THE DOCTORS LABORATORY

SEXUAL HEALTH COLLECTION KIT

A capillary blood and vaginal swab sample collection kit used for the collection and transportation of samples for laboratory analysis of serum based parameters and 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 KT358 CE UKCA

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 1–27)

- **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.**

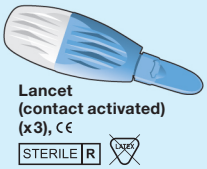
Your sample collection kit contents

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.

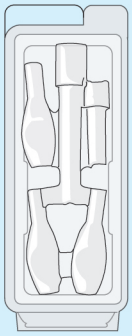
Blood collection tube (microtainer), CE

Plaster (x2), CE STERILE EO

Moist wipe (x2), CE STERILE R



Lancet (contact activated) (x3), CE STERILE R

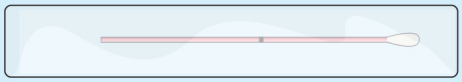


Sample collection tube case
Please note your kit contains one blood collection tube only

Sample label (x2)

Alcohol swab (x2), CE

Return security label



Sample collection swab, CE STERILE EO

Swab specimen transport tube, IVD

Return postal envelope

Collection kit outer box

IMPORTANT!
The sample collection tube case has been designed to provide a stable way of holding a sample collection tube whilst a sample is taken.

Please insert the sample tubes as shown in the following instruction steps whilst you take your sample.

Do not mix up tube caps, only replace them back on to the tube(s) they came from.

IMPORTANT!
The BLUE lancet activates on contact when positioned and pressed against the skin. Lancets are for single use only.

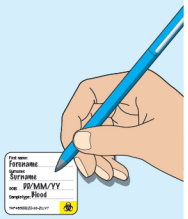
BLOOD SAMPLE COLLECTION

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 the blood collection tube label using a ball point pen with:

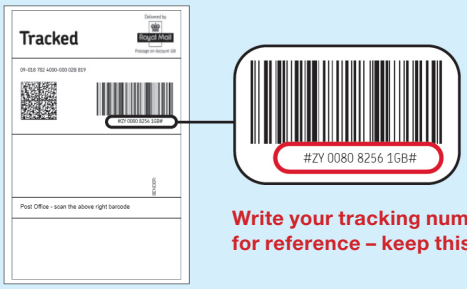
- Your First name
- Your Surname
- Your Date of birth
- Sample type: Blood

Do not affix it to the tube at this stage.



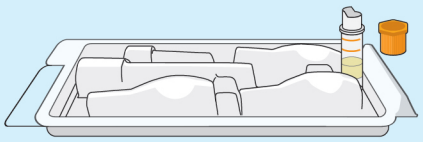
3 **IMPORTANT SAMPLE TRACKING INFORMATION!**

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 Take the blood collection tube out of the case and insert the tube as shown. Remove the cap and put it to one side whilst you take your sample.



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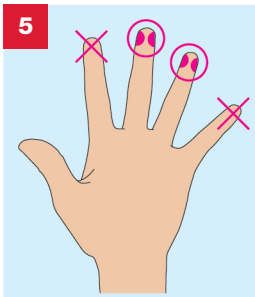

The best location for collecting a finger prick sample is from the side of your middle or ring finger (see shaded area). Open the pack of lancets.

6

Wash your hands in warm soapy water. **It is much easier to collect your sample if your hands are warm.** Dry them thoroughly with a clean, dry towel.

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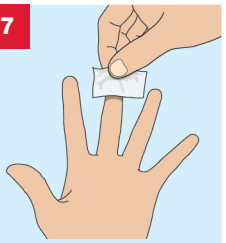
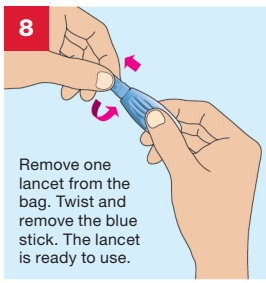


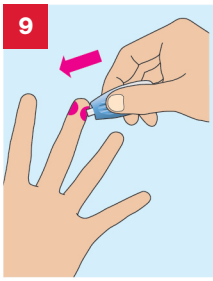
Using the Alcohol Swab clean the selected finger. Wipe dry with a clean tissue. **Be sure your finger is completely dry as blood will not form a drop at the puncture site of a moist finger.**

8



Remove one lancet from the bag. Twist and remove the blue stick. The lancet is ready to use.

9



Position the lancet against the side of your chosen finger. The lancet will activate in one step only when positioned and pressed FIRMLY against the skin until a click is heard. Should you need to repeat the process to help obtain enough blood use one of the remaining lancets.

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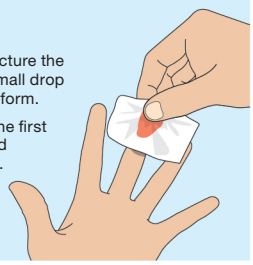

This will puncture the skin and a small drop of blood will form.

Wipe away the first drop of blood with a tissue.

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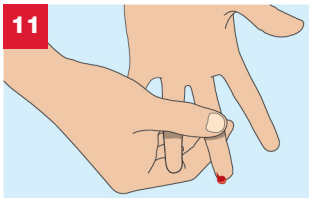
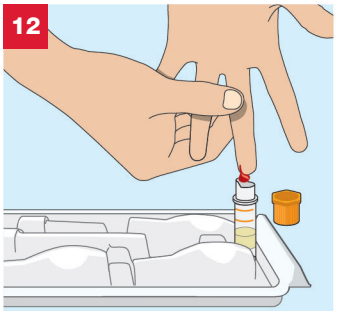


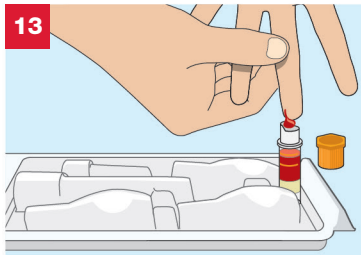
Holding your hand/arm downwards, firmly massage your hand down to your finger, without squeezing, to encourage blood flow.

12



Firmly massage your hand and finger, without squeezing, to help the blood drop into the blood collection tube as shown.

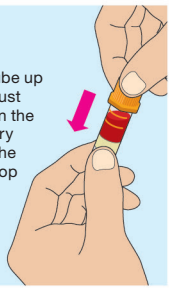
13



Fill the blood collection tube to the upper line on the side of the tube. NB: If you are unable to collect enough blood use the second lancet on a middle or ring finger on the other hand. Alternatively, try wiping the finger you have been using with a dry tissue. Pause for 5-10 seconds and blood drops are likely to reform, and you can then start collecting again.

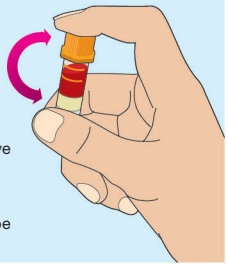
14

Once you have filled the tube up to the top fill line, or even just over, stop collecting. Clean the finger with a moist wipe, dry it with a tissue and apply the supplied spot plaster to stop the bleeding. Then push on the cap of the blood collection tube securely until you hear an audible click to confirm closure.



15

Once you have replaced the cap, gently invert the collection tube 5 to 10 times.

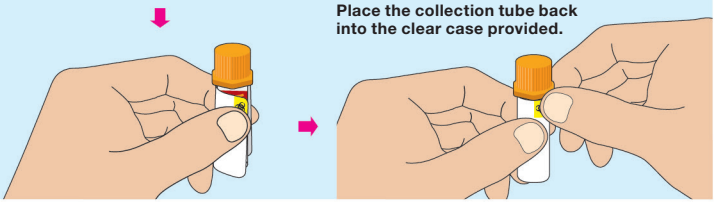


16

Make sure your tube is labelled with your details using the blood collection tube label supplied. **This is very important as unlabelled samples cannot be accepted.**

Affix the label by placing the tube in the middle of the label and wrapping the label around the tube, as shown below.

Place the collection tube back into the clear case provided.

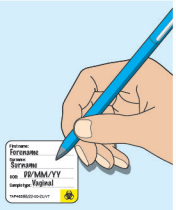


VAGINAL SWAB SAMPLE COLLECTION

17

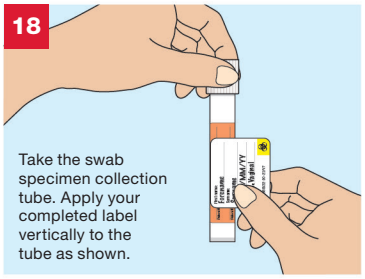
Clearly complete the sample collection tube label using a ball point pen with:

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



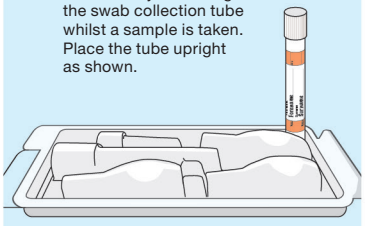
18

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



19

The sample collection tube case has been designed to provide a stable way of holding the swab collection tube whilst a sample is taken. Place the tube upright as shown.



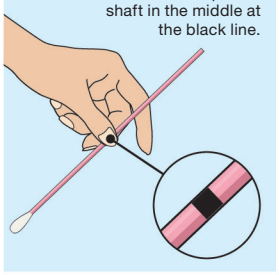
20

Carefully unscrew the top, taking care not to spill any of the liquid.

Place the top to one side while you take your sample. **Do not touch or pierce the foil top of the lid.**

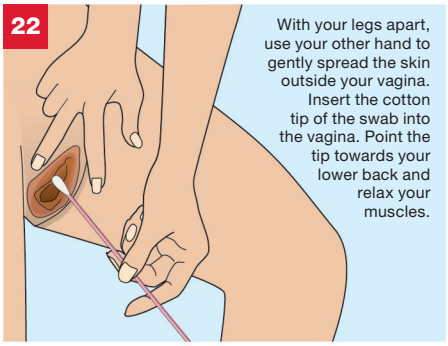
21

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



22

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.



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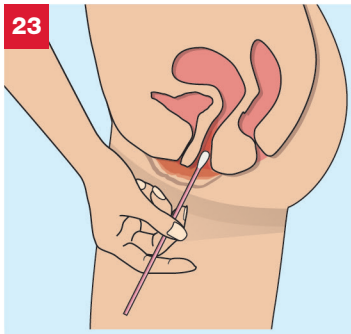
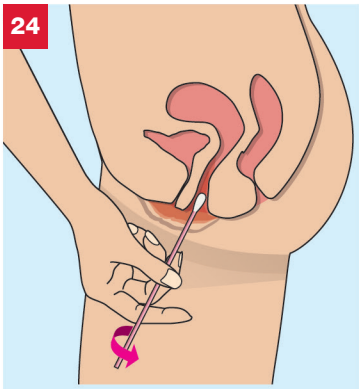


Gently insert the swab about 5 cm into your vagina. Your fingers on the black line will stop you going in too far. If the swab does not slide easily, gently rotate it as you put it in. If it is too difficult, do not attempt to continue.

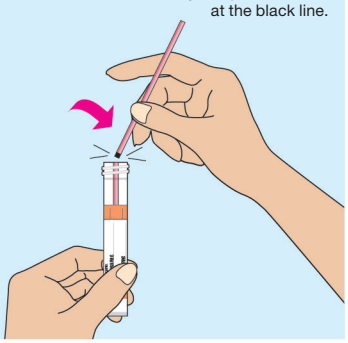
24



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

25

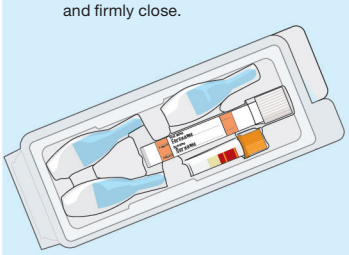
Carefully put the swab into the collection tube. Holding the tube steady, snap the stick off at the black line.



26

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.

Place all lancets into the case and firmly close.



27 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 blood collection tube is labelled**
- ☐ **Make sure the blood collection tube and any used and/or spare lancets are placed into the protective packing case**
- ☐ **Make sure the swab specimen transport tube is labelled and is placed inside the protective packing case**
- ☐ **Place the protective 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.
- For persons with bleeding or clotting disorders, those taking anti-coagulants, immunosuppressive drugs or undergoing chemotherapy this kit should be used with caution and under the clinical guidance of a healthcare professional.
- Do not affix the label to the blood collection tube until after you have collected your sample. You will not be able to see how much blood you have collected if the label covers the tube.
- 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 haemolysis, degradation or general damage or arrive after 6 days (capillary blood) and 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.**
- **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.

KEY TO SYMBOLS

IVD — For *in vitro* diagnostic use	Use by end of year-month	UK CA — UK Conformity Assessed
REF — Catalogue number	Manufacturer	CE — EU Conformity Assessed
LOT — Batch code	EC REP — EU Authorised Representative	Do not re-use
STERILE R — Sterilized using irradiation	4°–25° — Temperature limits: 4°–25°C	LATEX — Not made with natural rubber latex
STERILE EO — Sterilized using ethylene oxide	Caution, consult accompanying documents	Consult instructions for use
Biological risk. Biological sample, treat as potentially infectious	Keep away from sunlight	18+ — For use by persons aged 18 and over
Do not use if package is damaged	Distributor	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-030, TAP4948C/21-02-24/V21. Issue No. 2; Date 21/02/24.

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.