

MRSA COLLECTION KIT

A multi-site (nose, groin and axilla) sample collection kit used for the collection and transportation of samples for laboratory analysis of methicillin-resistant Staphylococcus aureus (MRSA) by culture and nucleic acid technique (NAT)

This kit contains the materials required for either sample self-collection or collection by a health/social care professional.



For in vitro diagnostic use sample self-collection

Carefully read the

leaflet before use

enclosed instruction



KT422





Important: Do not use kit if security seal is broken Keep out of reach of children

For use by persons

aged 18 and over





- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- · Use with caution if allergic to nylon fibre.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare organisation who arranged the test.

Sample collection kit contents

Please check that the kit contains all of the items outlined below. Do not proceed with sample taking if any items are missing or damaged, contact the healthcare organisation who arranged your test for assistance.



Sample collection swab and tube x 3 STERILE R CE IVD





Transport pouch with absorbent pad



Return postal box

Return security label Sample label x 3



Wash hands using soap and water and dry them.

Take the next sample collection packet and peel it open from the top. Take out the collection tube.

GROIN SWAB SAMPLE COLLECTION



Clearly complete a sample collection tube label using a ball

- point pen with: Your First name
- Your Surname
- Your Date of birth



Take out the swab from the same packet. Hold the swab by placing thumb and forefinger in the middle of the swab shaft. Do not touch the soft swab end or let it come into contact with surfaces.

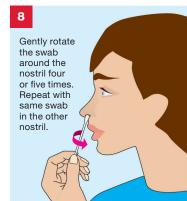


Clearly complete a sample

collection tube label using a ball point pen with:

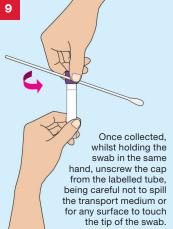
 Your First name Your Surname Your Date of birth

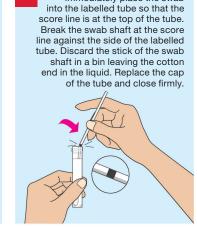
• Sample type: Nose



Affix the completed sample label to the sample collection

tube as shown below.

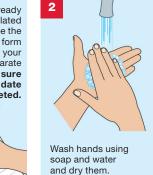


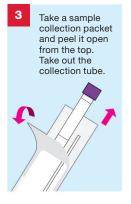


Immediately place the swab

NOSE SWAB SAMPLE COLLECTION

If not already pre-populated please complete the test request form provided by your doctor clinic, separate to this kit. **Make sure** the sample date is completed.



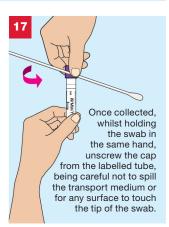








Do not touch the soft swab end or let it come into contact with surfaces. Rotate the swab gently over the skin of the groin (the fold of skin on the inside of the top of the your thighs). Repeat using the same swab on the other side of your groin.





Immediately place the swab into the labelled tube so that the score line is at the top of the tube. Break the swab shaft at the score line against the side of the labelled tube.

Discard the stick of the swab shaft in a bin leaving the cotton end in the liquid. Replace the cap of the tube and close firmly.

AXILLA SWAB SAMPLE COLLECTION



Wash hands using soap and water and dry them.

Take the next sample collection packet and peel it open from the top. Take out the collection tube.



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Clearly complete a sample collection tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- Sample type:



Affix the completed sample label to the sample collection tube as shown below.

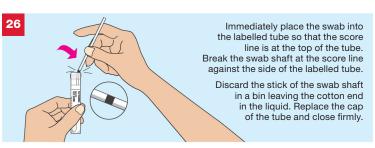


Take out the swab from the same packet. Hold the swab by placing thumb and forefinger in the middle of the swab shaft.



Do not touch the soft swab end or let it come into contact with surfaces. Rotate the swab gently over the skin of the axilla (armpit). Repeat using the same swab on the other axilla.







If you are returning the sample using Royal Mail post please follow step 28, otherwise go straight to step 29.

IMPORTANT SAMPLE TRACKING INFORMATION!

The return postal box has a postal tracking label applied. Please make a note of the unique tracking number displayed under the barcode on the postal tracking label, as shown below. Keep this in a safe place for future reference. You can track delivery of your Royal Mail parcel by entering this number using the following link: http://www.royalmail.com/track-your-item



30 CHECKLIST

Before you return the sample please do the following:

- Place the completed request form supplied by your doctor/clinic into the kit tray
- Make sure you have written your name, date of birth and the location of the swab on each swab tube
- Check that all three swab tubes are in the transport pouch and this is firmly sealed
- Place the transport pouch into the kit tray
 - Slide the kit tray back into the return postal box
- Close the return postal box and apply the return security label to seal the end of the box

Important information if returning the sample by post:

Please ensure that you have taken note of your postal tracking number. Please post the sample to The Doctors Laboratory as soon as possible (ideally on same day or within 24 hours of sample collection)



We would welcome feedback on your experience of using this self-collection kit to help us improve our services. To complete a short online survey please scan the code or visit:

https://forms.office.com/r/nriHyUX6kj

Warnings and precautions

- This kit is designed for use by persons aged 18 or over and upon request of a healthcare professional or healthcare organisation.
- Please consult with a healthcare professional for guidance on sample collection processes for adolescent and younger children.
- The kit is suitable for either health/social care professionally taken or self-collected nasal, groin and axillary sampling.
- The kit should not be used by individuals lacking the physical or mental capacity to correctly follow the self-collection instructions. If you have problems or feel unwell or lightheaded during the collection process, please pause and if necessary, consult with your advising healthcare professional.
- For persons who have had recent facial trauma, fracture or surgery (e.g. postoperative rhinoplasty or septoplasty) or who have known risk of recurrent nasal bleed this kit should be used with caution and under clinical guidance by a healthcare professional.
- For persons taking antibiotics or using antiseptic preparations which may impede the growth of MRSA, this kit should be used with caution and under the clinical guidance of a healthcare professional. As a minimum please wait 48hrs from completion of antibiotic or antiseptic medication before collecting your sample.
- The accuracy of your results may be compromised if you do not read and follow the instructions in full.
- Samples arriving at the laboratory which show evidence of the below may not be tested:
 - . No swab inside the collection tube
 - Two or more swabs inside the collection tube
 - . Swab placed upside down in the collection tube
 - Different swab type/brand to the one supplied
 - · General damage
- Samples arriving at the laboratory after 7 days of sample taking may not be tested.
- The Medical Wire Liquid Amies transport buffer contains no substances which at their given concentration, are considered to be hazardous to health. In the case of contact with eyes, skin or mouth please and rinse thoroughly with clean water, if ingested please drink plenty of water and if any symptoms occur please consult a medical professional. In the case of spillages please wipe with absorbent paper and dispose in normal household waste. For further information please refer to safety datasheets which can be found at www.mwe.co.uk
- Use with caution if allergic to nylon fibre and ABS (Acrylonitrile butadiene styrene) material. If any problems arise during the sample collection process please contact your healthcare organisation.
- This kit is not suitable for collecting alternative sample types or for the collection and transport of viruses or other microorganisms, other than those which have been verified by the testing laboratory.

Materials required but not provided

Test request form. This will be provided by your healthcare professional or healthcare organisation. Please complete the request form with your details as instructed.

Laboratory Tests

- The tests and procedures undertaken by The Doctors Laboratory Limited are verified and performed in line with supplier product instructions for use and supported by additional validation data for use with self-collection procedures.
- Test results are provided in line with clinically approved results pathways, agreed between The Doctors Laboratory Limited and the patients designated healthcare professional or healthcare organisation.

KEY TO SYMBOLS

IVD

REF

LOT

STERILE R

For in vitro diagnostic use

Batch code

Catalogue number

irradiation

Biological risk.

Distributor

Sterilized using

Biological sample, treat

as potentially infectious

package is damaged



EC REP

Use by end of year-month

Manufacturer

EU Authorised

Representative

Temperature

limits: 4°-25°C

Caution, consult

accompanying

documents

Keep away from sunlight



UK Conformity Assessed



EU Conformity



Assessed



Consult instructions





For use by persons aged 18 and over



Keep dry



REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CRO 4BD, UK Website: www.real-digital.co.uk

Distribution is restricted to regions in which the product is registered by the manufacturer.



Casus Europe BV, Lange Viestraat 2 B, 3511BK Utrecht, The Netherlands.



The Doctors Laboratory Limited

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RDI-IFU-063,	, TAP5096D/17-01-25/V10. Issue No. 3; Date 17/01/25.

Revision/Date		Change summary
1	02/2023	Initial RDi product for UK market
2	02/2024	RDi IVD product CE registration
3	01/2025	Componentry change: secondary and outer packaging.
lf o	nu corious inc	ident ecours in relation to the use of this kit, it should be reported to the manufacturar

and the competent authority of the Member State in which the user and/or the patient is established.