is approximately the length of a thumb).
   Rotate the swab for 20 seconds, touching the sides of the vagina.



5. Remove the swab from the vagina and place the swab into the tube, press the cap on tightly, place the tube into the bag provided.



6. Thoroughly wash your hands with soap and water, then dry them.

7. Return the swab back to the healthcare provider.

N.B. if the tube contains two identical barcodes, one of these can be peeled off and attached to your paperwork when returning the U-SWAB™ to be analysed.

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PRECAUTIONS

For self-sampling procedures on people over 13 years of age
NOT FOR USE on Children under the age of 13.
DO NOT USE on Disabled patients or patients requiring care.
For in vitro diagnostic use only.
All U-SWAB™ VAGINAL swabs are Single Use Devices and therefore cannot be reused.
DO NOT USE IF PACKAGE SEAL IS BROKEN.

Specific arrangements for the shipment and handling of specimens should be in full compliance with national laws. Additional regulations may apply for transport of specimens within healthcare facilities.

MATERIAL SAFETY INFORMATION

U-SWAB™ VAGINAL plastic components do not contain latex or PVC.

STORAGE

U-SWAB™ VAGINAL should be stored in a dry place at temperatures between + 5°C to 25°C away from direct sunlight.
DO NOT FREEZE.

EXPIRY DATE

3 years from date of manufacture, the expiration date is shown on the tube label and box label.

PROCESSING SPECIMENS

For specific recommendations about the processing of specimens for microorganisms and primary isolation techniques, consult national guidelines, or publications such as Cumitech (various)[1], Clinical Microbiology Procedures Handbook[2], or Manual of Clinical Microbiology[3].
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

A representative sample of bulk DRYSWAB™ swabs are taken at random from every batch and used for testing and reference.

Samples are tested to ensure that the minimal inoculant of organisms are recovered after a specified period of time. Suspensions of the following organisms are absorbed onto the swab.

Haemophilus influenzae	ATCC 10211	Aerobe
Bacteroides fragilis	NCTC 9343	Anaerobe

LIMITATIONS

Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results.

REFERENCES

1. Cumitech - Various American Society for Microbiology, Washington D.C., various dates. www.asm.org
2. Manual of Clinical Microbiology, 4 Volume Set, 13th Edition, ASM Press, ISBN: 978-1-683-67429-0
3. Clinical Microbiology Procedures Handbook, 4th Edition, ASM Press, ISBN: 978-1-683-67325-5

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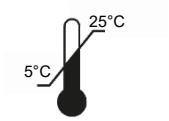
REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP

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

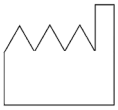
Medical Device

Method of Sterilisation Using Irradiation

Authorised Representative in the European Community


SGS Approval Mark


Use By (YYYY/MM)


Date of Manufacture

UKCA Mark

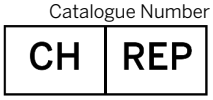
Catalogue Number

Batch Code


Consult Instructions for Use


Peel Here

Contains Sufficient for <n> Tests



Swiss Representative

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