

URINALYSIS AND URINE CULTURE COLLECTION KIT

A urine sample collection kit used for the collection and transportation of samples for laboratory analysis of urine chemistry, microscopy and bacterial culture

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



KT386







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



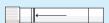
For use by persons aged 18 and over

Sample collection instructions (Steps 1-12)

- 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.



Urine specimen transport tube, ← IVD



Urine specimen transport tube (containing boric acid), ← IVD



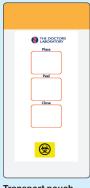
Urine collection box, €€



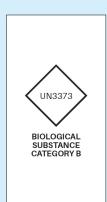
Return security label



Sample label x2



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 tubes into the larger holes, as shown when collecting your samples.



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

URINE SAMPLE COLLECTION

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.

Clearly complete both sample collection tube labels using

a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- · Sample type: Urine

Do not affix it to a tube at this stage.

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



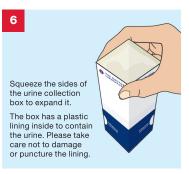
4

Wash hands using soap and water and dry them.

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

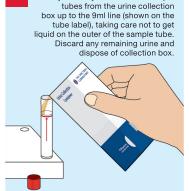
Place each tube upright in each of the larger holes of the tray. Carefully unscrew the cap of each sample tube and leave to one side, taking care not to spill any of the powder the tube contains.

Each tube will have a fill line displayed on the label. Fill the tube up to this mark.



Very carefully fill both urine sample



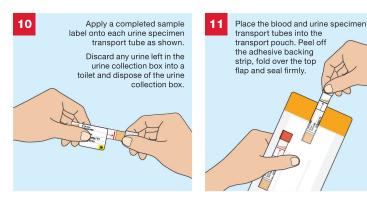


Screw the corresponding cap back firmly onto each urine specimen transport tube.

Take the tube with the red cap and **gently** invert the tube several times to mix the boric acid with the urine.

Do not shake the tube.





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 tubes are labelled		
		Make sure that both tubes are 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/nGdX6Z0s0e

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 please
 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.
- To ensure the correct concentration of boric acid preservative the sample must be filled to the fill line indicted on the tube. If filled incorrectly (too little urine)
 Boric acid may become inhibitory to some organisms and inhibit tests for leucocyte esterase.
- The accuracy of your results may be compromised if you do not read and follow the instructions in full.
- Antibiotics may affect the test result. If you are taking antibiotics, or have recently, discuss this with your healthcare professional.
- The International Scientific Supplies (ISS) boric acid tube contains pre-dosed boric acid in powder form. In the case of contact with eyes, skin, nose or mouth please rinse thoroughly with clean water and if irritation persists seek medical attention. Additionally, in the case of contact with eyes please remove contact lenses prior to rinsing. If ingested please drink plenty of water, do not induce vomiting and consult a medical professional. In the case of spillages avoid direct contact with eyes, skin, nose or mouth and wipe with tissue paper, and dispose in normal household waste. For further information please refer to safety datasheets which can be found at www.intscientific.com.
- Samples arriving at the laboratory which show signs of degradation or general damage or arrive after 6 days (universal container) and 4 days (Boric acid container) 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 UK Conformity For in vitro IVD Manufacturer diagnostic use Assessed **EU Authorised FU** Conformity EC REP REF Catalogue number Representative Assessed Temperature LOT Batch code Do not re-use Biological risk Caution, consult Consult instructions **S** Biological sample, treat accompanying documents as potentially infectious For use by persons aged 18 and over Use by end Keep away of year-month from sunlight Do not use if Distributor package is damaged



REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CRO 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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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.