

To all Practice Managers:

RE Faecal Immunochemical Test (FIT) in primary care

Dear Colleague

The Harrogate and District NHS Foundation Trust (HDFT) and NHS Harrogate and Rural District CCG (HARD CCG) have received Transformation Funding to implement a pilot for Faecal Immunochemical Test (FIT) in primary care for the group of patients without rectal bleeding who are classed as “low risk, but not no risk” of having colorectal cancer as set out in the 2015 NICE guidelines on the recognition and referral of patients with suspected cancer (NG12) and diagnostic guidance (DG30) published in July 2017.

This is one of many programmes of work aimed at increasing the proportion of cancers diagnosed at an early stage, and at reducing the numbers of people presenting with cancers in emergency settings. FIT in Primary Care in NHS Harrogate and Rural District CCG, will be implemented with effect from the 4 March 2019.

Please find enclosed written information and FAQs that have been designed to support this new process.

Please do not hesitate to contact us if you wish to discuss this.

Yours sincerely

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Information Pack for GP's
Symptomatic Faecal
Immunochemical Test (FIT)
Primary Care roll out
March 2019

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FIT test background

NICE Guidance DG-30 (July 2017) states: 'Faecal Immunochemical Tests (FIT) are recommended for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral'. The Harrogate and District NHS Foundation Trust and NHS Harrogate and Rural District CCG have received Transformation Funding to implement a pilot to explore FIT for the group of patients without rectal bleeding who are classed as "low risk, but not no risk" of having colorectal cancer as set out in the 2015 NICE guidelines on the recognition and referral of patients with suspected cancer (NG12). This is one of many programmes of work aimed at increasing the proportion of cancers diagnosed at an early stage, and at reducing the numbers of people presenting with cancers in emergency settings. As a pilot, the Faecal Immunochemical Test (FIT) is being implemented across Primary Care in NHS Harrogate and Rural District CCG, with effect from the 4 March 2019.

What is FIT?

The Faecal Immunochemical Test (FIT) is a test to detect hidden or 'occult' blood in stool samples. Unlike older FOB tests, FIT uses antibodies that specifically recognise human haemoglobin and so there is no need for patients to undergo dietary restriction prior to using the test. As it is antibody based, FIT is a more sensitive and specific test than the guaiac test, which most GPs would know as the old FOB test and reduces the chances of false positives.

Expected benefits of the FIT test

- Requires a single sample and will reduce the need for repeat tests.
- Sample collection devices are easier to use than guaiac-based faecal occult blood tests - more acceptable to people and so may increase test uptake.
- Possible reduction in invasive procedures.
- FIT specifically measures human haemoglobin (Hb) rather than any other blood in the diet.
- FIT has a high negative predictive value – as negative result makes colorectal cancer unlikely.
- They are also suitable for use with automated analysers, which allow high-throughput batch testing.
- FIT may have substantial analytical and practical advantages over guaiac-based faecal occult blood tests.

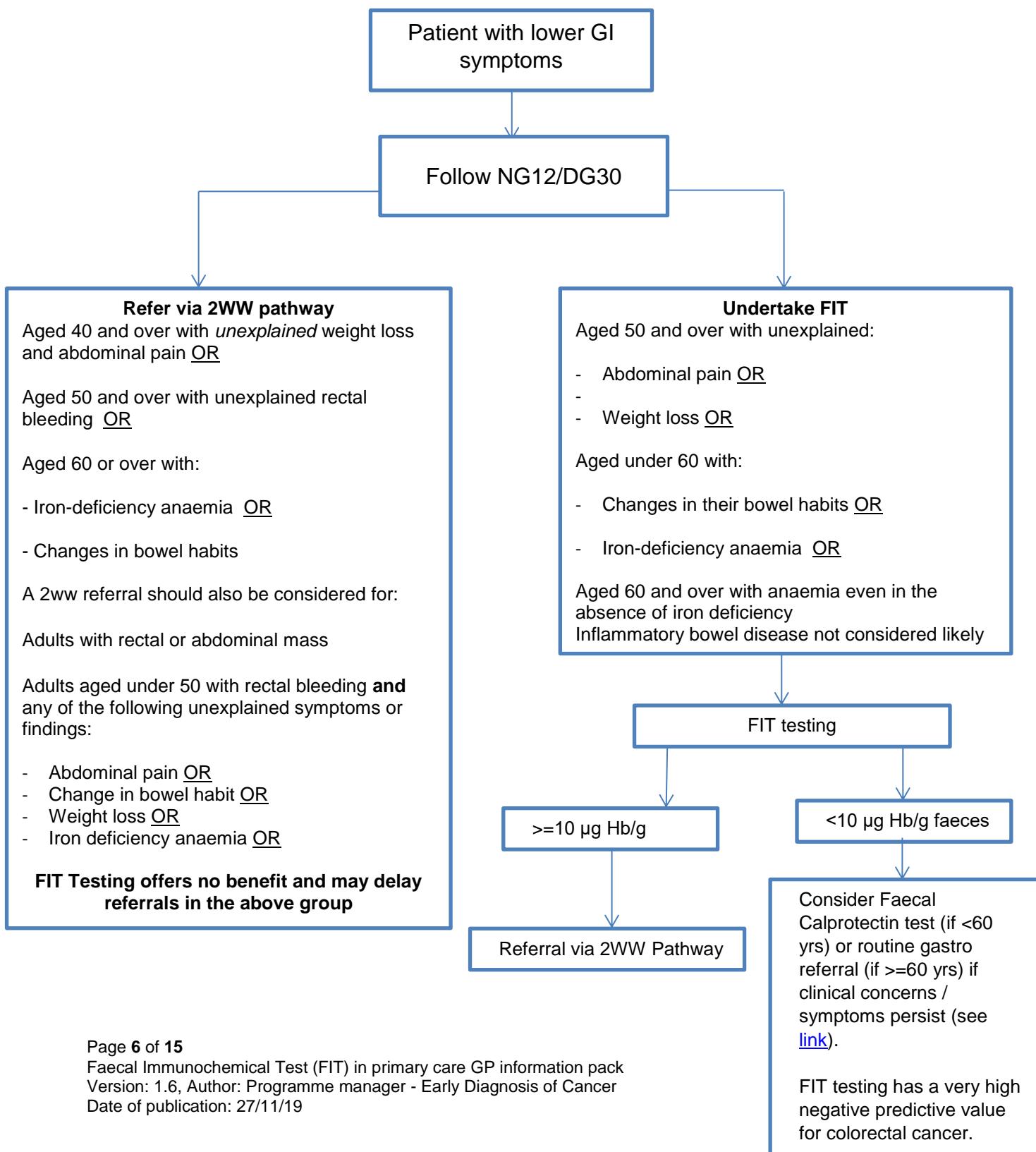
Which patients are eligible for FIT?

The NICE Guideline for Suspected Cancer (NG12) 2015 recommends that faecal occult blood tests should be offered to adults without rectal bleeding who were classed as "low risk, but not no risk" of having colorectal cancer. These are patients who:

- Aged 50 and over with unexplained Abdominal pain OR Weight loss OR

- Aged under 60 with changes in their bowel habits OR Iron-deficiency anaemia OR
- Aged 60 and over with anaemia even in the absence of iron deficiency
- Inflammatory bowel disease not considered likely

NICE published further guidance in July 2017 (DG30) which confirms that FIT is the faecal occult blood test of choice for this group of patients. DG30 guidance encourages use of the test for any patient with abdominal symptoms who doesn't fit the NG12 2WW criteria (refer to Figure 1 FIT clinical pathway).

Figure 1 FIT Clinical pathway**SUSPECTED CANCER: RECOGNITION AND REFERRAL****Faecal Immunochemical Test (FIT) in primary care pathway**NICE Guidance NG12: <https://www.nice.org.uk/guidance/ng12>Diagnostic Guidance 30: <https://www.nice.org.uk/guidance/dg30>

Testing kit:**When can GP's start using the test?**

The FIT test will be available to request from 4 March 2019 and the updated lower GI 2ww referral forms will also be available on ERS on the same date. ***Please remove old lower GI 2ww referral forms from your IT system as these will no longer be accepted after the 4 March 2019.***

How will we access the FIT test kits?

Your practice will receive a batch of FIT test kit from Harrogate and District NHS Foundation Trust pathology department. The FIT test kits will be delivered to your practice and will include:

- An outer printed envelope, including the lot number and expiry information of the picker for easier stock management
- A copy of patient information (Appendix 1)
- A patient Instruction Leaflet (Appendix 2)
- A sample picker and a sample bag
- A GP return envelope (this will not be a part of future FIT test kits)

How should we store the FIT test kits?

The FIT test kits should be stored at room temperature and they have extended expiry dates.

How do we order additional FIT test kits?

Practices need to have a stock management system to facilitate the reordering of kits, checking of expiry dates of kits.

If you do require additional FIT kits please contact the Pathology Blood Sciences reception on 01423 553000 (Lesley Bridson/Jeff Walker), via the email: hdft.pathology@nhs.net.

Pathology process (refer to Figure 2 FIT pathology pathway):**How will this process work?**

1. If a GP would like a patient to complete a FIT test, the GP would request a FIT test as an ICE referral (as with other test requests). It is important that the GP completes the clinical information requested on ICE to ensure an effective evaluation of the pilot.
2. FIT test can be found as part of **FIT & FC Integrated Pathway** under GPs profile on ICE. See figure/ [link](#)
3. GPs are advised to give the patient their usual safety netting advice.
4. The GP is required to print the completed ICE request form and attach the green ICE sample bag to the ICE request form.
5. The reception staff (or GP; practice level processes may vary) to

provide the patient with the FIT test kit and attach a printed patient label from the completed ICE request form to the green **FIT** sample bag in the FIT test kit. This is the small green bag in the FIT test kit and is separate from the green **ICE** sample bag mentioned in step 3.

6. The reception staff (or GP; practice level processes may vary) to hand the completed ICE request form (with attached green **ICE** sample bag) and FIT test kit to patient.
7. The GP Return envelope can be removed and discarded. GP Return envelope removal from the FIT test kits has been escalated to the provider and will not be a component of FIT tests kits in the future.
8. The reception staff (or GP; practice level processes may vary) to explain to the patient to put the sample picker (with sample) in green **FIT** sample bag, add Date of Sample to green **FIT** sample bag, put this in the green **ICE** sample bag. Hand this into practice reception along with the completed ICE request form as soon as possible (within 2 days).
9. Patients should be advised to follow the collection instructions in the patient leaflet carefully, including taking care not to let the stool sample touch the water in the toilet bowl. The patient instruction leaflet will give more detail on this.
10. The results will be sent to the GP practice via ICE.
11. The GP will need to advise patients to contact GP practice for results and next steps after **14 days of returning sample**.

Tracking of tests issued to patients but not returned to practice

A request has been submitted to Embed portal requesting DQ support for the EMIS practices and development of a SystmOne audit report to support the FIT pilot for tracking non returned tests. Practices will be informed once the report is ready, to facilitate practice level discussion for implementation of tracking of tests issued to patients but samples not returned to the practice. This tracking and audit will contribute to effective evaluation of the FIT pilot.

GP Practice READ codes

Once a sample pack has been given to the patient – the READ code should be entered onto the patient record.

Code hierarchy = Quantitative faecal immunochemical test

Systm1 = Xaf0H

EMIS = 47K

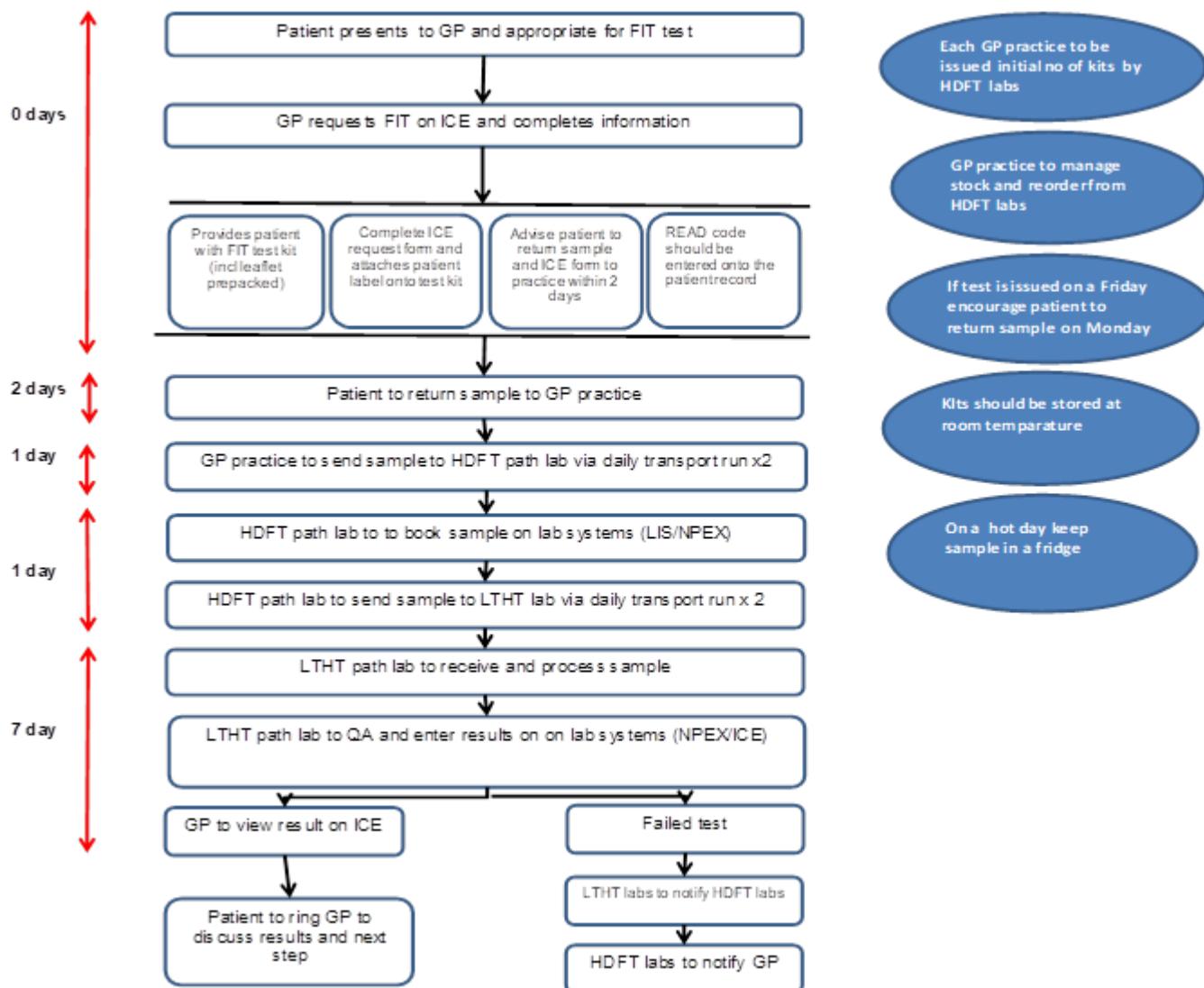
Snomed Code = 1049361000000101

Please note on SystmOne the code will be added automatically if you use the HARD FIT Pack template. This can be found on the TWR pilot page. HARD FIT Pack template has been added to the CCG S1 unit and published to the HaRD CCG Organisational group. SystmOne practices within the HaRD CCG will now be able to access the template via one of the following two methods:

The “PILOTS tab on the TWR Template” and the “Search facility at the bottom left corner of the screen (when in the patient’s record)”. For details and screenshots please refer to **Appendix 3 - How to access the HARD FIT Pack template for SystmOne practices**. If you have any comments/improvements that you would like to be made to the template please email Melissa.bayley@nhs.net.

A request has been submitted to Embed to develop a process for EMIS practices, updates will be sent to EMIS practices as soon as they are available.

Figure 2 FIT pathology pathway



Results:**How soon can I expect the results?**

GPs will be notified of the results through ICE (as with other tests) within 10 working days from the date the sample is received at the Harrogate and District NHS Foundation Trust pathology department from the GP practice.

What do I need to do with the results?

FIT test result	Action
> or = 10 ug Hb/g faeces	The GP should consider a lower GI 2ww referral for suspected cancer. The 2ww referral form has been updated to include a FIT test result. <i>Please remove old lower GI 2ww referral forms from your IT system as these will no longer be accepted after 4 March 2019.</i>
< 10 ug Hb/g faeces	Although a negative FIT test should give us a very high degree of confidence of the absence of a cancer, it is important to note that a negative test result cannot absolutely rule out colorectal cancer as occasionally tumours do not bleed, or bleed intermittently.
	Anaemia – The GP should consider an urgent OGD for investigation of anaemia.
	Diarrhoea - The GP should consider IBD esp. if the patient <45 years and/or any of the following: increased platelet increased CRP & increased Calprotectin (available for under 18-60 yrs only). If 60 years or over consider routine gastro referral if symptoms persist.
	If all above negative and clinical suspicion of cancer persists then GP should consider a lower GI 2ww referral.

Other:**What if a patient has a query about the test?**

If a patient has questions about the test or requires the information in different language, they will be signposted back to the GP practice and interpreting services should be requested as usual.

What if a patient has recently completed their Bowel Cancer Screening?

Irrespective of how recently your patient was screened by the national screening programme, their test result should be ignored in considering a patient presenting with new symptoms of concern.

Where can I access further information and support?

- Contact Dr Sian Greenwood (sian.greenwood@nhs.net), 01423 503035, Macmillan GP, NHS Harrogate and Rural District CCG if you have any questions about the pilot.
- Contact Dr Bruce Willoughby (brucewilloughby@nhs.net), 01423 799300 GP Lead for Planned Care, NHS Harrogate and Rural District CCG, if you have any questions about the pilot.

- Contact Dr Nuthar Jassam (Nuthar.jassam@hdft.nhs.uk), 01423 555665 Consultant Clinical Biochemist, HDFT, if you have any questions about the pilot.
- Your local Cancer Research UK Facilitator can also offer bitesize (15 minute) symptomatic FIT sessions in practice if you would like more information and can also offer training for non-clinical staff to support patients who may need to complete the test. If you would like to arrange a visit or call to discuss FIT please contact: Lubna Latif (Lubna.Latif@cancer.org.uk), 07827 986437.
- All the information provided will also be available on Intranet for NHS Harrogate and Rural District CCG practices.

Appendix 1 Patient information

Faecal Immunochemical Test (FIT) in primary care – for patients with symptoms

You are being asked to complete a Faecal Immunochemical Test (FIT). This checks for blood in your poo. If the test is positive, your GP will know that you have bleeding somewhere in your gut. This blood loss could be due to early bowel cancer or other non-cancer conditions. A FIT test will help your GP decide if you need to be seen by the hospital.

- **This is different from the FIT test for the national bowel cancer screening programme. That is for patients who do not have any symptoms.**
- It is very important that you follow the instructions on the leaflet you have been given whilst taking the sample.
- You need to return your sample to your GP practice soon as possible (within 2 working days) of receiving the kit.
- **You need to contact your GP practice for results and next steps after 14 days of returning sample to practice.**

What is being tested?

The Faecal immunochemical test (FIT) checks for a trace of blood in your poo. A positive FIT test will tell your doctor that you have bleeding occurring somewhere in your gastrointestinal gut. This blood loss could be due to ulcers, polyps, inflammatory bowel disease, haemorrhoids (piles), swallowed blood from bleeding gums or nosebleeds, or it could be due to early gut cancer. Anything that sticks out into the gut, like a polyp or tumour, and is rubbed against by the poo as it passes through, has the potential to bleed now and again. Often this small amount of blood is the first, and sometimes the only, symptom of early bowel cancer.

Which patients will be asked to complete FIT?

FIT is used to find early bowel cancer. Blood in the poo may be the only symptom of early cancer. If the cancer is detected before it spreads to other areas, there is a

good chance it will be cured. The signs and symptoms of bowel cancer are not always easy to see. In some patients, these signs and symptoms are clearer. In other patients where the signs and symptoms are less clear your GP may think it is unlikely you have bowel cancer but wants to be more certain that this is the case. In these circumstances a FIT test will help them decide. This is in accordance with national guidance.

How do you get tested?

1. Your GP will give you a pack containing all the information and equipment you need to collect your poo sample. Inside the pack you will find the
 - Outer printed envelope, including lot number and expiry information of picker for easier stock management
 - Patient information sheet
 - Patient instruction leaflet
 - Sample picker and sample bag
 - GP return envelope
2. Your GP will give you a completed GP test request form, if this has not been done then please ask the practice to do this for you.
3. Read the Patient instruction leaflet carefully before taking your sample.
4. Return the request form with the FIT sample to your GP practice soon as possible (within 2 working days).

How soon can I expect the results?

Your GP will receive results of analysis. **Please contact your GP practice for results and next steps after 14 days of returning sample to practice.**

Contact for queries:

Please contact your GP practice with any queries.

If you require this information in an alternative language or format (such as Braille, audiotape or large print), please ask the staff who are looking after you.

Appendix 2 Patient Instruction leaflet

**Patient Instructions for
Collecting Your Poo Sample**

NHS
Harrogate and District
NHS Foundation Trust

BEFORE YOU BEGIN...
Your GP has asked you to complete this essential test for diagnostic purposes.
It is important that you do this as soon as possible.
Please note: This kit is different from the Screening Kit and is a Diagnostic Test.

How to Collect Your Poo Sample

1 It is essential that you write your full name and the date the sample was taken on the tube label as shown here.

2 On the green bag label write your full name, date of birth AND the date that your poo sample was taken, using a ball point pen.

3 HOW TO CATCH YOUR POO SAMPLE
It is important that your poo sample does not touch the toilet water as this may affect the result. There are different ways to collect your sample, try:
A. Several layers of folded toilet paper
B. Hand inside a small plastic bag/glove
C. A clean disposable container

You may find a way that is easier for you, but **REMEMBER**
do not let your poo sample touch the water as this may affect the result.

Instructions continued overleaf...

4 COLLECTING YOUR POO SAMPLE
Unscrew the top of the sample tube anti-clockwise and scrape the end of the stick in the poo sample.

5 Ensure that the end of the stick is covered in sample but do not coat the rest of the stick. Replace the stick into the tube and twist clockwise to close securely. Only do this ONCE.

6 PACKAGING THE SAMPLE
Place your sample tube into the green plastic bag and press along the seal.

7 Place the green sample bag AND the GP request form in the GP return envelope.

8 Please check you have completed all the steps and return your sample to your GP surgery immediately.

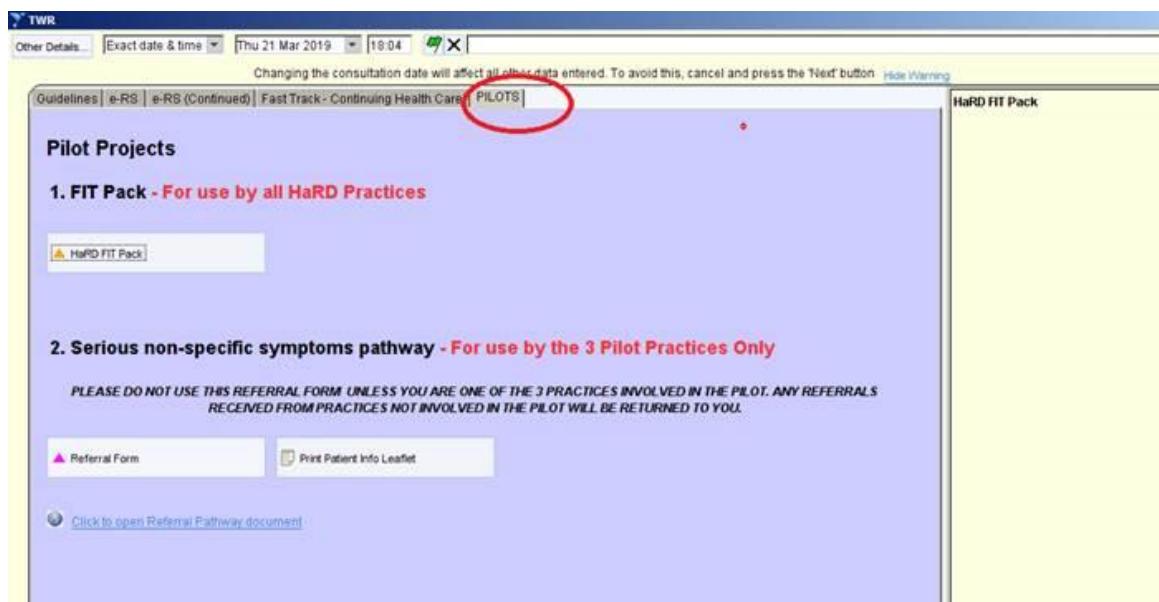
Your test result will be returned directly to your GP within 10 days.
You need to contact your practice for next steps after 14 days.
If you have any additional queries please contact your GP.

Alpha Laboratories Ltd - Harrogate IFU 02/2019 - V1.2

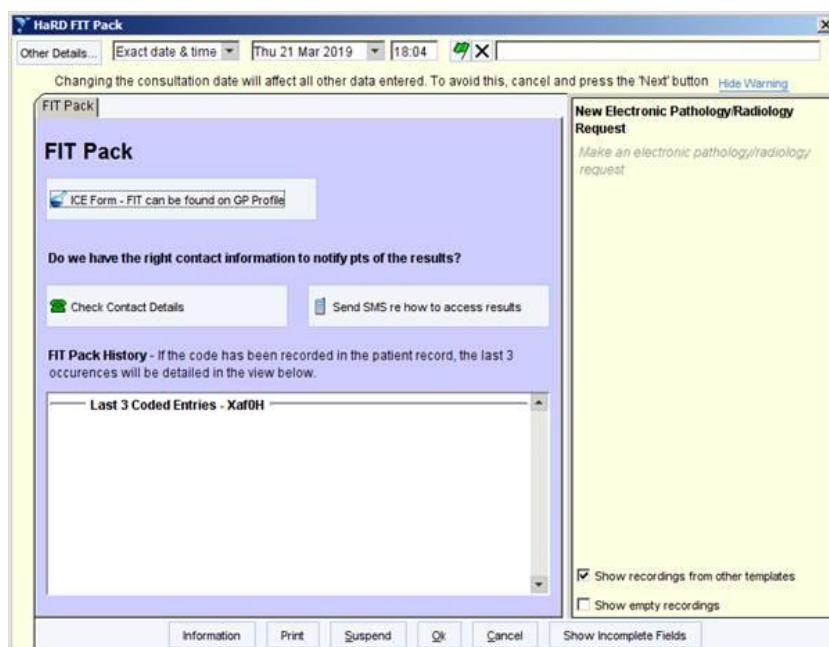
Appendix 3 - How to access the HARD FIT Pack template for SystmOne practices

SystmOne practices within the HaRD CCG will now be able to access the template via one of the following two methods:

Via the PILOTS tab on the TWR Template



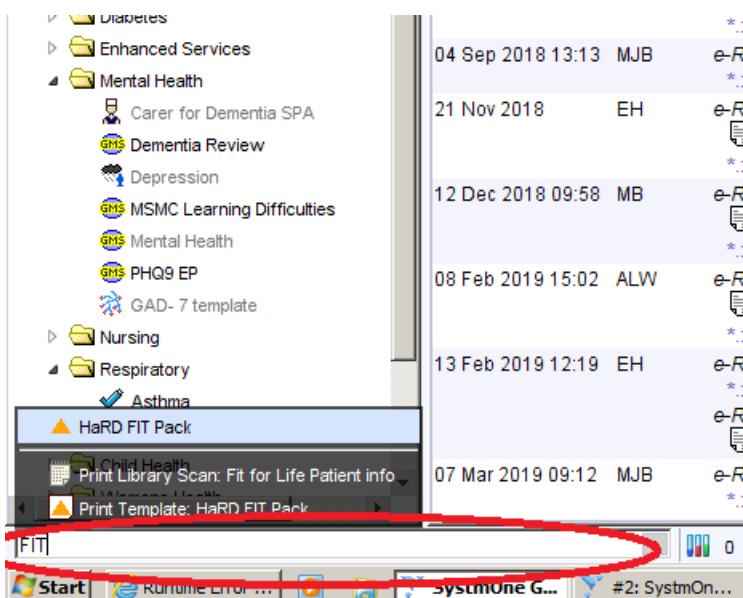
Then click on the HaRD FIT Pack button and the template will be presented.



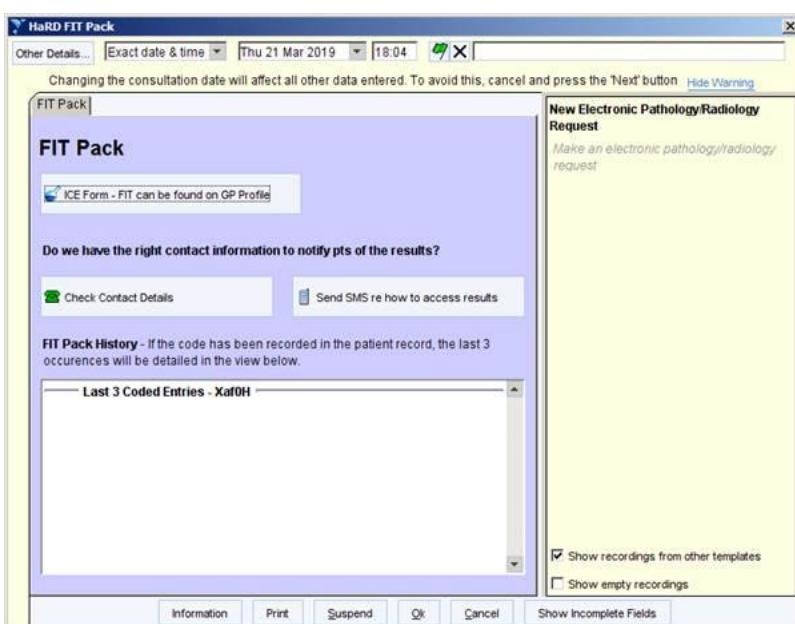
PLEASE NOTE: The doctor MUST click OK on this template once the ICE form has been generated as it is this that will trigger the Read code to be added automatically to the record. At that point the doctor can cancel out of the TWR template so that they are not forced to generate a task for referral team.

Or

Via the search facility at the bottom left corner of the screen (when in the patient's record)



Then click on the HaRD FIT Pack option that is displayed



PLEASE NOTE: The doctor MUST click OK on this template once the ICE form has been generated as it is this that will trigger the Read code to be added automatically to the record.