

QFIT COLLECTION KIT

A faecal sample collection kit used for the collection and transportation of samples for laboratory analysis of human haemoglobin (blood)

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 KT362



i 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 1–12)

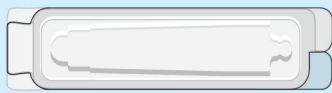
- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare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

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



Protective packing case

First name: _____
Surname: _____
DOB: _____
Sample type: _____
16796338623-10-21-17

Sample label

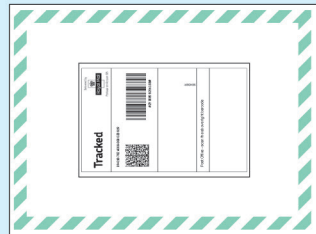
Security Seal

To Open Box – Tear Seal & Lift Flip

Return security label



Collection kit outer box



Return postal envelope

FIT TEST (QFIT) SAMPLE COLLECTION

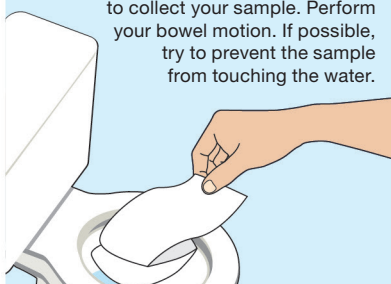
About the FIT Test (QFIT)

This is a simple test that looks for tiny amounts of blood in your bowel motion (also called a stool). In order to do this test you will need to produce a bowel motion.

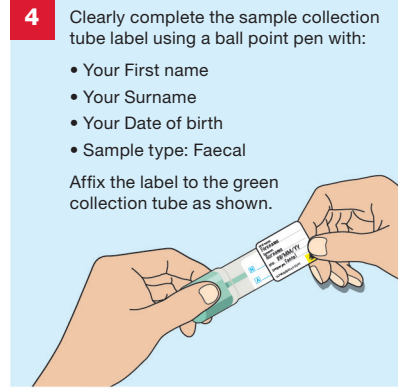
- 1** If not already pre-populated please complete the test request form, provided by your doctor/clinic, separate to this kit. **Make sure the sample date is completed.**



- 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.



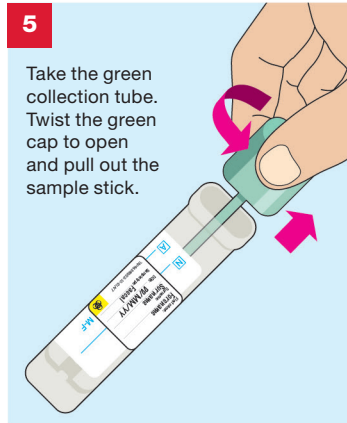
Wash and dry your hands.



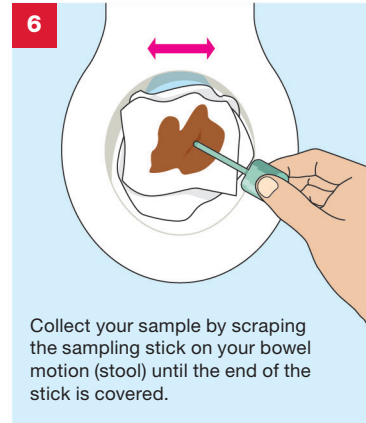
- 4** Clearly complete the sample collection tube label using a ball point pen with:

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

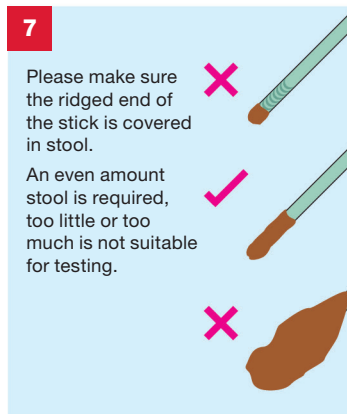
Affix the label to the green collection tube as shown.



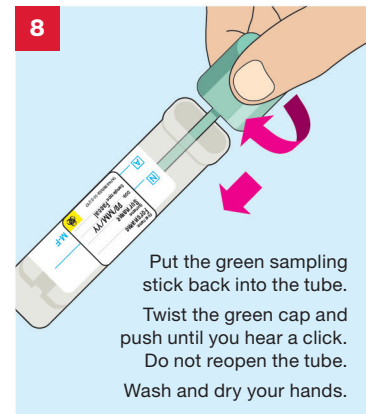
- 5** Take the green collection tube. Twist the green cap to open and pull out the sample stick.



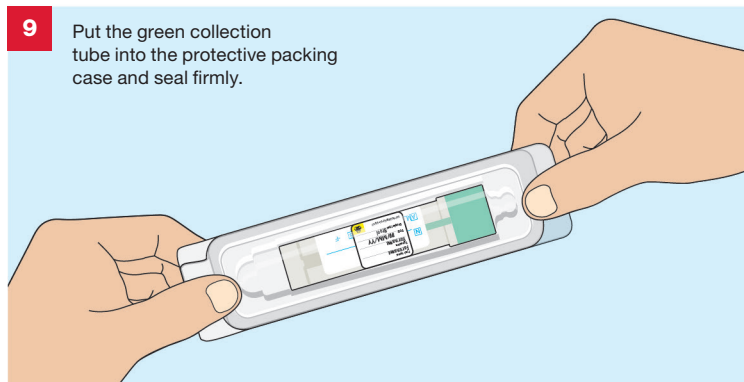
- 6** Collect your sample by scraping the sampling stick on your bowel motion (stool) until the end of the stick is covered.



- 7** 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.



- 8** 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. Wash and dry your hands.



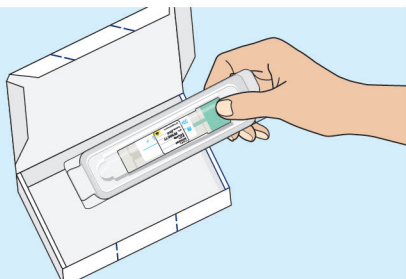
- 9** Put the green collection tube into the protective packing case and seal firmly.

- 10** 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.

- 11** Place the protective packing case into the collection kit outer box.



12 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 that the green collection tube is labelled and has been placed inside the protective packing case
- Place the protective packing 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/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 QFIT 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 after 14 days 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 <i>in vitro</i> diagnostic use	Manufacturer	UK CA	UK Conformity Assessed
REF	Catalogue number	25° 4° Temperature limits: 4°-25°C	CE	EU Conformity Assessed
LOT	Batch code	Caution, consult accompanying documents	Do not re-use	
	Biological risk. Biological sample, treat as potentially infectious	Keep away from sunlight		Consult instructions for use
	Do not use if package is damaged			For use by persons aged 18 and over
	Use by end of year-month			Keep dry
	EU Authorised Representative			

REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CR0 4BD, UK
Website: www.real-digital.co.uk

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	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.