

qFIT to support primary care
assessment of symptoms to
detect possible colorectal cancer

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GP Information Pack

December 2020

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Interactive training link: 5 minute module on quantitative Faecal Immunochemical Test (qFIT) for suspected colon cancer

https://docs.google.com/forms/d/e/1FAIpQLSerx7BU5tCjx41LooQOsA_ADAU5UQDMxBEVhtXodTZrH7QB-Q/viewform

Useful link: <http://youtu.be/IUU4kUMJLh8>

Guidance for GPs on the quantitative Faecal Immunochemical Test (qFIT) for patients with low risk cancer bowel symptoms. This video is produced by North Central and East London Cancer alliance and though NOT specific to Kent & Medway it still provides useful information for GPs for low risk patients

Local Guidance: Some areas of Kent & Medway have additional guidance and/or pathways for GPs which may also be helpful in deciding which test or pathway is most appropriate for patients with lower GI symptoms. GPs are encouraged to check for any local guidance.

1. Introduction to quantitative Faecal Immunochemical Test (qFIT) for low risk cancer symptoms

What is qFIT?

qFIT test is a very specific test for the presence of human blood in the faeces. According to current data, patients with low-risk symptoms and a negative q-FIT result have a very low risk of colorectal cancer (evidence from NICE guideline DG30). qFIT has a number of advantages over the guaiac haemoccult test (FOBT):

- it is specific for human blood
- only one sample is needed
- no dietary restriction is needed
- patient acceptability is higher than FOBT
- it is quantitative

How can qFIT be used in general practice?

1. qFIT to rule out significant disease in those who do not meet the criteria for a suspected cancer referral as per NICE guideline on suspected cancer (NG12) but who do meet the criteria in NICE DG30. Patients with a negative qFIT, normal Hb and vague symptoms can be reassured that the risk of colorectal cancer is very low.
2. qFIT to guide referral in patients with low risk symptoms and with a positive qFIT test should be referred on a suspected cancer pathway.

Which patients should be offered qFIT in general practice?

NICE DG30 recommends that GPs offer qFIT for adults **without rectal bleeding but with unexplained symptoms** that **do not meet the criteria for a suspected cancer pathway** referral defined in NICE guidelines for suspected cancer (NG12 September 2020).

Note: qFIT is not the best test to detect IBD. If IBD is suspected use faecal calprotectin (FCP) test

What is the significance of the level in low risk symptomatic patients?

A qFIT test with a value of <10ug/ml counts as a negative result for low risk symptomatic patients. With a level as low as this there is essentially no detectable blood in the stool and the risk of bowel cancer or significant polyp is extremely low. However, in some patients with cancer, qFIT can be negative – in trials to date, all of these patients have had an iron deficiency anaemia so it is recommended to check the Hb at the time of a qFIT test.

In July 2019 the National Bowel Screening Programme (NBSP) stopped using FOBT and now use qFIT. The threshold for referral for suspected cancer is different in the NBSP (non-symptomatic patients) than for low risk symptomatic patients and this is explained further in the FAQs section of this document (Q3)

What the results mean

- **If qFIT positive: 2ww referral for suspected colorectal cancer.**
- **If qFIT negative: colorectal cancer is extremely unlikely**

Requesting the test

- Requesting clinicians are advised to make an entry in the patient's record that a test has been requested as below, and ensure a process is in place to follow this up, in addition to giving the patient their usual safety netting advice. Using a standard term will allow you to search for patients who have been advised to send qFIT tests but for whom you have not received a result:
 - The clinical term "Faecal Occult Blood Requested" is recommended
 - READ Code 4791
 - SNOMED ID 167666002
- Keep your tests in a single location in the practice.
- Give the pack to the patient and advise them to read the instructions carefully before they return the pack to the GP surgery
- Expect a result within 14 days of sending it away and have a safety netting system in place. The template in Appendix A (qFIT symptomatic log: safety netting checklist) can be used as a recall system to identify outstanding results
- If you have not had the results within 14 days of issuing the test then please use your safety netting system to ensure that the sample was: 1) returned to your practice by the patient and 2) sent to the lab by your practice. If both of these actions were completed, then please contact the lab.

Problems with qFIT

- Patients who have had a recent negative result from the bowel cancer screening programme but present with symptoms to their GP may still require a q-FIT test. Please do not be falsely reassured by the negative q-FIT screening result as the threshold for reporting a test as positive is much higher in an asymptomatic person attending for screening (i.e. 120 micrograms Hb/g faeces) compared with a patient who has symptoms (i.e. 10 micrograms Hb/g faeces).
- qFIT is not appropriate for all patients with gastrointestinal symptoms – if IBD is suspected then faecal calprotectin is still the most useful adjunct and referral pathways to gastroenterology are unaffected.

Data and Audit collection

Practices should have safety netting in place to ensure that samples are returned and the results are received and acted upon. A data log and safety netting checklist template is shown in Appendix A.

2. qFIT Frequently Asked Questions

Q1. Why does colorectal cancer matter?

A. Colorectal cancer is the UK's second biggest cancer killer, but if diagnosed early enough there's more than a 90 per cent chance of successful treatment. Colonoscopy is considered to be the gold standard of colorectal cancer detection but the procedure can be uncomfortable and carries a small risk of bleeding and perforation.

Q2. Where is the test being used?

A. The test is being used in 3 cohorts of patients as follows:

Cohort 1 – By the national bowel screening programme since July 2019

Cohort 2 – For low risk symptomatic patients using NICE guideline DG 30 (rollout across the whole of the country by 2021) <https://www.nice.org.uk/guidance/dg30>

Cohort 3 – Selected centres trialling qFIT in higher risk patients that meet NICE suspected cancer guideline NG12

Q3. Does a patient need a qFIT test if they have already had a screening qFIT?

A. Using qFIT in symptomatic patients is different than using it for screening. In symptomatic patients qFIT is used as a 'rule out' test. qFIT is designed to be as sensitive as possible (positive for referral if ≥ 10 micrograms Hb/gram faeces) so that the chance of missing cancer is minimised. In screening, the test is used as a 'rule in' test and is much less sensitive (>120 micrograms Hb/gram faeces). Therefore, a negative screening qFIT is very different from a negative symptomatic qFIT. If your patient has symptoms, don't be falsely reassured by a negative screening qFIT test as there is still the potential for pathology to be present. Refer to the local lower GI guidance for information on appropriate pathways for symptomatic patients.

Q4. Can I use qFIT in place of Faecal Calprotectin test for Inflammatory Bowel Disease (IBD)?

A. No. In essence, qFIT is a test for 'red cells', whilst calprotectin is a test for 'white cells'. They have very different roles. Calprotectin is an excellent test to decide between IBS and IBD but qFIT has no value in this decision making process. Conversely, calprotectin is not good at excluding bowel cancer diagnosis.

Q5. What are the benefits of offering a qFIT for patients rather than making a referral to secondary care where they may get a colonoscopy via the "straight to test" suspected cancer pathway?

A. qFIT is an excellent way of avoiding your patient going through the risk, inconvenience and unpleasantness of a colonoscopy. A negative qFIT result in the absence of high risk features such as iron deficiency anaemia, a rectal mass, or strong clinical suspicion, makes the risk of bowel cancer very low.

Q6. What do I do if a qFIT test is positive for my patients?

A. A positive qFIT result necessitates a two week wait referral for a colonoscopy or CT colon to exclude colorectal cancer.

Q7. What do I do if a qFIT test is negative for my patients?

A. A negative qFIT result in the absence of high risk features such as iron deficiency anaemia, a rectal mass, or strong clinical suspicion, makes the risk of bowel cancer very low and the patient does not require a referral on a 2 week wait pathway. However, we would always encourage standard measures to provide safety netting for the patient, in the same way you might for a normal CA-125 or PSA.

Q8. What is the level of confidence in the test?

A. The patient population for whom qFIT is recommended are already at low risk – less than 3% - as they do not meet the NG12 suspected cancer referral criteria. At the test threshold of 10ug/ Hbg faeces, research reviewed in NICE DG30 demonstrates a **negative predictive value of over 99%**.

Q9: How will I obtain new stock/kits?

A. An initial supply of 20 kits will be issued to the practice who can then reorder in batches as required - usual stock rotation systems should be used. Kits can be obtained from one of these three pathology labs at Maidstone Hospital, Dartford Hospital or William Harvey Hospital.

Q10: Where do I send samples?

A. Samples should be sent to your usual lab who will then ensure that they are transported to Maidstone Hospital who will be undertaking the analysis for all samples in Kent and Medway.

Q11: How will I get results?

A. Your local lab will send you the results in the usual way within 2 weeks and if they are positive they will be highlighted so that you can act on them.

Q12: How do I dispose of expired or damaged kits?

A. The use of a clinical waste bin is sufficient for disposal.

Q13: How should the practice store returned samples from the patient?

A. If the sample cannot be collected by the courier on the same day it is received from the patient, then the practice is requested to refrigerate the sample until it is collected.

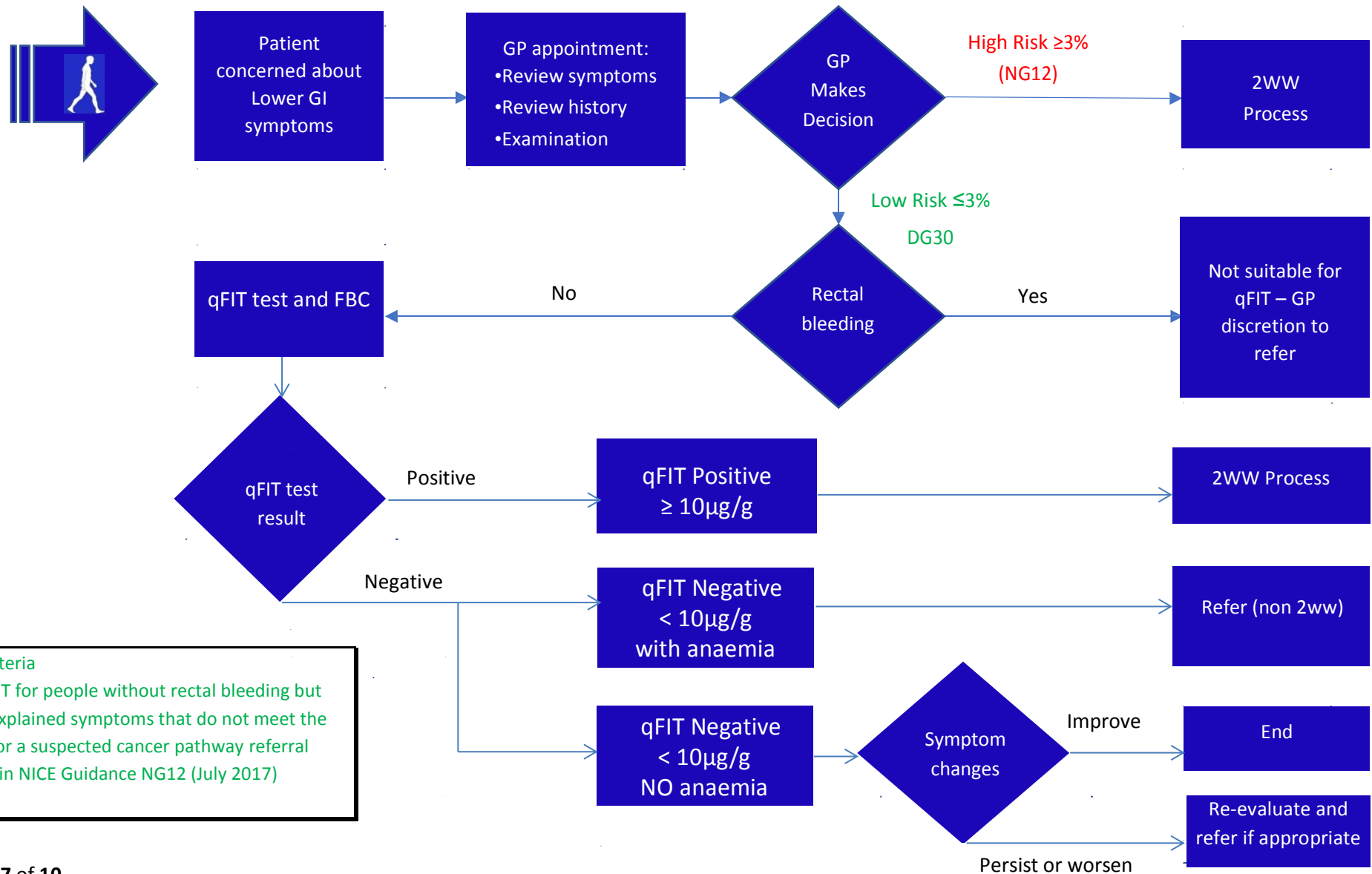
Q14: How do I label the sample?

A. It is anticipated that practices will attach patient labels to the picker for the patient to complete and these should not be affixed in a way that the lab barcode is obscured and not readable by the lab scanner.

Q15: What information does the patient need to put on the sample?

A. The patient should complete the label with their first and last names, date of birth and the time and date the sample was taken; this instruction is included in the patient information leaflet.

quantitative Faecal Immunochemical Testing (qFIT) in Primary Care Clinical Pathway



DG30 Criteria

Offer QFIT for people without rectal bleeding but with unexplained symptoms that do not meet the criteria for a suspected cancer pathway referral outlined in NICE Guidance NG12 (July 2017)

APPENDIX A – QFIT Symptomatic Data Log & Safety Netting Checklist

Data and safety netting log for qFIT low risk									
Name of practice:									
Data for the month of:									
NHS Number	Patient Age	Patient Gender M/F	Requesting GP	Date Test recommended	Date result received by GP	Result (positive/negative)	2 week wait referral? Yes or No	Other Action by GP (discharge, further investigation, routine referral etc)	Further comments

APPENDIX B – qFIT Patient Leaflet



Faecal Immunochemical Test: Step-by-step instructions. Start here

Your GP has asked you to complete a qFIT sample. What is a qFIT test?

qFIT stands for quantitative Faecal Immunochemical Test. The test detects tiny amounts of blood in your stool (poo) not visible to the naked eye.

How do I collect my sample?

A test kit has been provided to you by your GP for completion at home. The test comes with easy to follow instructions on how to collect a poo sample; found on the back of this leaflet.

- Do not collect your poo sample during menstruation.
- You may wish to purchase a pair of disposable gloves (not essential).
- Use the dedicated qFIT collection bottle to complete your test.

What do I do with my completed qFIT Kit?

Please return your completed qFIT to your GP practice as soon as possible. Return on the same day as creating the sample is best. Your sample will be sent to the laboratory for testing.

What happens next?

Your GP will receive the result of your test within 9 working days, after which, you are advised to contact your practice to obtain the result.

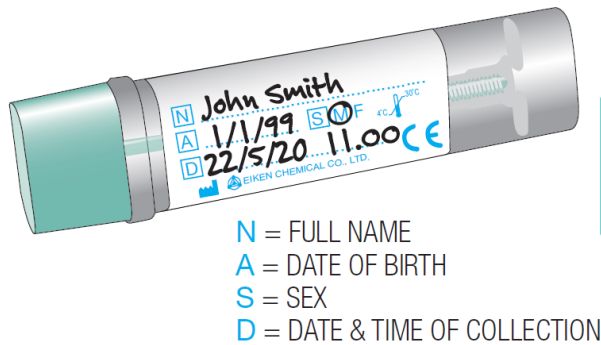
If the result is:

- **Normal** but you are still concerned about your symptoms; contact your practice for a review appointment. If your symptoms have resolved you will not need further investigations.
- **Abnormal**, you will be referred to the hospital by your GP for further investigations and management within two weeks.

If you have any further queries or concerns regarding your test result, please contact your GP practice for advice

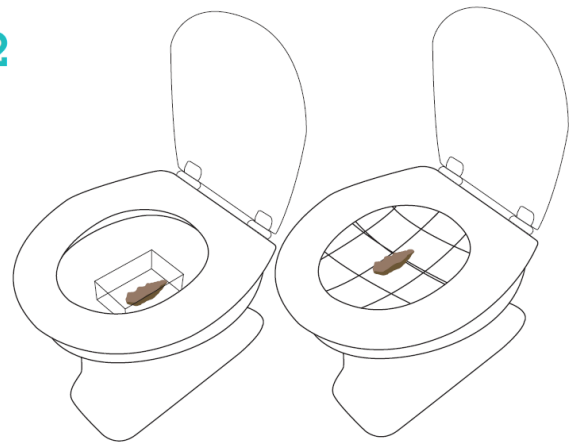
How to do your test

1



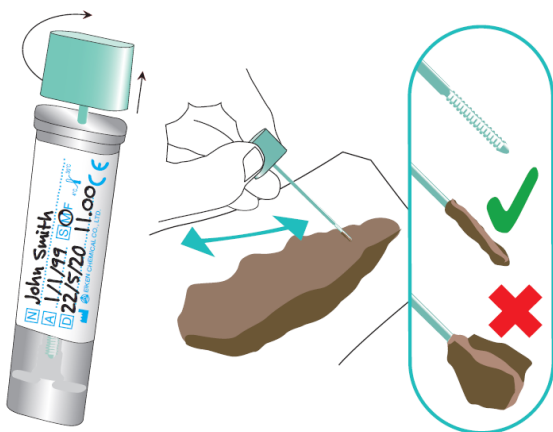
- Using a permanent pen, clearly write on your qFIT sample bottle with your full name, date of birth and date and time of collection; as shown above.

2



- First, empty your bladder to avoid contamination with urine
- Place a clean empty container in the toilet bowl
- OR**
- Place clean newspaper over the toilet seat under the lid (not suitable for a runny sample)
- Poo directly into the container or onto the newspaper.

3



- Twist cap to open sample bottle. The bottle contains liquid preservative – DO NOT pour this away.
- Collect sample by scraping the green stick along the poo until all the grooves are covered – DO NOT add extra poo, only a small amount is needed for the test.

4



- Put stick back into the bottle and 'click' the green cap to close it.
- Your qFIT sample is now complete, DO NOT repeat the collection.
- Place the completed qFIT sample into the plastic bag provided.
- Wash hands with Soap and warm water.

Return your completed qFIT to your GP practice as soon as possible, the same day as creating the sample is best.