



Royal Preston
Hospital and
OC sensor
see **pages 3-5**

Get your laboratory FIT for the future

In 2015 the National Institute for Health and Care Excellence (NICE) amended NICE Guidelines 12 Suspected cancer: recognition and referral, to include Faecal Occult Blood Tests (FOBT)

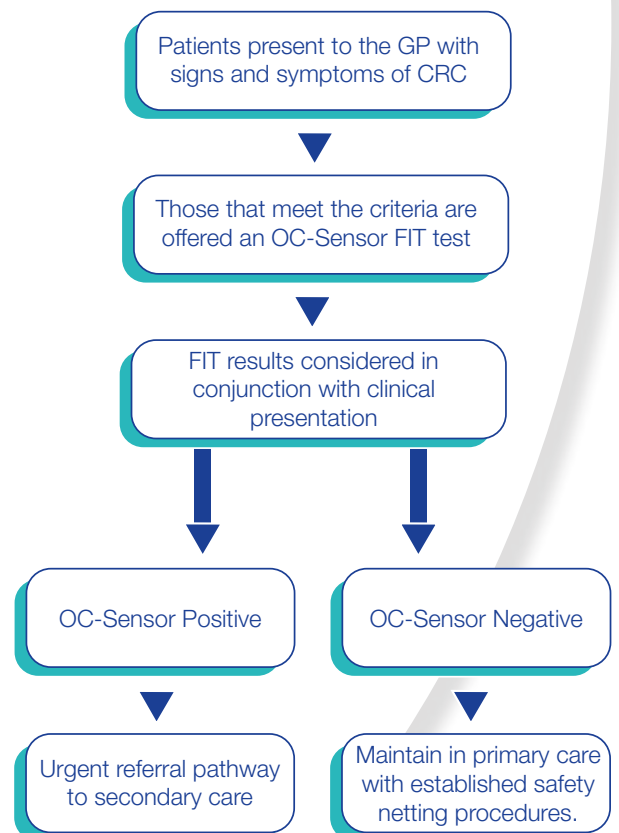
Under the revised NG12, patients presenting to their GP meeting required criteria should be offered a test for Occult Blood in faeces. The results would guide decisions about patient management and referral pathways to secondary care.

Fortunately, the old fashioned guaiac FOBT is rarely available in UK laboratories and given the limitations of test should not be reinstated. With over 200 publications supporting the OC Sensor, the benefits of quantitative FIT over guaiac are well documented. Almost all Bowel Cancer Screening programs are adopting FIT as the test of choice.

OC Sensor is the leading FIT product, used by over 2500 laboratories in

over 43 countries. Since its launch in 1989, OC Sensor has achieved FDA registration (the only quantitative FIT to do so) and grown internationally to distribute 75 million samples annually (~98% of the worldwide market). The use of FIT in the symptomatic population is supported by a growing number of peer-reviewed publications and has been supported by the NICE Diagnostics Guidance Document on quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care (July 2017).

The NICE Diagnostic Guidance document considered available published data and concluded at a cut off of 10 μ g/g, the OC Sensor demonstrated a NPV of 99.8% for colorectal cancer and proved more cost effective than offering both Guaiac and Straight-to-Test pathway models. Research is ongoing into fine tuning the FIT pathway for symptomatic patients. You can quickly and efficiently offer FIT, simply by installing the OC Sensor.



Featured in this issue:

- Royal Preston Hospital Adopts the OC-Sensor Faecal Immunochemical Test
- Advantages of the OC-Sensor FIT Sampling Device




OC-SENSOR io


No purified water. Please supply.
OK

“In primary care, undetectable Fhb is a good ‘rule-out’ test for significant bowel disease and could guide who requires investigation”

Mowat et al. BMJ August 2015¹

Royal Preston Hospital Adopts the OC-Sensor Faecal Immunochemical Test



The Royal Preston Hospital, Lancashire, has adopted OC-Sensor Faecal Immunochemical Test (FIT) into their Clinical Pathology services to provide a fast, accurate method for the diagnosis of colorectal diseases.

Lancashire Teaching Hospitals NHS Foundation Trust, of which the Royal Preston Hospital is part, provides acute services to a local population of around 400,000 and provides a number of tertiary services to around 1.6 million people. The Royal Preston Hospital provides specialist regional oncology (radiotherapy and chemotherapy) and complex cancer surgery services to the population of Lancashire and South Cumbria.

Dr Martin Myers, Consultant Clinical Scientist and Laboratory Director of Clinical Biochemistry at Lancashire Teaching Hospitals NHS Foundation Trust and Dr Natalie Hunt, Principal Clinical Biochemist discuss the introduction of the OC Sensor FIT technology into the Royal Preston Hospital.

Where did you first hear about the - FIT?

Dr Martin Myers: We read about FIT in the NICE guidelines. We stopped the faecal occult blood test (FOBT) here about 5 to 8 years ago. We liked the principal of an occult blood test but rejected the old assay as we felt that it was not very specific. When FIT was introduced, we believed that we had found an assay that would produce the accurate results that we were looking for.

Dr Natalie Hunt: The representative from MAST visited the laboratory to introduce us to the OC-Sensor FIT product.

What prompted you to explore the adoption of the OC-Sensor FIT?

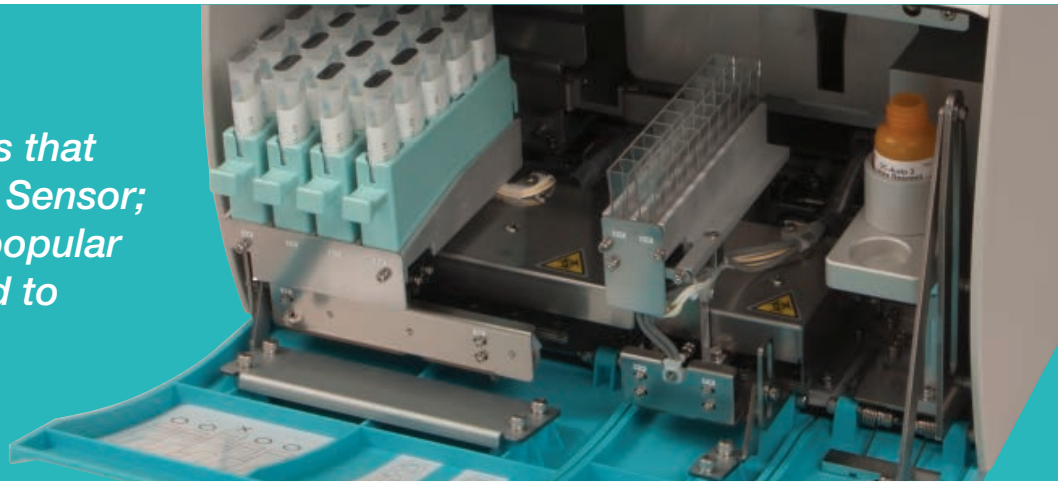
Dr Natalie Hunt: Most of the research papers and studies that I have read use it; worldwide it is the most popular FIT assay and we decided to implement a trial. We did a parallel study sending patients two collection devices, one sample was sent to a reference lab and the other tested here at the Royal Preston on the OC-Sensor for comparison. It was on the basis of this study that we decided to adopt the use of the OC-Sensor. When we verified the OC-Sensor in the laboratory, we got very good results. It is easy to use and the clinical outcomes are a major plus point.



Susan Wareing, Lead Biomedical Scientist Clinical Biochemistry.

Dr Martin Myers: We were interested in the test and were fortunate to be supported by General Practitioners in the area through our GP liaison group where we meet to discuss current and future practice. There are always a number of ways to go live with a test: we can push it forward onto our clinicians, recommending it as best practice, or sometimes the clinicians will come to us and ask for a certain test. The beauty of FIT is that the driver for adoption came from both directions; it was our CCG that asked we implement it in the end. Initially the reference lab were able to support us with testing while we introduced the OC-Sensor here at the Royal Preston. We liked the new assay as scientists and

“Most of the publications that I have read used the OC Sensor; worldwide its the most popular FIT assay, so we decided to have a trial”



GPs embrace decision diagnostics to inform them as to which care pathways to put their patients on, which the FIT provides.

How did you escalate this further and what challenges did you face?

Dr Martin Myers: We always have to discuss certain requirements as it is a new test. However in terms of clinical obstacles, none were presented from the team that wrote the local cancer guidelines and the GP practices just wanted assurance from ourselves that the test was of acceptable quality. There was no real opposition to introducing the OC-Sensor, everybody wanted it.

How many tests are you doing now?

Dr Martin Myers: The Royal Preston has just gone live with the OC-Sensor. We started with about 20 faecal immunochemical tests per week and we are seeing the numbers of tests referred to the department increase from hospitals outside of the Trust.

What stakeholders were involved in the adoption of FIT and how do you engage with them?

Dr Martin Myers: We are about to publish a FIT information sheet for GPs so we are expecting the uptake from them to increase significantly. We also have a series of aligned meetings planned with endoscopists, GP lead cancer clinicians and oncology surgeons as part of the multi stakeholder strategy we are adopting to ensure that the assay meets the requirements of all the interested parties. Because it is a clinical diagnostic we have to get the clinicians on board. We have received positive feedback from them to date. The last part of the jigsaw is the endoscopy department as the FIT should reduce the pressure on them. There are some interesting studies being undertaken currently looking at patients completing a faecal immunochemical test while waiting for an endoscopic procedure. Dependent on the results of the test this would speed up their position in the queue.

Dr Natalie Hunt: We have also involved other stakeholders in the care pathway, such as gastroenterology, who have seen the guidelines and are keen to use faecal immunochemical testing to triage patients and use resource on the most appropriate people. The clinical biochemistry laboratory at the Royal Preston Hospital has a protocol to repeat any negative results obtained from a

faecal immunochemical test. This provides reassurance for surgical colleagues working in the colorectal and oncology departments providing an additional safety net. The department also collects the audit data on these clinical outcomes for future reference.

How did you go about implementing the service?

Dr Martin Myers: We spoke to all the individual groups of stakeholders and it has all been very positive. One reason is that the OC-Sensor FIT provides a biomarker that will make an economic difference to the patient pathway. Clinicians and healthcare practitioners at the Trust are now examining the health economics of the pathway: One FIT test is far cheaper than an endoscopic procedure. In nearly every pathway in the NHS, the pathology cost is probably the smallest by far. By utilising new technologies in pathology, we can drive down costs in other areas. This is exactly what the FIT allows us to do.

What improvements has FIT delivered in the care pathway?

Dr Natalie Hunt: The long shelf life of the OC-Sensor enables stocks of sample collection devices to be retained by both the Trust and GP practices, which eliminates the need to call the laboratories to request the test. The result is better and faster logistics - from a patient being asked to provide a sample to getting the results back from the laboratory to the GP.

Dr Martin Myers: This is one of the main practical improvements from the previous system. The improved logistics makes the processing of the samples and hence obtaining the results far quicker and more streamlined. The decision process is speeded up which provides reassurance to the patient and a clear care pathway objective for the clinicians treating the patient.

What are the outcomes of implementing FIT?

Dr Martin Myers: We went online with the test here in June. It is early days for us in terms of assessing patient outcomes, however, we are very aware of the increasing pressure on the endoscopy department and we are keen to assess the role of FIT in triaging patients in secondary care. We believe the number of endoscopy procedures requested will decrease due to the introduction of the faecal immunochemical test. The result of this will be that

“Operationally it is great, the collection device is great and the use of the machine is great”

more appropriate patients will be seen faster by the endoscopy department. In turn, these patients will have a shorter wait for their results and those people in need of further treatment will be seen faster.

Ms Susan Wareing, Lead Biomedical Scientist Clinical Biochemistry and Carol Wignall, Senior Biomedical Scientist at The Royal Preston Hospital discussed the introduction of the OC-Sensor to the laboratory.

What has your experience been with the OC Sensor products?

Susan Wareing /Carol Wignall: We have seen the value of the faecal immunochemical test. Everyone has picked up the test very easily. OC-Sensor is very easy to use with minimal maintenance. We are currently processing one run a week at the moment but this is expected to increase. We have sent out 600 sample collection devices to GPs so the long shelf life of the product is a huge advantage.

What are your thoughts about the use of the OC-Sensor and FIT for the future?

Dr Martin Myers: Operationally the OC-Sensor is great, the collection device is great and the use of the machine is great. We are becoming a reference site for FIT because we have the expertise and people have the confidence not only in the reputation

of the department but also in the science behind it. A huge amount of verification goes on at Preston, getting through the filter here is a very high bar to cross. We know that we have confidence in the OC-Sensor for this reason.

My main question is: Is what we have now better than what we had before?

The answer is yes.



REFERENCES

Peer reviewed publications for the use of FIT as a decision making tool for the symptomatic population.

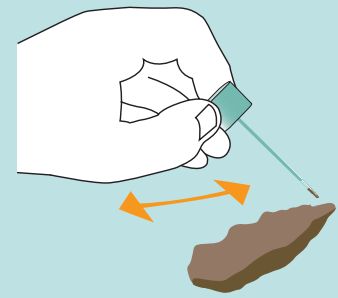
1. McDonald PJ, Didby J, Innes C, et al. Low faecal haemoglobin concentration potentially rules out significant colorectal disease. *Colorectal Dis* 2013; 15e151-9.
2. Cubiella J, Salve M, Diaz-Ondina M, et al. Diagnostic accuracy of faecal immunochemical test for colorectal cancer in symptomatic patients: comparison with NICE and SIGN referral criteria. *Colorectal Dis* 2014; 160273-82.
3. Auge JM, Fraser CG, Rodriguez C, et al. Clinical utility of one versus two faecal immunochemical test samples in the detection of advanced colorectal neoplasia in symptomatic patients. *Chem Lab Med* 2015 Jun 27. pii: /j/cclm.ahead-of-print/cclm-2015-0388/cclm-2015-0388.xml. doi: 10.1515/cclm-2015-0388 [Epub ahead of print].
4. Rodriguez-Alonson L, Rodriguez-Moranta F, Ruiz-Cerulla A et al. An urgent referral strategy for symptomatic patients with suspected colorectal cancer based on a quantitative immunochemical faecal occult blood test. *Dig Liver Dis* 2015 May 15. pii:S1590-8658(15)00310-2. doi: 10.1016/j.dld.2015.05.004. [Epub ahead of print].
5. Mowat C, Digby J, Strachan JA, et al. Faecal haemoglobin and faecal calprotectin as indicators of bowel disease in patients presenting to primary care with bowel symptoms. *Gut* Published online First: 20 August 2015 doi:10.1136/gutjnl-2015-309579 – open access.
6. Godber IM, Todd LM, Fraser CG, et al. Use of a faecal immunochemical test for haemoglobin can aid in the investigation of patients with lower abdominal symptoms. *Clin Chem Lab Med* 2015; in press.

Advantages of the OC-Sensor FIT Sampling Device

Sample collection

Since it is often not possible to produce a faecal sample on demand, FIT sample collection devices need to be robust and intuitive for home use.

With 75 million sold every year, the user friendly state-of-the-art design and construction of the OC Sensor collection device is well proven.

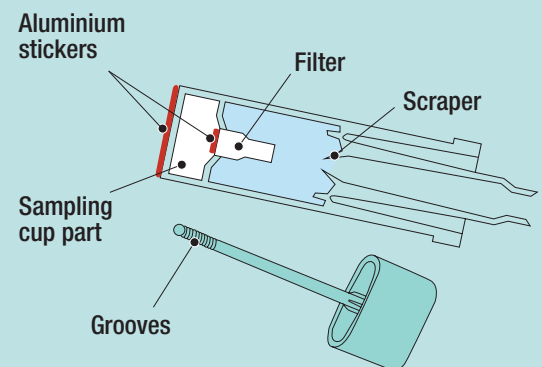


Tough and Robust

The construction of the OC Sensor sample collection device.

The robust design of the sample bottle is down to the double walled polypropelene construction. You can literally jump up and down on them!

Although exempt, the OC Sensor surpasses the testing required by UN3373, ensuring hygienic transportation and that the laboratory receives a viable sample each and every time.

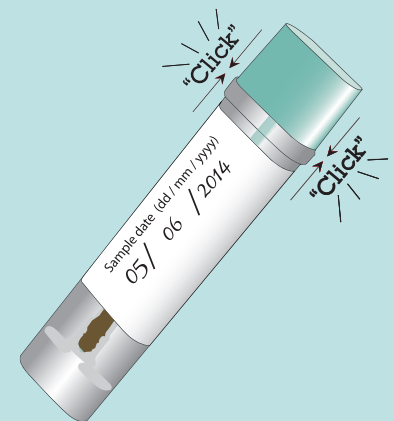


Hygienic

Collection of stool samples is not pleasant, but with the OC Sensor it has never been easier or more hygienic.

The sample lid is removed with a simple twist and pull action, then the probe is scraped across the stool sample and re-inserted into the sample bottle, which closes with an audible "click" to confirm the cap is securely fastened and sample contained.

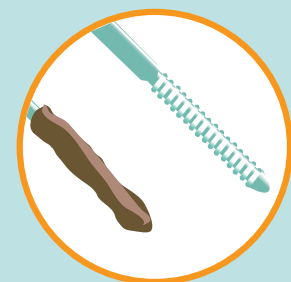
Excess sample is contained within the bottle recess and the hollow lid to ensure that excess stool matter does not escape during closure.



Accuracy in sample collection

Thanks to exceptional manufacturing quality. The groove of the sample collection probe accurately holds 10mg of stool sample (+/- 7%) across a full range of stools.

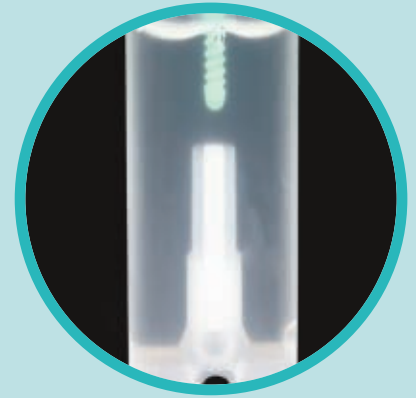
Passage through the scraper in the bottle ensures that all excess stool is withheld and that only 10mg of sample is inserted into 2ml of buffer, the basis of quantification.



Unique integrated filter

The inclusion of an integrated filter into the sample bottle is essential to prevent particulate matter and faecal fats from contaminating and blocking the analyser. This is key to preventing carry over but also keeps hands-on maintenance in the laboratory to a minimum.

The filter also makes the sample device spill proof, even after opening! Liquid is only available in the sample cup portion when squeezed by the analyser during processing. When released, the sample is withdrawn back through the filter to prevent contact with laboratory staff and saves the need to recap prior to storage.



Intuitive

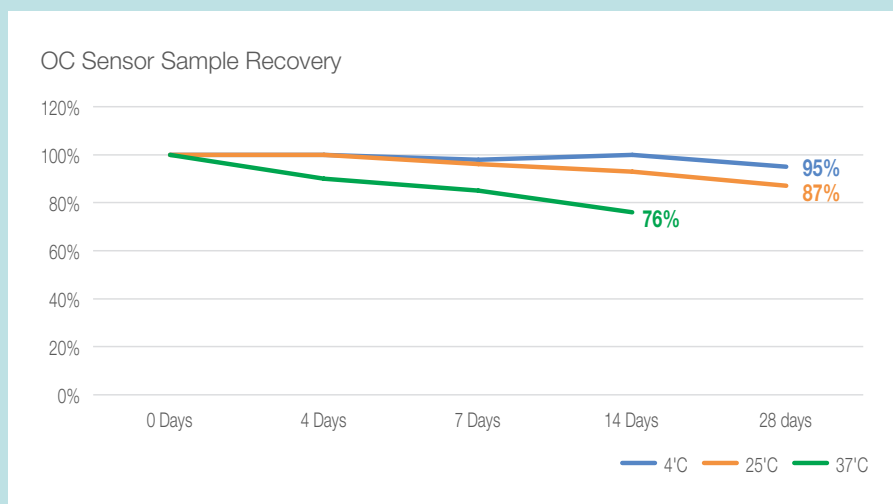
Simplicity of use of the OC Sensor sampling device has been demonstrated

In Scottish population based trials, only 0.2% of samples (n=>40,000) were returned to the laboratory and determined not suitable for testing. This was mirrored by Zobero et al in a Spanish population based comparison showing that errors for OC Sensor were more than 10 times lower than the alternative product.

Taking the Heat!

Haemoglobin is a very unstable protein. Because FIT in the symptomatic patient cohort is looking for extremely low volume of haemoglobin in the stool, it is essential that the patient collect the sample directly into the sample container to preserve it.

Over 30 years of ongoing research has gone into the development of the OC-Sensor sample collection buffer. While trials vary in methodology. Studies in Australia by Symmonds EL, *et al* 2017 have shown naturally positive OC-Sensor samples to be stable (defined as retaining >80% of the starting concentration) for 8 days when exposed to a constant 35°C. This mirrors manufacturers data which demonstrates 87% recovery after exposure to 25°C for 28 days and 76% recovery after storage at 37°C for 14 days.



FITnewsletter



www.FIT-Screening.co.uk

Established as a knowledge base for GP's and laboratory professionals, the FIT-screening.co.uk is an informative and easy to navigate site for all FIT related information.

Visit www.FIT-Screening.co.uk for the very latest!



IVD solutions through partnership

MAST® Group Ltd.

Mast House, Derby Road, Bootle, Merseyside L20 1EA
Tel: + 44 (0) 151 933 7277 Fax: + 44 (0) 151 944 1332 e-mail: sales@mastgrp.com

MAST® Diagnostica GmbH

Feldstrasse 20, DE-23858 Reinfeld
Tel: + 49 (0) 4533 2007 0 Fax: + 49 (0) 4533 2007 68 e-mail: mast@mast-diagnostica.de

MAST® Diagnostic

12 Rue Jean-Jacques Mention CS 91106 80011 Amiens CEDEX 1
Tél. + 33 (0) 322 80 80 67 Fax + 33 (0) 322 80 99 22 e-mail: info@mast-diagnostic.fr

www.mastgrp.com