









RESPIRATORY VIRUS SWAB SAMPLE COLLECTION KIT

An oropharyngeal and nasal swab sample collection kit used for the collection and transportation of respiratory virus samples for laboratory analysis by nucleic acid technique (NAT).

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

 IVD For <i>in vitro</i> diagnostic use, sample self-collection	 REF KT293	 CE	 UK CA
 Carefully read the enclosed instruction leaflet before use	 Important: Do not use kit if security seal is broken. Keep out of reach of children		
 Do not re-use	 For use by persons aged 18 and over		

Sample collection instructions (Steps 1–16)

- 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.

Important information if returning the sample by post

Please note that COVID-19 samples can only be posted in a Royal Mail priority post box in the UK. This is so that the sample can be handled with care and will reach the laboratory as a priority.

To find out your closest Royal Mail priority post box, please visit <https://www.royalmail.com/services-near-you/#/> or use the Royal Mail app, see <https://www.royalmail.com/downloadapp>

Please do not use any other Royal Mail post box as the sample may not reach the laboratory in time to process.

If you need assistance please contact The Doctors Laboratory on 020 7307 7373 or email samples@tdlpathology.com

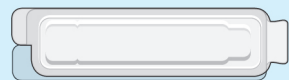
Sample collection kit contents

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 containing 2mL Virocult transport medium

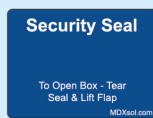
STERILE 



Protective packing wallet



Sample label



Return security label




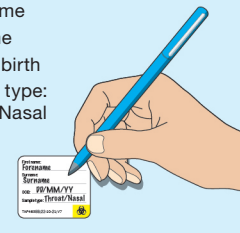
Return postal envelope



Collection kit outer box

Note: The colour of the sample collection tube lid may differ from what is shown, this does not affect the performance of the test.

SWAB SAMPLE COLLECTION

<p>1 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.</p> 	<p>2 Clearly complete the swab collection tube label using a ball point pen with:</p> <ul style="list-style-type: none"> • First name • Surname • Date of birth • Sample type: Throat/Nasal 
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3 If you are returning the sample using Royal Mail post please follow step 4, otherwise go straight to step 5.

4 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.

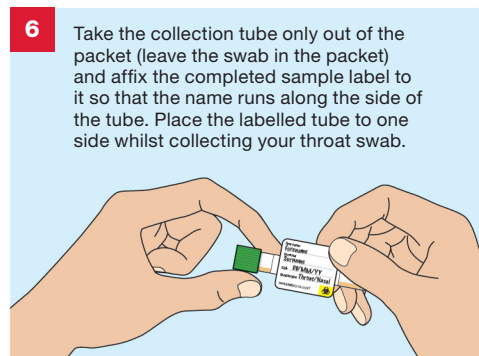


You can track delivery of your Royal Mail parcel by entering this number using the following link: <http://www.royalmail.com/track-your-item>

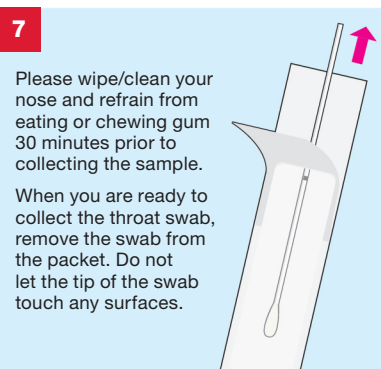
Write your tracking number here for reference – keep this safe.



Wash hands using soap and water and dry them.

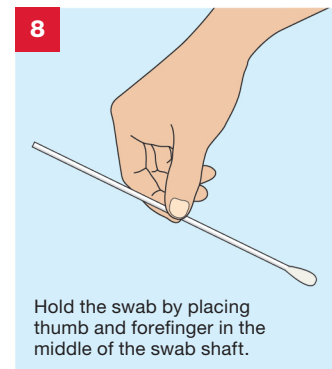


Take the collection tube only out of the packet (leave the swab in the packet) and affix the completed sample label to it so that the name runs along the side of the tube. Place the labelled tube to one side whilst collecting your throat swab.



Please wipe/clean your nose and refrain from eating or chewing gum 30 minutes prior to collecting the sample.

When you are ready to collect the throat swab, remove the swab from the packet. Do not let the tip of the swab touch any surfaces.

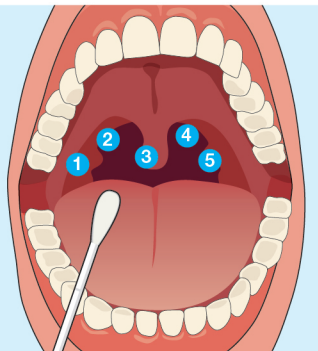


Hold the swab by placing thumb and forefinger in the middle of the swab shaft.

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Carefully insert the swab into the mouth ensuring contact with the 5 key areas:

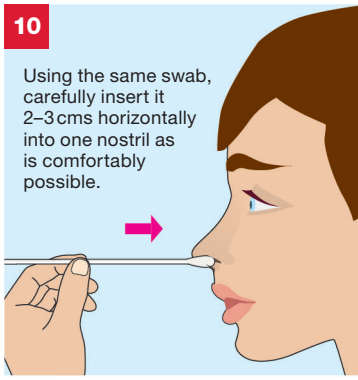
- 1 Tonsil
- 2 Posterior wall
- 3 Uvula
- 4 Posterior wall
- 5 Tonsil



Please do not let the end of the swab touch other areas of the mouth.

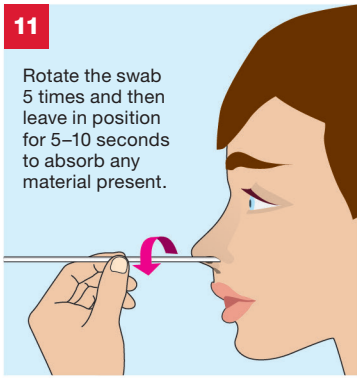
10

Using the same swab, carefully insert it 2–3cms horizontally into one nostril as is comfortably possible.

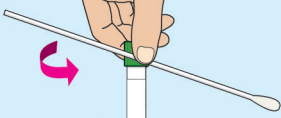


11

Rotate the swab 5 times and then leave in position for 5–10 seconds to absorb any material present.



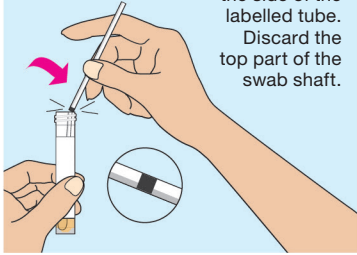
12



Once collected, whilst holding the swab in the same hand, unscrew the cap from the labelled tube, being careful not to spill the saline or for any surface to touch the tip of the swab.

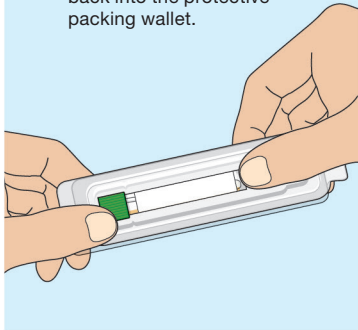
13

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 top part of the swab shaft.



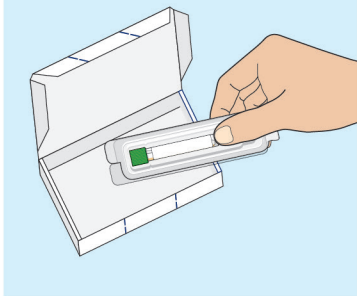
14

Screw the cap back on tightly and place the tube securely back into the protective packing wallet.



15

Place the protective packing wallet into the collection kit outer box.



16 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 the tube is labelled, is securely placed inside the protective packing wallet and is placed inside 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/3eyFWJ3LF2>

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 oropharyngeal and nasal 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 please 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.
- 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:
 - Leaking sample/no liquid present in collection tube
 - No swab inside the collection tube
 - Two or more swabs inside the collection tube
 - Swab placed upside down in the collection tube
 - More than 1 collection tube per return box
 - 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 sample collection swab has a score line, which after sampling helps the swab break at the correct position when pressure is applied to allow it to fit in the collection tube. If this score line is broken, appears damaged or the swab arrives in two broken parts, do not use and request another kit from your healthcare organisation.
- 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.
- Please refrain from eating or chewing gum 30 minutes prior to collecting your sample.
- This kit is not suitable for Nasopharyngeal sampling or for the collection and transport of bacteria or other microorganisms, other than those which have been validated by the testing laboratory.
- If the Virocult transport medium is spilled at any time during the collection please request a new kit from your healthcare organisation.
- The Medical Wire Virocult liquid 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





















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	For in vitro diagnostic use		Use by end of year-month	 UK CA	UK Conformity Assessed
 REF	Catalogue number		Manufacturer	 CE	EU Conformity Assessed
 LOT	Batch code	 EC REP	EU Authorised Representative		Do not re-use
 STERILE R	Sterilized using irradiation		Temperature limits: 5°–25°C		Not made with natural rubber latex
	Biological risk. Biological sample, treat as potentially infectious		Caution, consult accompanying documents		Consult instructions for use
	Do not use if package is damaged		Keep away from sunlight		For use by persons aged 18 and over
	Distributor		Keep dry		

 REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CR0 4BD, UK
Website: www.real-digital.co.uk

 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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RDI-IFU-015, TAP4869E/13-03-24/V25. Issue No. 2; Date 12/03/24.

Revision/Date	Change summary
1 02/2023	Initial RDi product for UK market
2 07/2023	Changed components (swab and tube)
3 03/2024	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.

