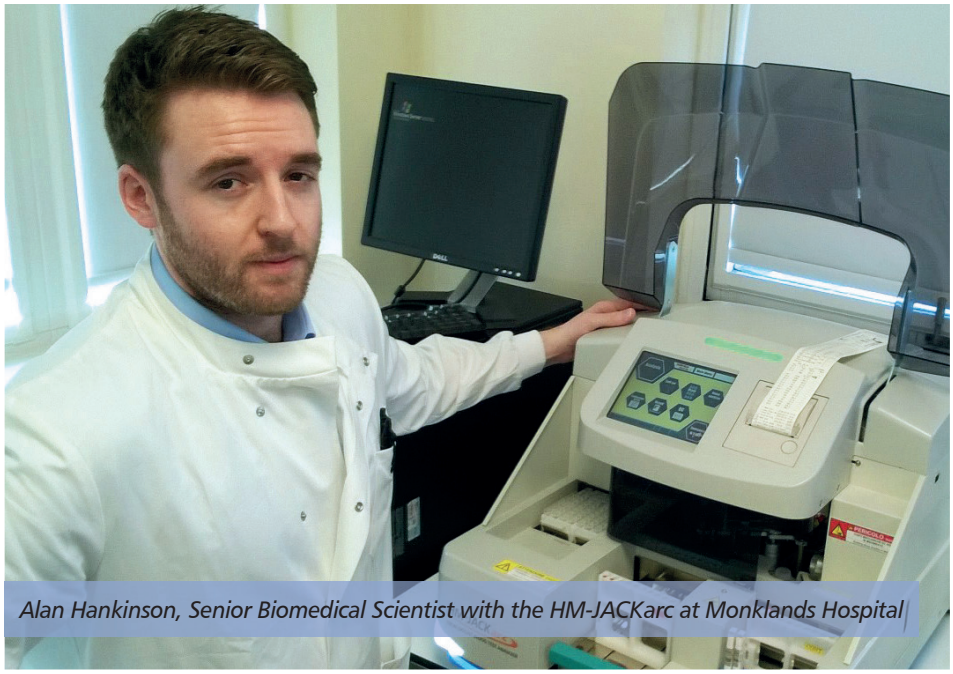
Evaluating a Faecal Immunochemical Test System for Symptomatic Patient Assessments

by Dr Ian Godber, Consultant Clinical Scientist, Clinical Lead (Biochemistry), Monklands Hospital, NHS Lanarkshire



Alan Hankinson, Senior Biomedical Scientist with the HM-JACKarc at Monklands Hospital

Dr Ian Godber's team at NHS Lanarkshire has evaluated the HM-JACKarc automated FIT analytical system for assessment of patients referred from primary care to endoscopy because of lower GI symptoms. As a result of this successful study, the process of rolling out a FIT service to their local General Practitioners (GP) is now well under way.

Matthew Davis, Alpha Laboratories Senior Product Manager, met recently with Ian to find out more from one of the first hospitals in the UK to offer a quantitative Faecal Immunochemical Test for haemoglobin (FIT) service.

Matthew: What prompted your laboratory to consider providing the FIT service?

Ian: We initiated investigations on Faecal Immunochemical Tests for haemoglobin (FIT) due to the withdrawal of traditional guaiac-based gFOBT, following Professor Callum Fraser's audit (ACB Scotland 2005). This highlighted that gFOBT should not be used to investigate symptomatic patients because of false positives and false negatives inherent when using this test.

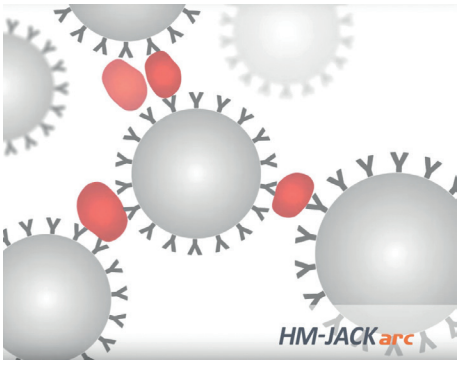
Our Gastroenterologists and GI surgeons agreed with the cessation of gFOBT but the knock-on effect has been an increased demand for lower GI tract endoscopy. In consequence, we needed to find a way to relieve this additional pressure on the endoscopy service.

The directorate structure of NHS Lanarkshire aided discussion. The divisional management to which I report is the same for both Diagnostics and Cancer Services, with similar structure and goals.

This helped to simplify communication and coordination on this project.

Matthew: Where did the original enquiry for the FIT service come from?

Ian: In 2013, we were approached by Alpha Labs, who asked if we would be interested in undertaking a pilot project. The current evidence in the literature at the time was limited but positive and showed favourable results, so we decided this project was worth progressing.



Matthew: How did you engage with all the necessary departments to progress the pilot project?

Ian: There was sufficient data in publications on FIT to suggest that the ability to "rule in" patients who potentially had cancer and fast track them through endoscopy was good. In addition, the potential to "rule out" patients with no significant pathology was interesting from a cost saving and improved efficiency perspective. The proposal was taken to the Chief of Medicine for NHS Lanarkshire, at the Wishaw General Hospital site, Mr Hakim Ben Younes, who is also a GI surgeon, and he was keen to proceed. There was sufficient evidence to put the concept forward as a proposal to the Gastroenterologists, in order to relieve the pressure on the endoscopy service. This was a key factor in gaining approval to proceed with the project.

Matthew: What were the outcomes from the pilot project?

Ian: With support from Gastroenterologists and GI Surgeons, the project was driven forward to a successful conclusion, which resulted in a publication: Clin Chem Lab Med. 2016 Apr;54(4):595-602. doi: 10.1515/cclm-2015-0617. The conclusions in the paper were essentially that the high negative predictive value of this test, at a cut off of 10μg Hb/g faeces, allows you to triage patients without missing any cancers, where the clinical sensitivity for colorectal cancer was 100%. In this study, all cancers had a f-Hb concentration greater than 150 μg Hb/g faeces.

There still remain a number of questions, mainly around other bowel pathologies that also generate a positive FIT result, and how these patients are managed. It may be that patients with very high f-Hb concentrations, say 150μg Hb/g faeces are sent straight to endoscopy, whereas those who are below that, but above 10 μg Hb/g faeces, are followed up clinically.

We think that there is potential to develop a clinical pathway that involves an initial screen with FIT, with patients then being seen in a clinic if the result is positive. The patient characteristics such as age, as well as the symptoms, may lead the clinician down a different track, favouring referral to Gastroenterology, with the possibility of a calprotectin test being more appropriate. However, the higher the f-Hb concentration initially the more important it is to initiate an urgent colonoscopy.

But, what about the negative FIT results? They may still need to be considered further and, depending on the clinical symptoms, there is possibly a case for following up these patients in 6 to12 months time with another FIT test.

Matthew: How did you manage to secure funding for a new test?

Ian: At present, the funding still isn't guaranteed and there is an on-going discussion as to where resources will come from. The NHS Board has indicated that the funding required could be moved from the endoscopy budget through into the laboratory budget. However, this becomes a bit of a grey area in that the test is actually being offered to patients seen in primary care, but the results are going back to secondary care, so it becomes part of the referral process for lower GI endoscopy.

Matthew: How did you work with the community GPs to implement the new test service?

Ian: We've engaged with a limited number of GP practices to start with and, over the next few months, we are starting to review how we actually provide this service and then fine-tune it. We've gone out and met with these practices and educated them, discussing how we are going to accept referrals for patients that present with lower GI symptoms.

We explain that they would normally have been referred for a lower GI endoscopy but now they will first be provided with patient FIT collection kits, pre-paid envelopes and patient instructions for collection of faecal samples.

So, the idea is that all referrals are done through an electronic mechanism for referral. At the time of referral in primary care, the patient is given an easy to use, hygienic, HM-JACKarc specimen collection device and asked to collect their sample and return it, with the laboratory request form, which identifies them, in the pre-paid envelope provided. They're told to do that immediately, with their next bowel motion, and send it off as soon as possible. All the devices go back to a central hub, here in Monklands Hospital in Airdrie.

We can't be seen as a delaying factor in triage. The endoscopy team receives the electronic referral, and they know to expect the f-Hb concentration result, therefore there's a time window which is currently being fine-tuned for us to return a FIT result. Based on the FIT result, they may choose to fast track that patient straight to colonoscopy.

There is then the potential to avoid expensive, unpleasant and potentially risky colonoscopies where they are not necessary. Pretty much every GP we've spoken with, to date, thinks this is a useful addition to the health service. Remember, at present, they don't have gFOBT, and currently the only option for patients with lower GI symptoms is to offer a referral for colonoscopy. Sometimes the patients' symptoms have resolved by the time they receive an appointment. Others are put on a long waiting list. Both the patient and the GP can now feel that something is being done at an earlier stage. Patient feedback will be surveyed once this approach is rolled out to a higher number of GPs. However, there is the potential for this not to work! There are over 100 general practices in NHS Lanarkshire and, when FIT kits were sent out during the pilot project, there was only a 50-60% return rate, so we really want to ensure we have full engagement with the GPs and patients before rolling it out any further. We would like to engage more with general practices first, to ensure they are fully briefed to gain maximum participation from the patients, before rolling it out to all of NHS Lanarkshire.

Matthew: What were the outcomes from the new test implementation?

Ian: The lessons to be learnt are to engage with all parties concerned, maybe forming a group to discuss the patient pathway and implementation involving the laboratories, GPs, GI surgeons and Gastroenterologists, as well as the endoscopy services.

Impacting Abdominal Pain Patient Pathways Through Diagnostics