THE DOCTORS LABORATORY

SEXUAL HEALTH COLLECTION KIT

A capillary blood and urine 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 KT360 — 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

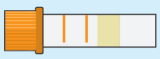
18+ — For use by persons aged 18 and over

Sample collection instructions (Steps 1–27)

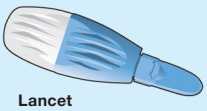
- **Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.**
- **If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the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

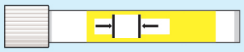


Blood collection tube (microtainer), CE IVD

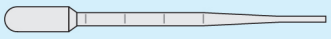


Lancet (contact activated) (x3), CE
STERILE R

Moist wipe (x2), CE
STERILE R



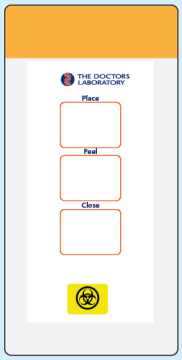
Urine specimen transport tube, IVD



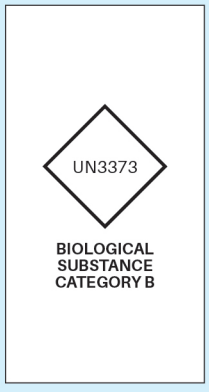
Sample transfer pipette

Plaster (x2), CE
STERILE EO

Alcohol swab (x2), CE



Transport pouch with absorbent pad



Return postal box

Urine collection box CE

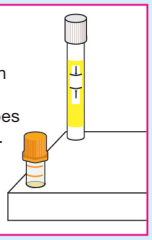
Return security label

Sample label (x2)

IMPORTANT!

The kit contents are supplied in a tray, please empty the tray contents and push through the holes in the base. Then turn the tray upside down and place your tubes as shown when collecting your samples.

Do not mix up tube caps, only replace them back on to the tubes that they came from.



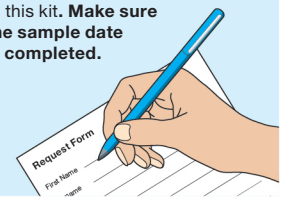
IMPORTANT!

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.**

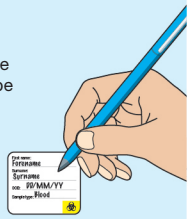


2

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!

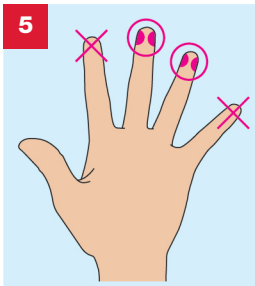
The return postal box has a postal tracking label applied. Please make a note of the unique tracking number displayed under the barcode on the postal tracking label, as shown below. Keep this in a safe place for future reference. You can track delivery of your Royal Mail parcel by entering this number 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 and insert the tube into one of the smaller holes in the tray as shown. Remove the cap and put it to one side whilst you take your sample.

5

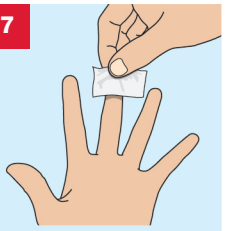


The best location for collecting a finger prick sample is from the side of your middle or ring finger (see shaded area). Open the pack of lancets.

6

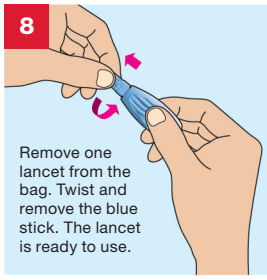
Wash your hands in warm soapy water. **It is much easier to collect your sample if your hands are warm**. Dry them thoroughly with a clean, dry towel.

7



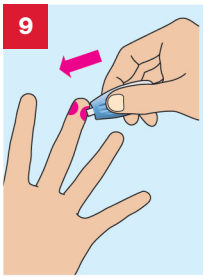
Using the Alcohol Swab clean the selected finger. Wipe dry with a clean tissue. **Be sure your finger is completely dry as blood will not form a drop at the puncture site of a moist finger.**

8



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

9

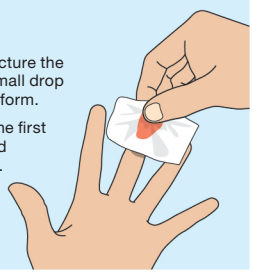


Position the lancet against the side of your chosen finger. The lancet will activate in one step only when positioned and pressed FIRMLY against the skin until a click is heard. Should you need to repeat the process to help obtain enough blood use one of the remaining lancets.

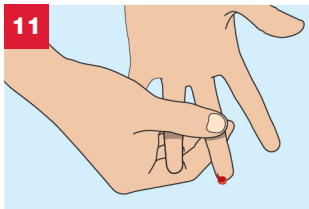
10

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

Wipe away the first drop of blood with a tissue.

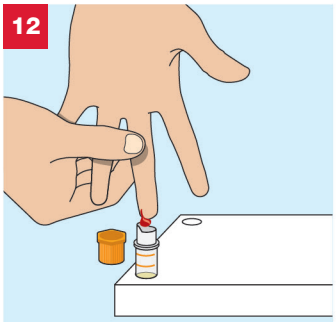


11



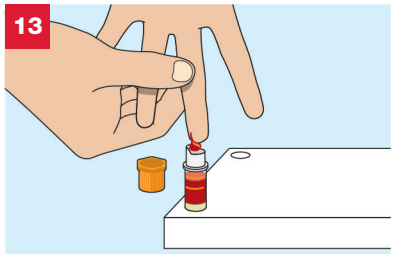
Holding your hand/arm downwards, firmly massage your hand down to your finger, without squeezing, to encourage blood flow.

12



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

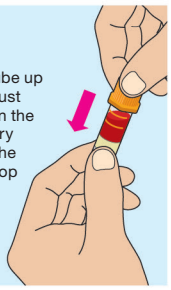
13



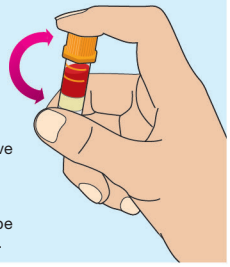
Fill the blood collection tube to the upper line on the side of the tube. NB: If you are unable to collect enough blood use the second lancet on a middle or ring finger on the other hand. Alternatively, try wiping the finger you have been using with a dry tissue. Pause for 5-10 seconds and blood drops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

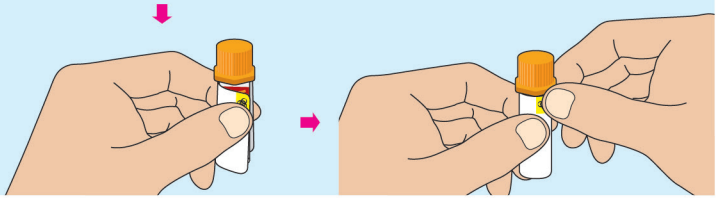


Once you have replaced the cap, gently invert the collection tube 5 to 10 times.

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.



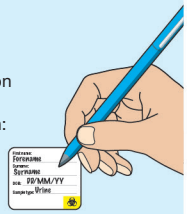
URINE SAMPLE COLLECTION

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: Urine

Do not affix it to the tube at this stage.



18

Wash hands using soap and water and dry them.

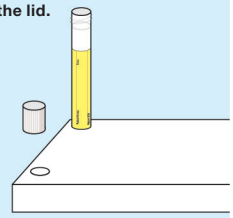
19

Note: You should not have urinated for at least 1 hour before sample taking.

Take the urine specimen collection tube from your kit.

20

Place the tube upright in one of the larger holes, as shown. Remove the cap and put it foil side up, 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.**



21

Squeeze the sides of the urine collection box to expand it.

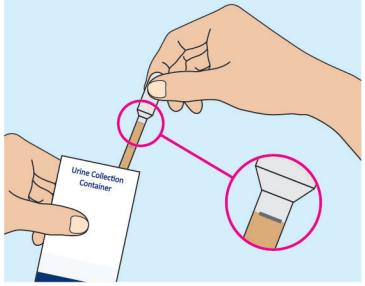
The box has a plastic lining inside to contain the urine. Please take care not to damage or puncture the lining.

22

Pass the first part of your urine into the urine collection box until it is half full then finish in the toilet.

23

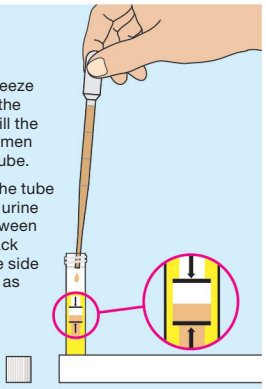
Gently place the end of the pipette into the urine collection box, taking care not to puncture the plastic lining and squeeze the end of the pipette to draw urine up – up to the top mark.



24

Gently squeeze the end of the pipette to fill the urine specimen transport tube.

Please fill the tube so that the urine level is between the two black lines on the side of the tube as shown.

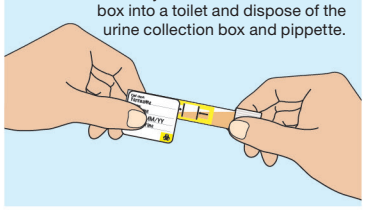


25

Screw the cap back firmly onto the urine specimen transport tube.

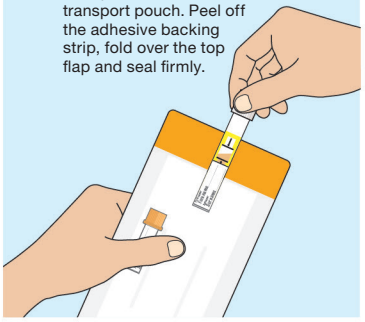
Apply the completed sample label onto the urine specimen transport tube as shown taking care not to cover the fill lines.

Discard any urine left in the collection box into a toilet and dispose of the urine collection box and pippette.



26

Place the blood and urine specimen transport tubes into the transport pouch. Peel off the adhesive backing strip, fold over the top flap and seal firmly.



27 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- ☐ **Place your completed request form supplied by your doctor/clinic into the kit tray**
- ☐ **Make sure the blood collection tube is labelled**
- ☐ **Make sure the urine specimen transport tube is labelled**
- ☐ **Make sure that both tubes are in the transport pouch and this is firmly sealed**
- ☐ **Place the transport pouch and all lancets into the kit tray**
- ☐ **Slide the kit tray back into the return postal box**
- ☐ **Close the return postal box and apply the return security label to seal the end of the box**
- ☐ **Check that you have taken note of your postal tracking number**

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.
- Do not affix the label to the urine specimen transport tube until after you have collected your sample. You will not be able to see how much urine you have collected if the label covers the tube.
- 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.
- 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 30 days (Aptima urine) 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-042, TAP4950D/26-02-25/V25. Issue No. 3; Date 26/02/25.

Revision/Date		Change summary
1	02/2023	Initial RDi product for UK market
2	02/2024	RDi IVD product CE registration
3	02/2025	Componentry change: secondary and outer packaging.

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.