CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
M200141	U-SWAB™ MRSA Triple – 1 Standard Plastic Foam Printed Breakpoint + 1 Blue Plastic Foam + 1 Red Plastic Foam – 12x80mm Vial – 1.5ml Liquid Amies Medium	Skin, Nasal
M200142	U-SWAB™ MRSA Double – 1 Standard Plastic Foam Printed Breakpoint + 1 Red Plastic Foam – 12x80mm Vial – 1.5ml Liquid Amies Medium	Skin, Nasal

MDD: European Medical Devices Directive 93/42/EEC

INTENDED USE

U-SWAB™ MRSA Specimen Collection and Transport System is intended to preserve the viability and infectivity of microbiological specimens after their collection and during transport from the collection site to the testing laboratory. U-SWAB™ MRSA specimens are processed using standard clinical laboratory procedures for microbiological specimens.
The U-SWAB™ MRSA is designed for self-collection patient samples for MRSA Screening.

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 of the patient's illness or for screening purposes. U-SWAB™ MRSA devices include one, two or three swabs with cellular foam, with a tube of liquid medium to maintain any microorganisms in a viable condition until they can be investigated at the laboratory. 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 publications such as Cumitech (various)[1], Clinical Microbiology Procedures Handbook[2], or Manual of Clinical Microbiology[3].

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

U-SWAB™ includes a tube of Liquid Amies Medium
Formulation
Deionised water
Sodium chloride
Potassium chloride
Magnesium chloride
Calcium chloride
Potassium di-hydrogen phosphate
Di-sodium hydrogen phosphate
Sodium thioglycollate

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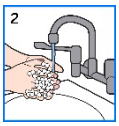
INSTRUCTIONS FOR USE

DOUBLE SWAB INSTRUCTIONS

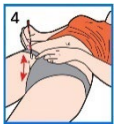
(This pack includes a vial, a red swab with no markings, and a white swab with a single black mark)

1. Clear any nasal discharge by blowing your nose.

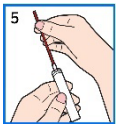


2. Thoroughly wash your hands with soap and water, then dry them.

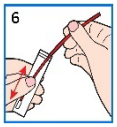
3. Open the peel pouch and remove the RED swab only from the peel pouch.



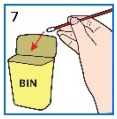
4. Take the RED swab and rub along the RIGHT groin rubbing front to back 2-3 times.
   Repeat the process with the LEFT groin rubbing from front to back 2-3 times.



5. Place the RED swab into the tube.

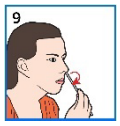


6. Rub and squeeze bud of RED swab against the inside of the tube.

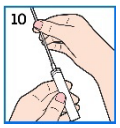


7. Remove the RED swab from the tube and discard.

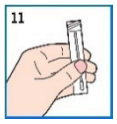
8. Remove the WHITE swab (Single mark line) from the peel pouch.
   Bring the WHITE swab to tip of nose, avoiding contact with external skin.



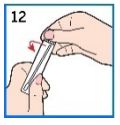
9. Insert the swab approximately 2cm into one nostril, gently rotate for 3-5 seconds.
   Repeat the process with the other nostril.



10. Place the WHITE swab fully into the tube.



11. Carefully bend the WHITE swab against the tube until it breaks. Discard non-swab end.



12. Firmly screw cap back onto the tube.

13. Thoroughly wash your hands with soap and water, then dry them.
    Fill in the required details on the tube label or supplied label and place them into the bag provided. Return the device back to the healthcare provider.

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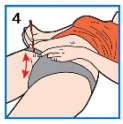
TRIPLE SWAB INSTRUCTIONS

(This pack includes a vial, a red swab with no markings, a blue swab with 2 black marks, and a white swab with a single black mark)

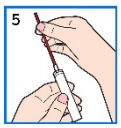
1. Clear any nasal discharge by blowing your nose.

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

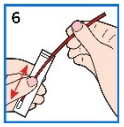
3. Open the peel pouch and remove the RED swab (no mark lines) only from the peel pouch.



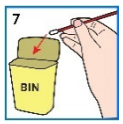
4. Take the RED swab and rub along the RIGHT groin rubbing front to back 2-3 times.
   Repeat the process with the LEFT groin rubbing from front to back 2-3 times.



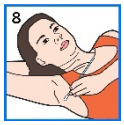
5. Place the RED swab into the tube



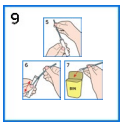
6. Rub and squeeze bud of RED swab against the inside of the tube.



7. Remove the RED swab from the tube and discard.



8. Remove the BLUE swab from the peel pouch rub over the LEFT armpit swabbing back and forth 5 times, repeat with the RIGHT armpit.

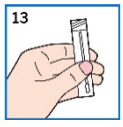


9. Repeat steps 5, 6,7 with the BLUE swab.

10 Remove the WHITE swab from the peel pouch
   Bring the WHITE swab to tip of nose, avoiding contact with external skin.

11. Insert the swab approximately 2cm into one nostril, gently rotate for 3-5 seconds.
    Repeat the process with the other nostril.

12. Place the swab fully into the tube.



13. Carefully bend the WHITE swab against the tube until it breaks. Discard non-swab end.

14. Firmly screw cap back onto the tube.

15. Thoroughly wash your hands with soap and water, then dry them.
    Fill in the required details on the tube label or supplied label and place them into the bag provided.
    Return the device back to the healthcare provider.

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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™ MRSA swabs are Single Use Devices and therefore cannot be reused.
DO NOT USE IF PACKAGE SEAL IS BROKEN.

MATERIAL SAFETY INFORMATION

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

STORAGE

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

EXPIRY DATE

2 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 (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

Recovery within specification at 4°C and 25°C tested with a selection of organisms from the following panel, in accordance with CLSI M40-A2

Pseudomonas aeruginosa	ATCC®BAA-427
Streptococcus pyogenes	ATCC®19615
Haemophilus influenzae	ATCC® 10211
Streptococcus pneumoniae	ATCC® 6305
Bacteroides fragilis	ATCC® 25285
Peptostreptococcus anaerobius	ATCC®27337
Fusobacterium nucleatum	ATCC®25586
Prevotella melaninogenica	ATCC®25845
Propionibacterium acnes	ATCC®6915
Neisseria gonorrhoeae	ATCC® 43069

LIMITATIONS

The survival of bacteria within a transport medium depends on several factors, such as storage temperature, type of bacteria, concentration of bacteria, duration of transport. U-SWAB MRSA™ will maintain many microorganisms for a period of 24-48hrs at room temperature storage. For fastidious species such as *Neisseria gonorrhoeae* 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.

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REFERENCES

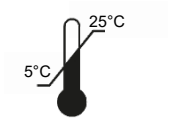
1. Cumitechs & Practical Guidance for Clinical Microbiology, https://asm.org/guideline/cumitechs-pgcms
2. Clinical Microbiology Procedures Handbook, 5th Edition, ASM Press, ISBN: 978-1-683-67483-2
3. Manual of Clinical Microbiology, 13th Edition, ASM Press, ISBN: 978-1-683-67481-8
4. CLSI Quality Control of Microbiological Transport Devices; Approved Standard – Second Edition, 2014. CLSI Document M40-A2. ISBN: 1-56238-963-7
5. UK Health Security Agency, www.gov.uk/government/collections/infectious-diseases-detailed-information
6. World Health Organisation, www.who.int
7. Centers for Disease Control and Prevention | CDC, www.cdc.gov
8. European Centre for Disease Prevention and Control, www.ecdc.europa.eu

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

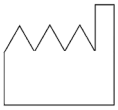
Medical Device

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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