

FAECAL COLLECTION KIT


A faecal collection kit used for the collection and transportation of samples for laboratory analysis of human haemoglobin, biochemical and/or immunological parameters


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 KT430



 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 1–18)

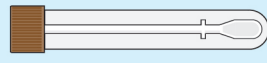
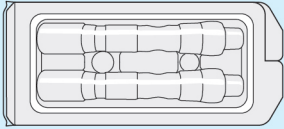
- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare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



Green sampling stick and tube for taking your sample x2



Brown sampling stick and tube for taking your sample x2

Protective packing case (x2)

Security Seal

To Open Box – Tear Seal & Lift Flap
MDX001.com

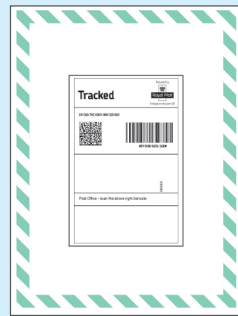
First name: _____
Surname: _____
DOB: _____
Sample type: _____
TAP46885210-CL1V7

Return security label

Sample label (x3)

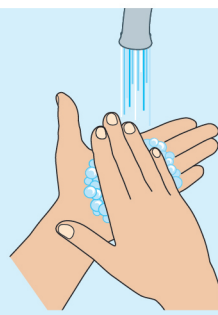


Collection kit outer box



Return envelope

3



Wash and dry your hands.

4

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

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



5

IMPORTANT SAMPLE TRACKING INFORMATION!

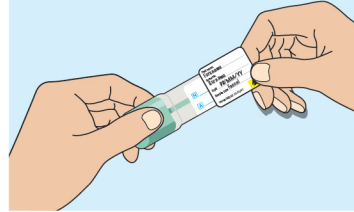
The enclosed postal envelope has a postal tracking label applied. Please make a note of the unique tracking number displayed under the barcode on the postal tracking label, as shown below. Keep this in a safe place for future reference. **You can track delivery of your Royal Mail parcel by entering this number using the following link: <http://www.royalmail.com/track-your-item>**



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

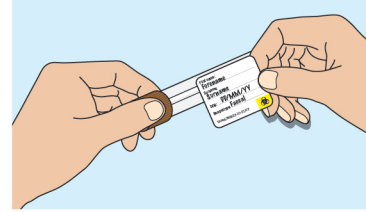
6

Affix the label to the green sampling stick collection tube as shown.



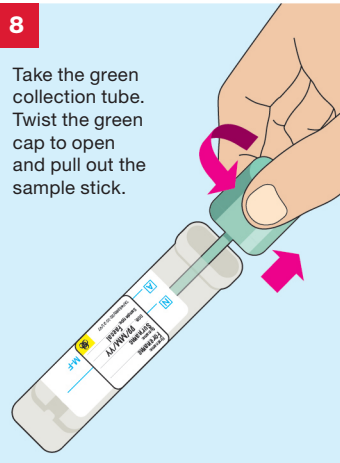
7

Affix a label to both of the brown sampling stick collection tubes as shown.

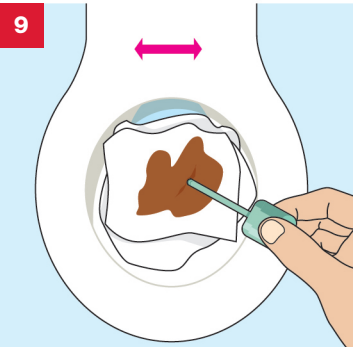


8

Take the green collection tube. Twist the green cap to open and pull out the sample stick.



9



Collect your sample by scraping the sampling stick on your bowel motion (stool) until the end of the stick is covered.

FAECAL 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.**



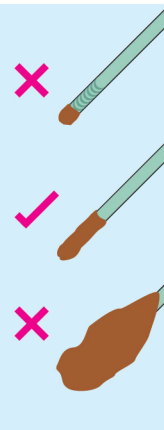
2

The test can be done at any time of day or night. Place a bed of toilet paper in the bowl to make it easier to collect your sample. Perform your bowel motion. If possible, try to prevent the sample from touching the water.

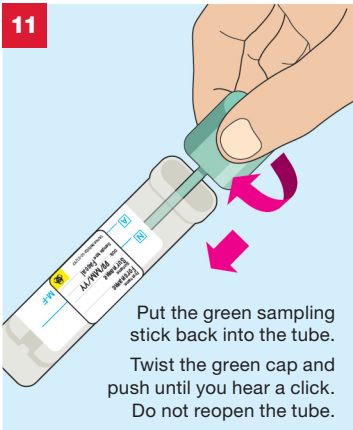


10

Please make sure the ridged end of the stick is covered in stool. An even amount stool is required, too little or too much is not suitable for testing.



11



Put the green sampling stick back into the tube. Twist the green cap and push until you hear a click. Do not reopen the tube.

12

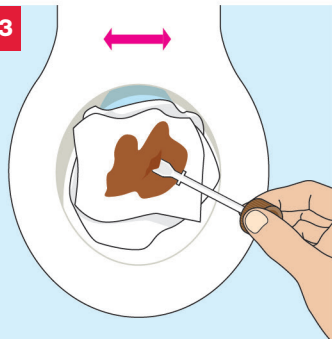
Take a brown collection tube. Hold it in clean toilet tissue.

Twist the cap to open and pull out the sample stick.



13

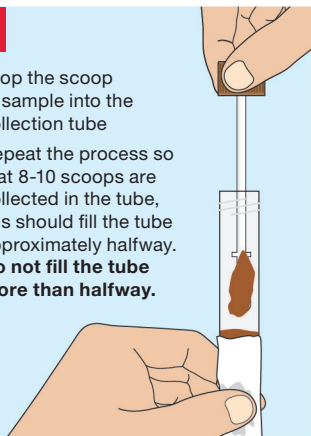
Collect your sample by scraping the sampling stick on your bowel motion (stool) until the end of the stick is covered.



14

Drop the scoop of sample into the collection tube

Repeat the process so that 8-10 scoops are collected in the tube, this should fill the tube approximately halfway. **Do not fill the tube more than halfway.**

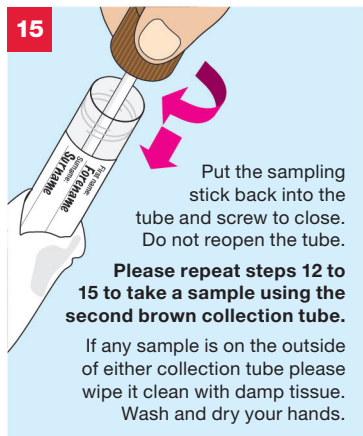


15

Put the sampling stick back into the tube and screw to close. Do not reopen the tube.

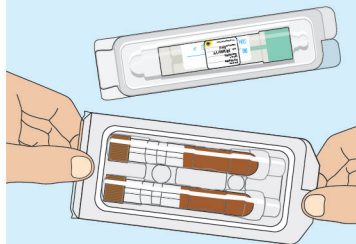
Please repeat steps 12 to 15 to take a sample using the second brown collection tube.

If any sample is on the outside of either collection tube please wipe it clean with damp tissue. Wash and dry your hands.



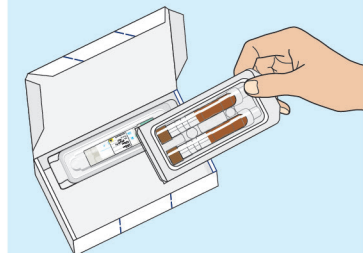
16

Place each collection tube into a protective packing case and firmly close.



17

Place all samples into the outer collection box.



18 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- Place your completed request form supplied by your doctor/clinic into the return envelope
- Make sure that the green collection tube is labelled and has been placed inside the protective packing case
- Make sure that both brown collection tubes are labelled and have been placed inside the protective packing case
- Place both protective packing cases 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 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/EZfeMc4TVs>

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 place the sampling stick directly into your body. The sample bottles are designed for collecting faecal samples, no other sample types.
- Do not obtain faecal samples during menstruation (your period) and avoid sample contact with lubricants, bleach and toilet cleaners.
- If your stool sample is excessively watery or hard please discuss this with your healthcare professional to ensure you are collecting a suitable sample for testing.
- Do not break the bottle seals, add water or remove the buffer.
- Liquid contained in the sealed sampling tube contains a hazardous material, sodium azide (NaN₃ <0.1%). Avoid contact with skin, eyes and mouth. In case of exposure, wash vigorously with water and contact a doctor for treatment advice. Further information can be found at www.fit-screening.co.uk
- Some haemoglobin variants may interfere with QFIT results, these results should be interpreted with caution.
- 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 between 3–7 days of sample taking (depending on test requested) 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 <i>in vitro</i> diagnostic use | | Manufacturer | UK CA | UK Conformity Assessed |
| REF | Catalogue number | EC REP | EU Authorised Representative | CE | EU Conformity Assessed |
| LOT | Batch code | | Temperature limits: 4°–25°C | | Do not re-use |
| | Biological risk. Biological sample, treat as potentially infectious | | Caution, consult accompanying documents | | Consult instructions for use |
| | Do not use if package is damaged | | Keep away from sunlight | 18+ | For use by persons aged 18 and over |
| | Use by end of year-month | | Distributor | | Keep dry |



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The Doctors Laboratory Limited

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Revision/Date Change summary

| | | |
|---|---------|---|
| 1 | 02/2023 | Initial RDI product for UK market |
| 2 | 09/2023 | Steps 14 & 15 updated with clearer instructions |
| 3 | 01/2024 | 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.