

SEXUAL HEALTH COLLECTION KIT

A vaginal 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.



For in vitro diagnostic use, sample self-collection



KT357





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 1-14)

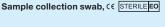
- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare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



Swab specimen transport tube,







Protective packing wallet



Sample label

Return security label

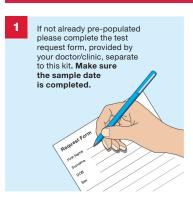




Return postal envelope

Collection kit outer box

VAGINAL SWAB SAMPLE COLLECTION



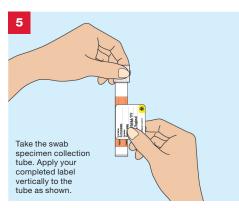
Clearly complete the sample collection tube label using a ball point pen with:

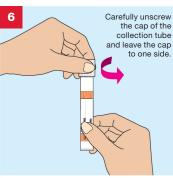
- Your First name
- Your Surname
- Your Date of birth

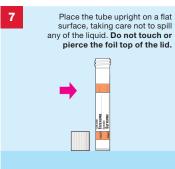


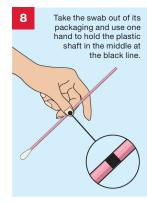








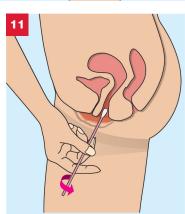




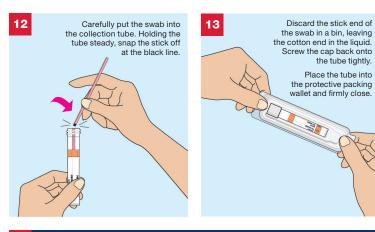




Gently insert the swab about 5 cm into your vagina. Your fingers on the black line will stop you going in too far. If the swab does not slide easily, gently rotate it as you put it in. If it is too difficult, do not attempt



Rotate the swab for 5 seconds (count to 5 slowly), making sure it touches the walls of your vagina. Carefully pull out the swab.



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 the swab specimen transport tube is labelled and is placed inside the protective packing wallet
 - Place the protective packing wallet 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

KEY TO SYMBOLS

IVD

diagnostic use





Catalogue number



Batch code



Sterilized using ethylene oxide Biological risk



Biological sample, treat as potentially infectious



Do not use if package is damaged

Website: www.real-digital.co.uk



Use by end



of year-month



Temperature limits: 4°-25°C



Caution, consult



accompanying



documents



Keep away from sunlight



Keep dry





Manufacturer



UK Conformity



EU Conformity



Assessed





Do not re-use



Consult instructions for use



For use by persons aged . 18 and over



REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CRO 4BD, UK

The Doctors Laboratory Limited

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

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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
 - . More than 1 collection tube per return box
 - · 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.