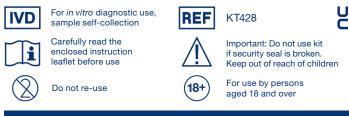


SEXUAL HEALTH COLLECTION KIT

A vaginal and 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.

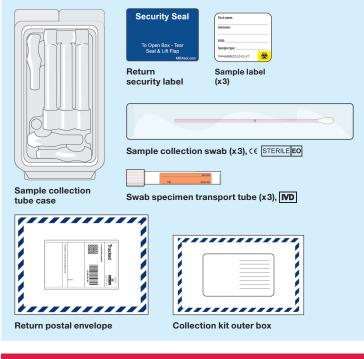


Sample collection instructions (Steps 1–29)

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

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



THROAT 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.

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

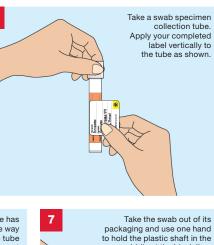
IMPORTANT SAMPLE TRACKING INFORMATION!

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



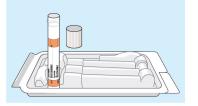


Wash hands using soap and water and dry them.



middle at the black line.

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.

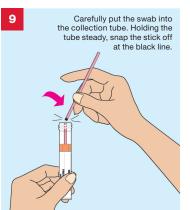


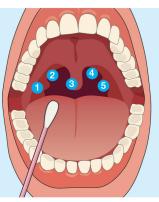
8

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

- 1 Tonsil
- 2 Posterior wall3 Uvula
- 4 Posterior wall
- 5 Tonsil

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

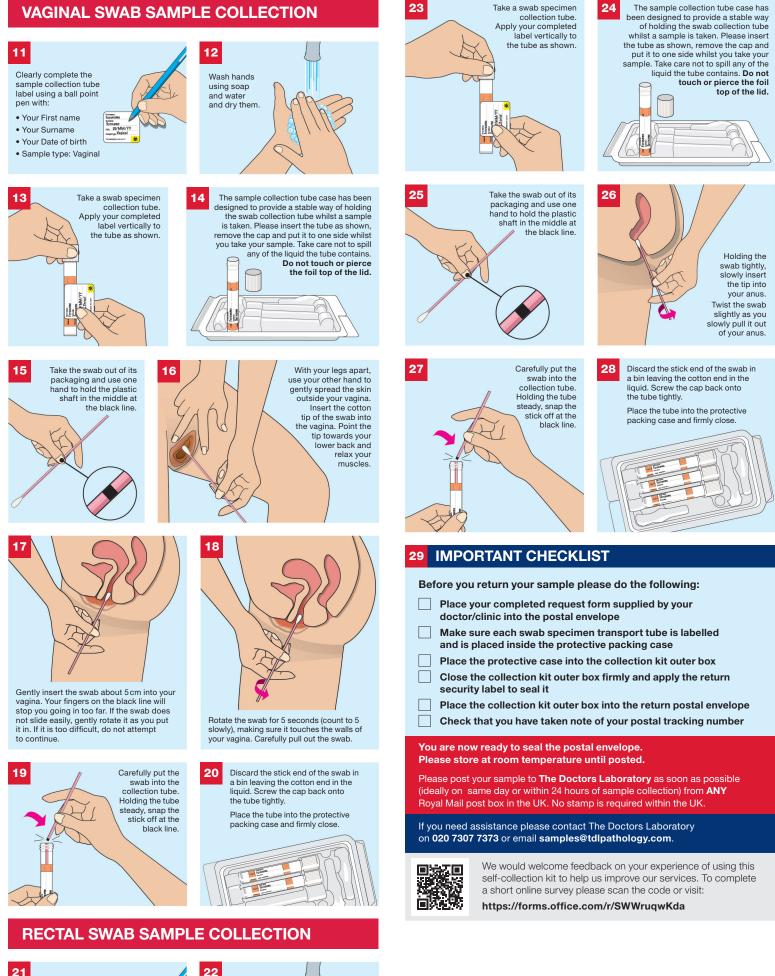




10 Discard the stick end of the swab in a bin leaving the cotton end in the liquid. Screw the cap back onto the tube tightly.

Place the tube into the protective packing case and firmly close.





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

Wash hands

using soap

and dry them.

and water

 Your First name Your Surname

- Your Date of birth
- Sample type: Rectal

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.
- If you have experienced recent pelvic pain, pain during or as a result of sexual intercourse and/or unusual vaginal discharge or odor please discuss this with your healthcare professional before collecting your sample.
- 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.
- Please note that some medicines or medicinal products may be considered interfering substances for certain biochemical or immunoassay investigations. Please consider the potential impact of interfering substances when interpreting results.
- Where appropriate, out of range, abnormal or positive test results deemed clinically significant should be confirmed with a confirmatory venous sample.

Materials required but not provided

Test request form

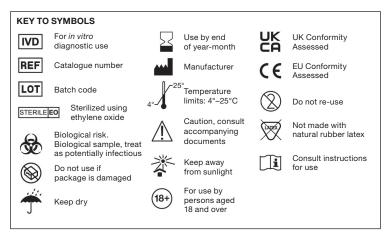
This will be provided by your healthcare professional or healthcare organisation. Please complete the request form with your details as instructed.

None EXAMPLE

Clean tissue paper

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.





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The Doctors Laboratory Limited

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