Logistics for Faecal Immunochemical Testing

Getting a FIT Sample from Patient to Laboratory

One of the challenges in clinical diagnostics is the logistics of getting a quality sample from the patient to the laboratory for analysis, to minimise pre-analytical variation.

When considering the detection of faecal haemoglobin (f-Hb), this is partly dependent on the technology to be employed.

In the days of guaiac based faecal testing, samples were sent to the lab in traditional blue-capped "stool pots". Whilst this was manageable using the old guaiac methodology, it is not appropriate for more advanced diagnostic techniques. Haemoglobin in native faeces is very unstable (Brown and Fraser[1]). It degrades rapidly at physiological and ambient temperatures. In passed faeces, which contains digestive enzymes, bacteria and fungi, it will degrade even more quickly.

With the move to a more sensitive technology based on an immunoassay, specific for human haemoglobin, it is vital to stabilise the haemoglobin present in the specimen collection device, prior to analysis, to protect it from degradation and maintain integrity.

Fortunately, the introduction of new quantitative faecal immunochemical testing (FIT) methods has vastly improved the method of faecal sample collection. This is an important aspect of the process since the clinical outcomes are dependent on the ability of the method to detect faecal haemoglobin at very low, versus undetectable concentrations.

Using the FIT kit sampling picker, the patient takes a small sample of their fresh stool and immediately places it into a preservative, contained within the FIT sample collection device.

The HM-JACKarc specimen collection device contains a proprietary buffer which can stabilise f-Hb in samples for up to 14 days at ambient temperature (up to 25 °C) or up to 120 days in the fridge (4°C). This was confirmed in a study by Carroll et al.[2] investigating the performance characteristics of four FIT methods.

To ensure the laboratory receives the best quality samples, the patient must be provided with the right tools and information to collect the sample correctly.

Based on extensive experience in delivering services for both screening and symptomatic programmes, Alpha Laboratories is able to help support the logistics for providing FIT testing. We can help patients, laboratories and clinicians, by developing complete customised FIT 'Patient Packs', that include everything the patient requires to take the sample correctly and return it to the laboratory.

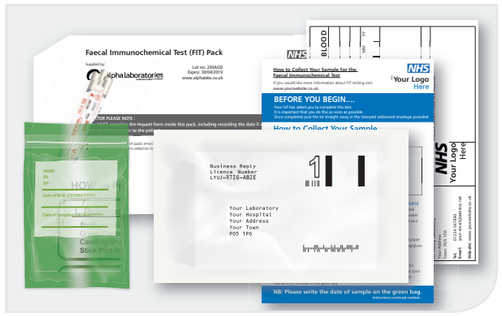
For The Logical Solution

START HERE...

1 The GP receives a box of FIT Patient Packs.
Each pack will include everything the patient needs to collect and return their sample.

Depending on individual programme arrangements this will include at minimum: the FIT sample collection device and detailed instructions for use, so the patient understands how to take their sample. It could also include any of the following: GP request form, Fe-Col® faeces collection paper, patient feedback survey card, green plastic bag for the sample device and a pre-paid return envelope, if it is necessary for the patient to mail their sample rather than return it to the GP surgery.

Each pack is clearly labelled with the lot number and expiry date of the collection device.



2 If a patient has presented to primary care with symptoms as described in NICE DG30, the GP completes the FIT request form, refers them for a FIT test and hands them the patient pack.

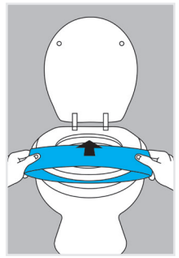
How to Complete the Test

3 Patients are often overwhelmed when asked to provide faecal samples. This can result in reduced uptake, or wasted kits if the sample is not collected correctly. To ensure trusts have the highest potential to engage with patients, bespoke instructions for use (IFUs) can be designed in collaboration with the trust. These provide step by step details, reassuring the patient about what to do and maximising the probability of the patient returning a viable sample.

4 Specific QR codes and/or web links to how-to videos and alternative instruction formats can also be included. This helps to ensure complete accessibility across all patient demographics.

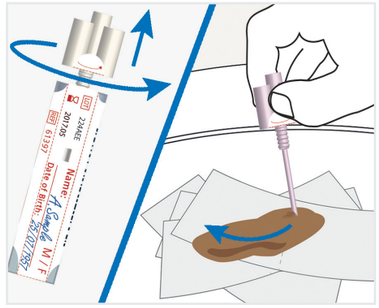
How to Collect the Sample

5 Obtaining a faecal sample can be challenging for patients. It is important that it does not touch the toilet water or come into contact with cleaning products. We recommend using Fe-Col® collection paper which enables the patient to use the toilet normally and collect a sample without risking contamination. After sample collection, the paper can be flushed away. Alternatively, patients may use wads of toilet tissue, a plastic bag or glove, or a clean plastic container to catch the sample.



How to Use the FIT Sampling Device

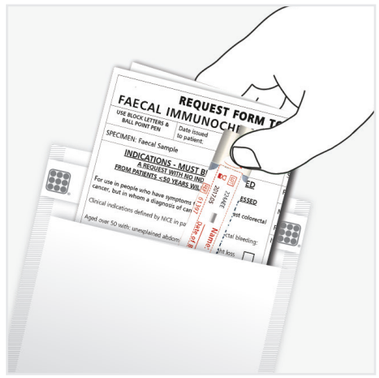
6 The FIT collection device (or "picker") is designed to be easy to use for patients. The small dimples on the sampling end of the device means an exact quantity (2 mg) of stool is collected and introduced to the buffer in the tube. Thus, there is no measuring required by the patient and the laboratory receives a sample that is pre-diluted in a 1:1 ratio.



Packaging and Returning the Sample

7 The collection device is pressure tested to withstand 95 kPa, and it has been verified by the Royal Mail that there are no special transportation requirements to send the sample by post. So, for programmes utilising a mail-in return process, patients can simply place the test into the return envelope, and drop it off in a post-box. Alternatively, some programmes just ask the patient to return the test to the GP surgery and these are added to the usual laboratory courier run.

8 For mailing purposes the collection device does not require specific transportation packaging and a small bubble lined poly-envelope can be provided to which a specific return address label is affixed. The envelopes provide some protection for the sample tube in the postal system and are water resistant so that any paperwork does not get damaged in transit.



9 The envelope can be sent as a standard large letter, which presents significant cost savings compared to transport for most patient samples.

Sample Received by the Laboratory

10 The sample arrives in the laboratory, pre-diluted, and ready for testing. The required paperwork is included with the test, so there is no need to match up tests and paperwork. The quantitative result can then be included on the paperwork, and returned to the GP or clinician for onward investigation.

No matter how you plan to facilitate the FIT test roll out, Alpha Laboratories can provide you with a flexible solution that works for you, to expand patient uptake and ensure viable samples are returned to the laboratory. By providing the right tools to complete the test correctly, you increase return rates, decrease waste, save money, and maximise the value of the service being offered.

References

1. Brown LF, Fraser CG. Effect of delay in sampling on haemoglobin determined by faecal immunochemical tests. Ann Clin Biochem. 2008;45:604-5.
2. Carroll MR, Seaman HE, Halloran SP Tests and investigations for colorectal cancer screening. Clin Biochem. 2014;47:921-39.

Find out how Alpha Laboratories can help support you in establishing a FIT service with education, product demonstrations and logistic solutions:
Please visit
faecal-immunochemical-test.co.uk