

## VAGINITIS COLLECTION KIT

**A vaginal swab sample collection kit used for the collection and transportation of samples for laboratory analysis of genital infections by culture and 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** KT441



**i** 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

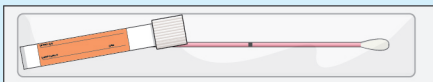
**18+** For use by persons aged 18 and over

### Sample collection instructions (Steps 1–25)

- 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.

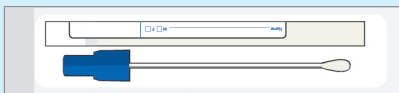
### Your sample collection kit contents

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.



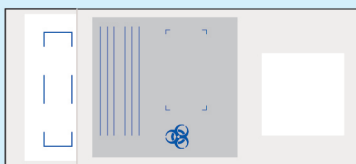
**PCR sample collection swab and tube**

STERILE **EO** **IVD** **CE**



**Culture sample collection swab**

STERILE **R** **CE**



**Sample return bag containing absorbent pad**



**Collection kit outer box**

#### Security Seal

To Open Box - Tear Seal & Lift Flap  
MDXtest.com

#### Return security label

First name: \_\_\_\_\_  
Surname: \_\_\_\_\_  
DOB: \_\_\_\_\_  
Sample type: \_\_\_\_\_  
TAN6888823-10-ELV7 

#### Sample label x 2



**Return postal envelope**

## VAGINAL CULTURE 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** Wash hands using soap and water and dry them.



**3** Clearly complete both sample collection tube labels using a ball point pen with:

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



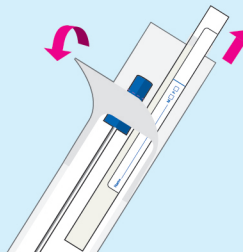
### 4 IMPORTANT SAMPLE TRACKING INFORMATION!

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.**

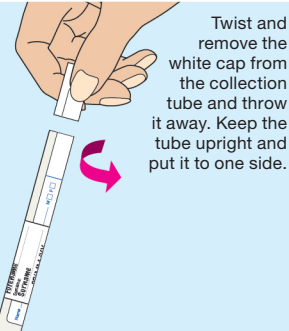
**5** Take the culture swab packet and peel it open from the top. Take out the collection tube.



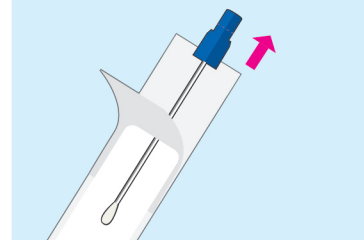
**6** Apply the completed label along the length of the collection tube as shown.



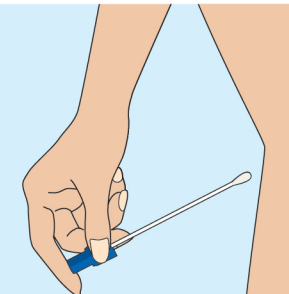
**7** Twist and remove the white cap from the collection tube and throw it away. Keep the tube upright and put it to one side.



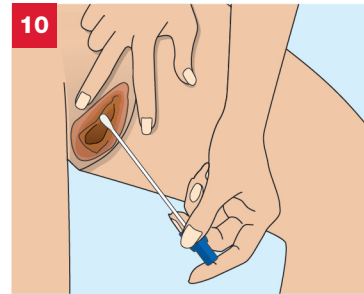
**8** Take out the blue topped swab. Do not touch the soft swab end or let it come into contact with surfaces.



**9** Hold the swab by the cap with one hand so the swab tip is pointing towards you.

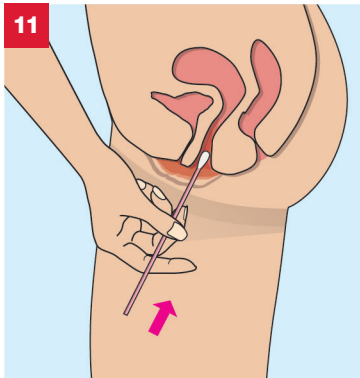


**10** With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vagina opening. Point the tip towards your lower back and relax your muscles.

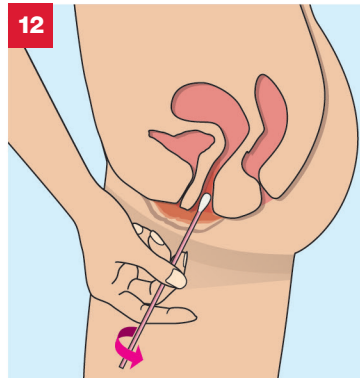


Hold the swab by the cap with one hand so the swab tip is pointing towards you.

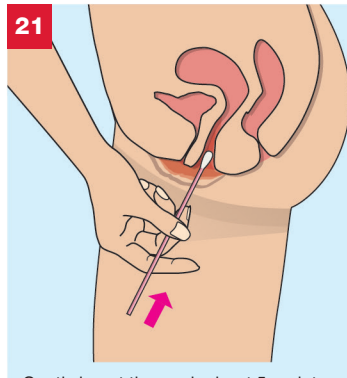
With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vagina opening. Point the tip towards your lower back and relax your muscles.



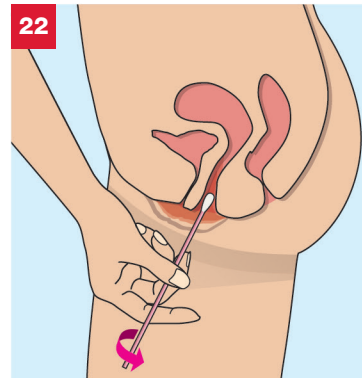
**11** Gently slide the swab **no more than 2-4 cm** into the vagina. If the swab does not slide easily, gently rotate it as you push. **If it is too difficult, do not attempt to continue.**



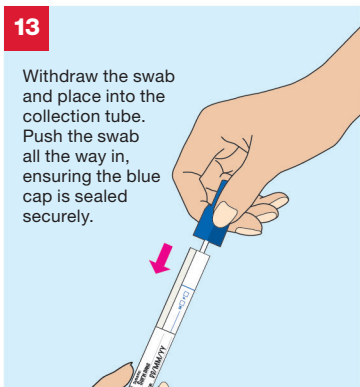
**12** Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Rotate the swab for 10-15 seconds.



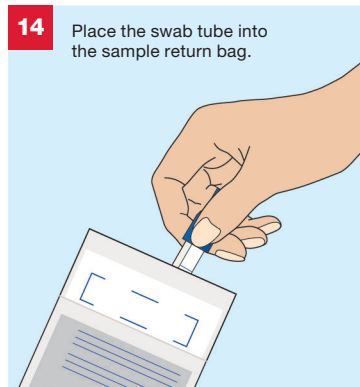
**21** Gently insert the swab about 5cm into your vagina. Your fingers on the black line will stop you going in too far. If the swab does not slide easily, gently rotate it as you put it in. If it is too difficult, do not attempt to continue.



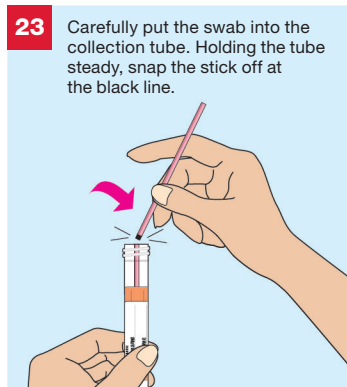
**22** Rotate the swab for 5 seconds (count to 5 slowly), making sure it touches the walls of your vagina. Carefully pull out the swab.



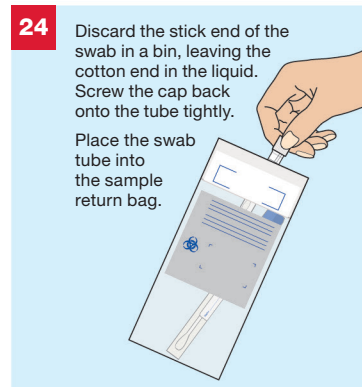
**13** Withdraw the swab and place into the collection tube. Push the swab all the way in, ensuring the blue cap is sealed securely.



**14** Place the swab tube into the sample return bag.



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

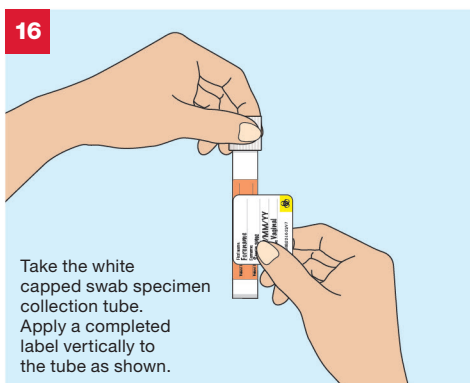


**24** Discard the stick end of the swab in a bin, leaving the cotton end in the liquid. Screw the cap back onto the tube tightly. Place the swab tube into the sample return bag.

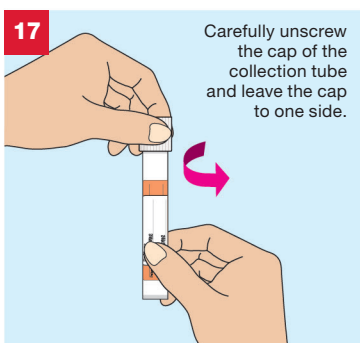
## VAGINAL PCR SAMPLE COLLECTION



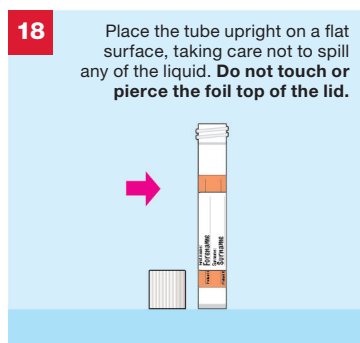
**15** Wash hands using soap and water and dry them.



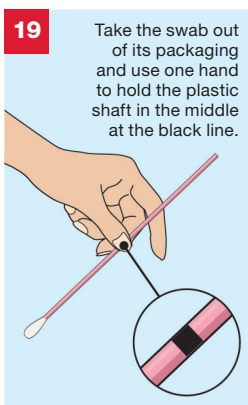
**16** Take the white capped swab specimen collection tube. Apply a completed label vertically to the tube as shown.



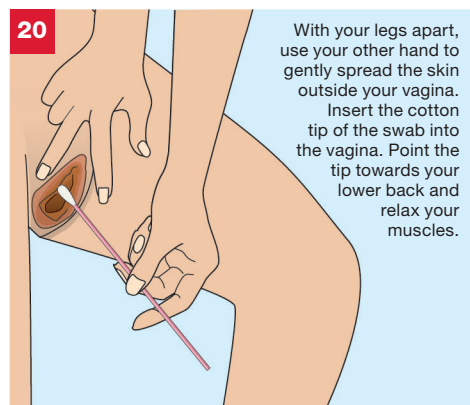
**17** Carefully unscrew the cap of the collection tube and leave the cap to one side.



**18** Place the tube upright on a flat surface, taking care not to spill any of the liquid. **Do not touch or pierce the foil top of the lid.**



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



**20** With your legs apart, use your other hand to gently spread the skin outside your vagina. Insert the cotton tip of the swab into the vagina. Point the tip towards your lower back and relax your muscles.

## 25 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 both swab specimen tubes are labelled and are placed inside the return sample bag and this is sealed
- Place the return sample bag 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](mailto: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 is suitable for either health/social care professionally taken or self-collected lower vaginal swab (LVS) sampling only. If a high vaginal swab (HVS) sample is required, this should be taken by a healthcare professional in clinic, under clean conditions.
- 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.
- For persons taking antibiotics, antifungals or using antiseptic preparations which may impede bacterial or fungal growth, this kit should be used with caution and under the clinical guidance of a healthcare professional. As a minimum, please wait 48 hours from completion of antibiotic or antiseptic medication before collecting your sample.
- 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 Aptima and Medical Wire Gel 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](http://www.hologic.com) or contact [MolecularSupport@hologic.com](mailto:MolecularSupport@hologic.com) or at [www.mwe.co.uk](http://www.mwe.co.uk)
- 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 Hologic Aptima 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 after 7 days of sample taking may not be tested.
- 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 <i>in vitro</i> diagnostic use		Manufacturer	 UKCA	UK Conformity Assessed
 REF	Catalogue number	 EC REP	EU Authorised Representative	 CE	EU Conformity Assessed
 LOT	Batch code		Temperature limits: 4°–25°C		Use by end of year-month
 STERILE EO	Sterilized using ethylene oxide		Caution, consult accompanying documents		Do not re-use
	Biological risk. Biological sample, treat as potentially infectious		Keep away from sunlight		Consult instructions for use
	Do not use if package is damaged		Keep dry		For use by persons aged 18 and over
	Distributor				

 REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CR0 4BD, UK  
Website: [www.real-digital.co.uk](http://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-084, TAP5257B/05-02-24/V9. Issue No. 2; Date 05/02/24.

## Revision/Date Change summary

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.

