

Introduction of FIT as a Primary Care Diagnostic Support Tool

Available in South Yorkshire, Bassetlaw and North Derbyshire
from 4th March 2019

What is FIT?

FIT (Faecal Immunochemical Test) is a type of faecal occult blood test to detect traces of blood in stool samples. Unlike another type of faecal occult blood test guaiac FOBt (gFOBt), FIT uses antibodies that specifically recognise human haemoglobin. FIT is a more sensitive and specific test than gFOBt and will not give false positive results if patients eat meat. An abnormal FIT result suggests that there may be bleeding within the lower gastrointestinal tract and should lead to referral for further investigation.

Why is there new NICE guidance on the use of FIT in certain symptomatic patients?

The 2015 cancer recognition and referral guidelines from NICE (NG12) recommended the use of testing for occult blood in faeces for certain groups of symptomatic 'low risk but not no risk' patients who did not meet the criteria for urgent referral for suspected cancer in light of their age or type of symptom or sign.

What do the new NICE guidelines (DG30) on the use of FIT in symptomatic patients recommend?

The guidelines recommend the use of FIT in primary care to guide referral for suspected colorectal cancer in patients without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer referral pathway (2WW) as outlined in NG12 (the 'low risk but not no risk' group of patients).

The guidelines recommend that 10 micrograms of Haemoglobin per gram of faeces ($\mu\text{g Hb/g}$) be used as the cut off for an abnormal result. Any positive FIT result should be referred on a 2 Week Wait Pathway (2WW).

Please refer to the South Yorkshire, Bassetlaw and North Derbyshire Cancer Alliance Lower GI Referral Pathway included in your pack.

What are the benefits of using FIT tests?

Earlier identification and treatment of patients who have colorectal cancer who do not meet the other NICE NG12 referral criteria. Currently a significant number of patients with colorectal cancer are not diagnosed through bowel screening or 2WW pathways.

Which patients should be offered FIT?

Offer testing for occult blood in faeces to assess for colorectal cancer in adults without rectal bleeding who:

- are aged 50 and over with unexplained:
 - abdominal pain or
 - weight loss, or
- are aged under 60 with:
 - changes in their bowel habit or
 - iron-deficiency anaemia, or
- are aged 60 and over and have anaemia even in the absence of iron deficiency.

DG30 Quantitative immunochemical tests to guide referral for colorectal cancer in primary care:

<https://www.nice.org.uk/guidance/dg30>

Which patients should NOT be offered FIT by their primary care clinician?

- Patients who meet the NG12 2WW referral criteria for suspected colorectal cancer. These patients should be referred and investigated by secondary care and do not need to have this additional test.
- Asymptomatic patients requesting FIT as a screening test. The threshold for this test to be used by primary care as a diagnostic support tool is very different to the levels that will be used by PHE when FIT is introduced in screening populations.
- Younger patients where inflammatory bowel disease is suspected. Faecal calprotectin should be used for this group.

How will the process of FIT testing work in practice?

Delivery of FIT kits to Practices

Practices will receive the new FIT test kits from STH Pathology in the usual way you receive blood test bottles etc. The kits will be delivered to Practices from w/c 11th February 2019, in preparation for the go live date of 4th March 2019. The number of kits delivered to each Practice will vary according to the population of each Practice and the % of that population who are over 50.

The FIT kits will include:

- the FIT test itself
- a pre-paid envelope for the patient to return the sample
- a patient instruction leaflet

Reordering kits

Following the initial 2-3 months' supply, Practices will order additional kits when stocks reach a minimum level. Additional stock should be ordered via your local laboratory as per your usual process.

The Process

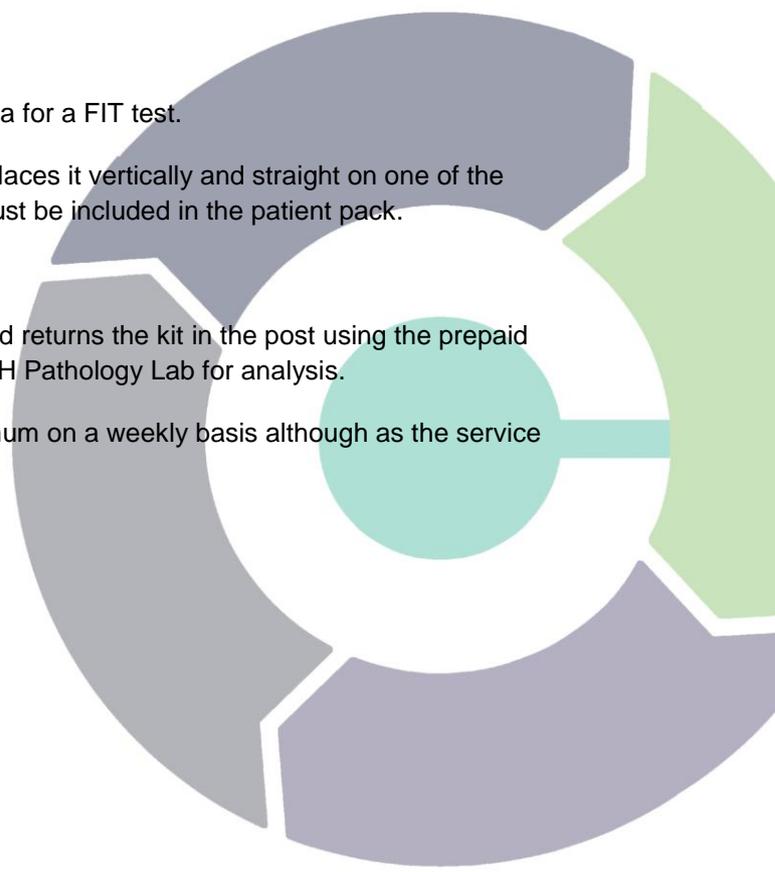
Patient presents with symptoms and meets the criteria for a FIT test.

GP orders FIT test on ICE, prints the ICE label and places it vertically and straight on one of the sample container flat sides. The ICE request form must be included in the patient pack.

The GP read codes the FIT request.

The patient takes the FIT kit, collects their sample and returns the kit in the post using the prepaid envelope. The sample will be delivered directly to STH Pathology Lab for analysis.

Analysis of the samples will be performed as a minimum on a weekly basis although as the service embeds, this will be more frequent.



Accessing Results

GPs/Practices will follow their current practice protocol for accessing test results. Results will be reported back to GPs as a figure. The results will clearly indicate whether it is positive or negative.

As for other tests, Practices can search for tests results and undertake necessary action e.g. follow up appointment with patient to discuss results/next steps.

The addition of a Read code when a test is requested makes checking compliance for FIT test completion possible.

The Read codes for EMIS and SystemOne are:

EMIS = 47K 'Quantitative faecal immunochemical test'

SystemOne = Xaf0H 'Quantitative faecal immunochemical test' i.e. Xaf0(zero)H

System Testing

End to end system testing will take place during February to ensure that the various IT systems connect and that you can order tests and access results.

Will any cancers be missed at a 10 µg Hb/g cut off?

Yes. Despite having greater sensitivity, a small number of colorectal cancers will be missed i.e. false negatives. In studies so far these tended to be either proximal cancers or in patients who were anaemic or had diarrhoea. Patients having a FIT test should have a full blood count checked as well. Primary care clinicians should safety net their patients and remain vigilant for ongoing/worsening symptoms. Patients need to be aware that a negative result does not guarantee that they do not have a cancer.

This is also important because symptoms identified as a feature of 'low risk' colorectal patients in NG12, such as abdominal pain, can be associated with other types of cancer, such as gynaecological or pancreatic. These patients will have a negative FIT.

What if the FIT test has come back as less than 10 µg Hb/g, but the GP is still concerned or suspicious?

Given the possibility of false negatives, and because symptoms may be linked to other cancer types, it is important that GPs use their clinical judgement alongside the FIT results. If there remain clinical concerns around cancer, patients should be referred for assessment.

Should patients who have had FIT in light of symptoms/signs still take part in the bowel screening programme?

Yes. Even if the symptomatic FIT comes back as normal at a particular point in time, the individual could still go on to develop colorectal cancer in the future and the bowel screening programme is intended to detect early signs of cancer before symptoms have a chance to develop. There may also be preventative benefits of participating in the bowel screening programme through identifying and removing polyps which may, if left untreated, develop into colorectal cancer.

Should patients who have taken part in bowel screening be offered a FIT test by primary care if they later develop symptoms ?

Yes. DG30 sets the cut off for an abnormal result in low risk but not no risk symptomatic patients at 10 µg Hb/g. This is a low cut off and potentially the lowest that can be reliably measured through the existing types of FIT that are available. While FIT has yet to be introduced into the local bowel screening programme, the cut off for an abnormal result will be significantly higher than 10 µg Hb/g. Patients should be managed on the basis of the symptoms/signs they are reporting and if these are not enough to trigger a 2WW referral, FIT testing should be considered.

Further information:

Contact the Cancer Alliance on sybndcancer.alliance@nhs.net

Contact your CCG for information on any local educational events.

Information video on FIT for Primary Care:

<http://bit.ly/FIT-VIDEO-INFO>

Information for patients on completing the test:

<http://bit.ly/FIT-FOR-PATIENTS>

For further information on the process, FAQs and to listen to recordings of the webex sessions held in November 2018 and January 2019, please access the Cancer Alliance Website <https://bit.ly/lower-gi>