

# MRSA COLLECTION KIT

A multi-site (nose and groin) sample collection kit used for the collection and transportation of samples for laboratory analysis of methicillinresistant 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



KT365





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



Do not re-use

Carefully read the

leaflet before use

enclosed instruction



For use by persons aged 18 and over

#### Sample collection instructions (Steps 1–22)

- 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.



To Open Box - Tea

**Security Seal** 

Return security label

Sample collection swab and tube x 2 STERILE R CE IVD



Sample return bag containing absorbent pad



Collection kit outer box





Sample label x 2



Return postal envelope

# 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.







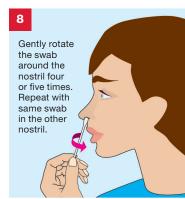
Clearly complete a sample collection tube label using a ball point pen with: Your First name

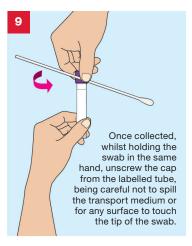
- Your Surname
- Your Date of birth
- Sample type: Nose



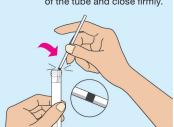
Take out the swab from the same packet. Hold the swab by placing thumb and forefinger in the middle of the swab shaft. Do not touch the soft swab end or let it come into contact with surfaces.







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





soap and water and dry them.



Take the

Clearly complete a sample collection

tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth



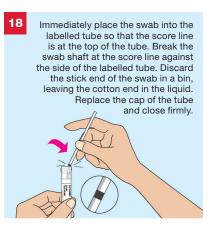
label to the sample collection tube as shown below

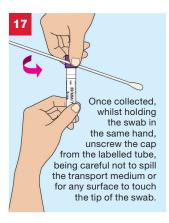
Affix the completed sample

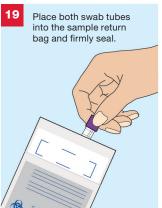
Take out the swab from the same packet. Hold the swab by placing thumb and forefinger in the middle of the swab shaft.



Do not touch the soft swab end or let it come into contact with surfaces. Rotate the swab gently over the skin of the 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.







If you are returning the sample using Royal Mail post please follow step 21, otherwise go straight to step 22.

Please make a note of the unique tracking number displayed under the barcode on the postal tracking label affixed to the front of the postal envelope, 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

Write your tracking number here for reference – keep this safe.

# 22 CHECKLIST

Before you return the sample please do the following:

- Place the completed request form supplied by your doctor/clinic into the return envelope
- Make sure you have written your name, date of birth and the location of the swab on each swab tube
- Check that both swab tubes are in the return sample bag and this is sealed
- Place the return sample bag into the collection kit outer box
- Close the collection kit outer box firmly and apply the return security label to seal it
- Place the collection kit outer box into the return postal envelope

#### 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)

You are now ready to seal the return envelope.



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 and groin 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** For in vitro UK Conformity Assessed Use by end IVD diagnostic use of year-month **EU** Conformity REF Manufacturer Catalogue number Assessed EU Authorised EC REP LOT Batch code Representative Do not re-use Sterilized using Temperature limits: 4°-25°C STERILE R Consult instructions irradiation Biological risk. Caution, consult For use by persons Biological sample, treat (18+ accompanying documents aged 18 and over as potentially infectious Do not use if Keep dry Keep away package is damaged from sunlight Distributor



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



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



#### **The Doctors Laboratory Limited**

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

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Revision/Date		Change summary
1	02/2023	Initial RDi product for UK market
2	02/2024	RDi IVD product CE registration

If any serious incident occurs in relation to the use of this kit, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.