THE DOCTORS LABORATORY

SEXUAL HEALTH COLLECTION KIT

An extra-genital (throat and rectal) swab sample collection kit used for the collection and transportation of samples for laboratory analysis of sexually transmitted infections 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 *in vitro* diagnostic use, sample self-collection

REF KT359 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

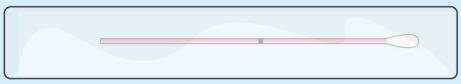
18+ For use by persons aged 18 and over

Sample collection instructions (Steps 1–19)

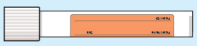
- **Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.**
- **If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the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

Your sample collection kit contents

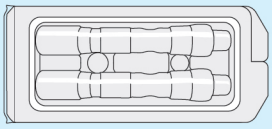
Please check that the kit contains all of the items outlined below.
Do not proceed with sample taking if any items are missing or damaged, contact the healthcare organisation who arranged your test for assistance.



Sample collection swab (x2), CE STERILE EO



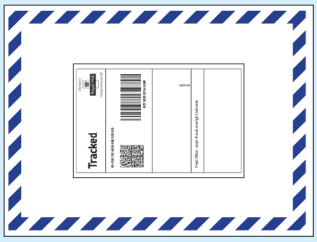
Swab specimen transport tube (x2), IVD



Protective packing case

Sample label (x2)

Return security label



Return postal envelope

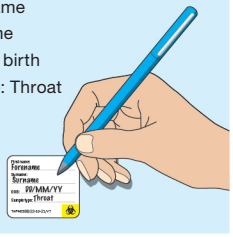
Collection kit outer box

THROAT SWAB SAMPLE COLLECTION

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.**

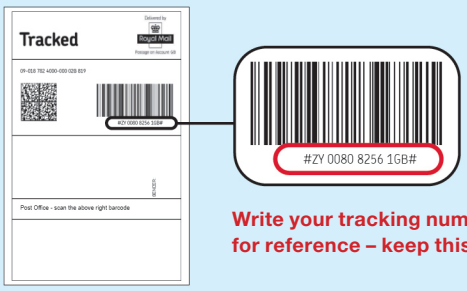
2 Clearly complete a sample collection tube label using a ball point pen with:

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



3 **IMPORTANT SAMPLE TRACKING INFORMATION!**

The enclosed postal envelope 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

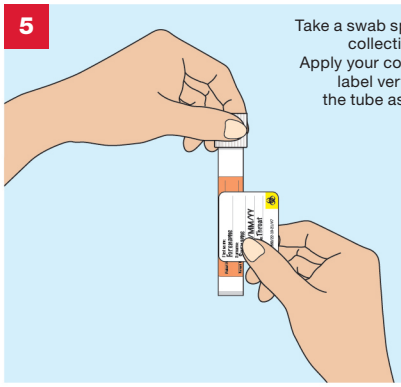


Write your tracking number here for reference – keep this safe.

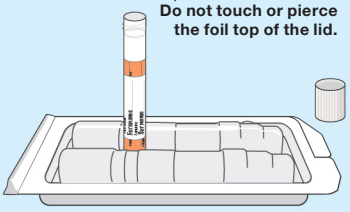
4

Wash hands using soap and water and dry them.

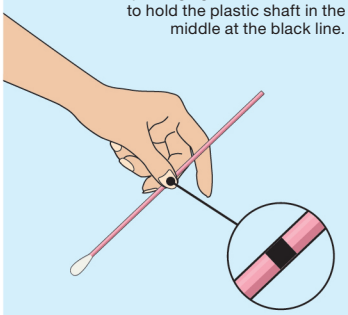
5 Take a swab specimen collection tube. Apply your completed label vertically to the tube as shown.



6 The sample collection tube case has been designed to provide a stable way of holding the swab collection tube whilst a sample is taken. Please insert the tube as shown, remove the cap and put it to one side whilst you take your sample. Take care not to spill any of the liquid the tube contains. **Do not touch or pierce the foil top of the lid.**



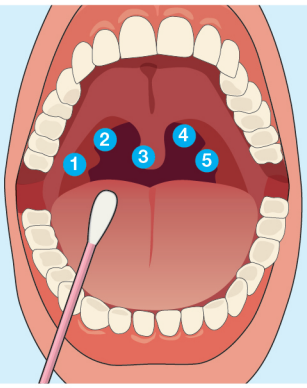
7 Take the swab out of its packaging and use one hand to hold the plastic shaft in the middle at the black line.



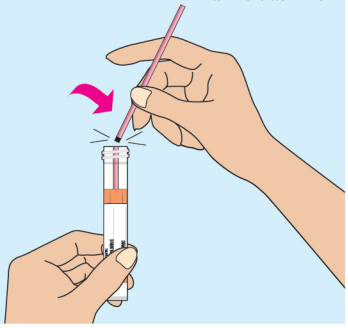
8 Carefully insert the swab into the mouth ensuring contact with the 5 key areas:

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

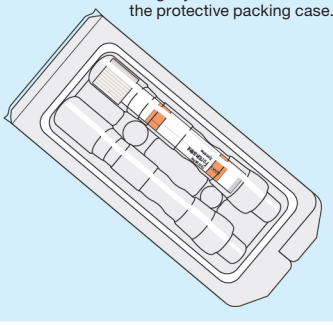
Please do not let the end of the swab touch other areas of the mouth.



9 Carefully put the swab into the collection tube. Holding the tube steady, snap the stick off at the black line.



10 Discard the stick end of the swab in a bin, leaving the cotton end in the liquid. Screw the cap back onto the tube tightly. Place the tube into the protective packing case.

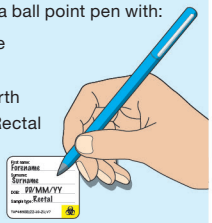


RECTAL SWAB SAMPLE COLLECTION

11

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

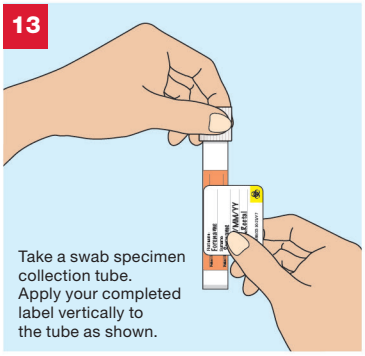
- Your First name
- Your Surname
- Your Date of birth
- Sample type: Rectal



12

Wash hands using soap and water and dry them.

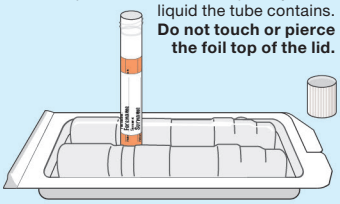
13



Take a swab specimen collection tube. Apply your completed label vertically to the tube as shown.

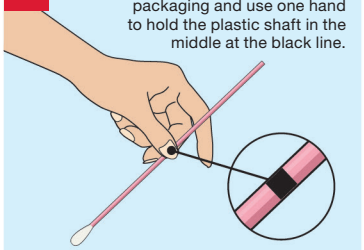
14

The sample collection tube case has been designed to provide a stable way of holding the swab collection tube whilst a sample is taken. Please insert the tube as shown, remove the cap and put it to one side whilst you take your sample. Take care not to spill any of the liquid the tube contains. **Do not touch or pierce the foil top of the lid.**

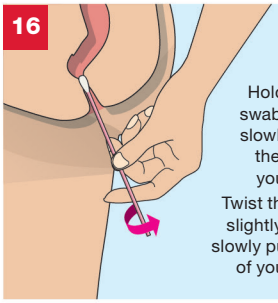


15

Take the swab out of its packaging and use one hand to hold the plastic shaft in the middle at the black line.

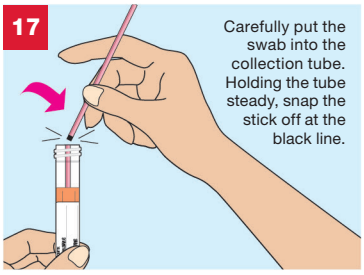


16



Holding the swab tightly, slowly insert the tip into your anus. Twist the swab slightly as you slowly pull it out of your anus.

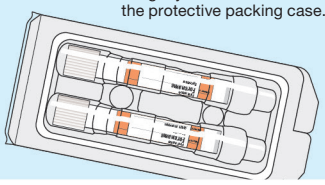
17



Carefully put the swab into the collection tube. Holding the tube steady, snap the stick off at the black line.

18

Discard the stick end of the swab in a bin, leaving the cotton end in the liquid. Screw the cap back onto the tube tightly. Place the tube into the protective packing case.



19 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- ☐ **Place your completed request form supplied by your doctor/clinic into the postal envelope**
- ☐ **Make sure each swab specimen transport tube is labelled and is placed inside the protective packing case**
- ☐ **Place the packing case 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**
- ☐ **Check that you have taken note of your postal tracking number**

You are now ready to seal the postal envelope.
Please store at room temperature until posted.

Please post your sample to **The Doctors Laboratory** as soon as possible (ideally on same day or within 24 hours of sample collection) from **ANY** Royal Mail post box in the UK. No stamp is required within the UK.

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

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/SWWruqwKda

Warnings and precautions

- This kit is designed for use by persons aged 18 and 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 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.
- The Hologic 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.hologic.com or contact MolecularSupport@hologic.com.
- 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
  - Different swab type/brand to the one supplied
  - General damage
- 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.
- 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 signs of degradation or general damage or arrive after 60 days (Aptima swab) of sample taking may not be tested.

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

REF — Catalogue number

LOT — Batch code

STERILE EO — Sterilized using ethylene oxide

Biological risk. Biological sample, treat as potentially infectious

Do not use if package is damaged

Distributor

Use by end of year-month

25° / 4° — Temperature limits: 4°–25°C

Caution, consult accompanying documents

Keep away from sunlight

Manufacturer

EC REP — EU Authorised Representative

UK CA — UK Conformity Assessed

CE — EU Conformity Assessed

Do not re-use

Consult instructions for use

18+ — For use by persons aged 18 and over

Keep dry

REAL Digital International Limited**,** 2 Queensway, Croydon, Surrey, CR0 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.

RDI-IFU-033, TAP4949C/05-02-24/V20. Issue No. 2; Date 05/02/24.

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.