

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.



For in vitro diagnostic use. sample self-collection



KT293





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 1–15)

- 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.
- . For alternative language versions of these kit instructions please visit www.tdlpathology.com

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.

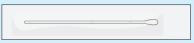
To find out your closest Royal Mail priority post box, please visit https://www.royalmail.com/services-near-you#/ or use the Royal Mail app, see https://www.royalmail.com/downloadapp

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, contact the healthcare organisation who arranged your test for assistance.



Sample collection swab STERILE EO CE



saline solution



Sample label



Return security label

Protective packing case



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

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

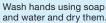
- Clearly complete the swab collection tube label using a ball point pen with: • First name Surname Date of birth Sample type: Throat/Nasal
- If you are returning the sample using Royal Mail post please follow step 4, otherwise go straight to step 5.
- Please make a note of the unique tracking number 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.



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.





Take the completed sample label and affix it to the collection tube (containing saline) 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.

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



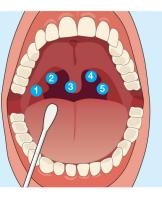


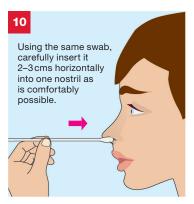
thumb and forefinger in the middle of the swab shaft.

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

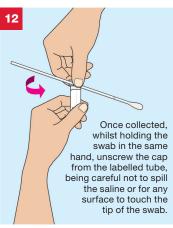
- Tonsil
- 2 Posterior wall
- 3 Uvula
- 4 Posterior wall
- 5 Tonsil

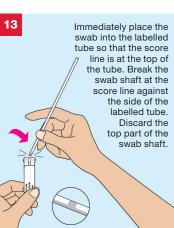
Please do not let the end of the swab touch other areas of the mouth.













15 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 case 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



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

The Doctors Laboratory Limited

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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
- 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 saline appears cloudy or is spilled at any time during the collection please request a new kit from your healthcare organisation.

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 diagnostic use



Use by end of year-month Manufacturer



UK Conformity Assessed EU Conformity

Assessed

Do not re-use

Not made with



STERILE EO

(

Batch code

Biological risk. Biological sample,

Do not use if

treat as potentially

package is damaged

Sterilized using

ethylene oxide



Temperature limits: 4°-25°C



Caution, consult



accompanying documents





Consult instructions

natural rubber latex







For use by persons aged 18 and over