

SEXUAL HEALTH COLLECTION KIT

A urine 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.

IVD For *in vitro* diagnostic use, sample self-collection

Carefully read the enclosed instruction leaflet before use

Do not re-use

REF KT356

! Important: Do not use kit if security seal is broken. Keep out of reach of children

18+ For use by persons aged 18 and over

CE **UK** **CA**

Sample collection instructions (Steps 1–12)

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

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.

Sample transfer pipette

Urine specimen transport tube, IVD

SECURITY SEAL

Return security label

Sample label

Urine collection box, CE

Transport pouch with absorbent pad

Return postal box

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 tube into one of the larger holes as shown when collecting your sample.



URINE 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 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.

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>**

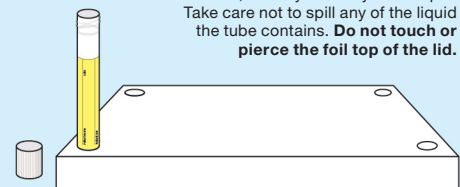


Write your tracking number here for reference – keep this safe.

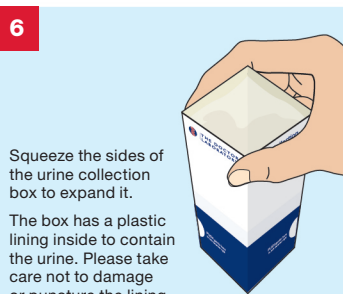
4 Wash hands using soap and water and dry them.



5 Note: You should not have urinated for at least 1 hour before sample taking. The tray has been designed to provide a stable way of holding the collection tube whilst a sample is taken. 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.**



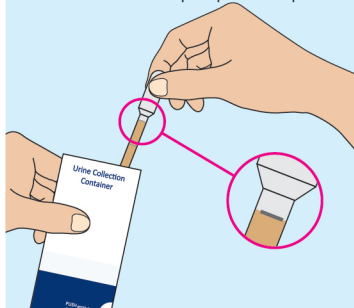
6 Squeeze the sides of the urine collection box to expand it. The box has a plastic lining inside to contain the urine. Please take care not to damage or puncture the lining.



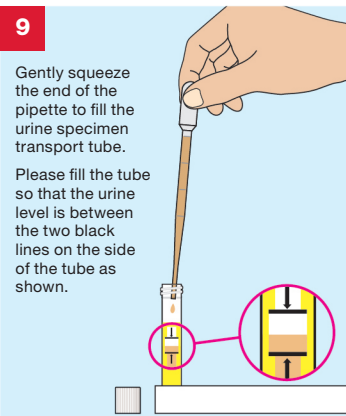
7 Pass the first part of your urine into the urine collection box until it is half full then finish in the toilet.



8 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.



9 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.

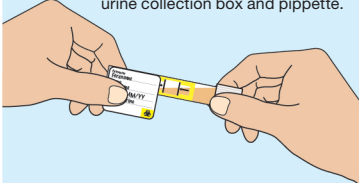


10

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 pipette.



11

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



12

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 urine specimen transport tube is labelled

☐

Make sure that the tube is in the transport pouch and this is firmly sealed

☐

Place the transport pouch 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.

• 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 degradation or general damage or arrive after 30 days (Aptima urine) 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.**

• **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

REF


Catalogue number

LOT


Batch code




Biological risk. Biological sample, treat as potentially infectious



Do not use if package is damaged



Use by end of year-month



Distributor

Manufacturer

EC

REP

EU Authorised Representative

Temperature limits: 4°–25°C

Caution, consult accompanying documents


Keep away from sunlight

UK CA


UK Conformity Assessed

CE

EU Conformity Assessed




Do not re-use




Consult instructions for use

18+

For use by persons aged 18 and over




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.

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RDI-IFU-018, TAP4871D/17-01-25/V23. Issue No. 3; Date 17/01/25.

Revision/Date

Change summary

1

02/2023

Initial RDi product for UK market

2

02/2024

RDi IVD product CE registration

3

01/2025

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.