IVD solutions through partnership

Mast Group

OC-SENSOR

Faecal Immunochemical Testing for Symptomatic Patients

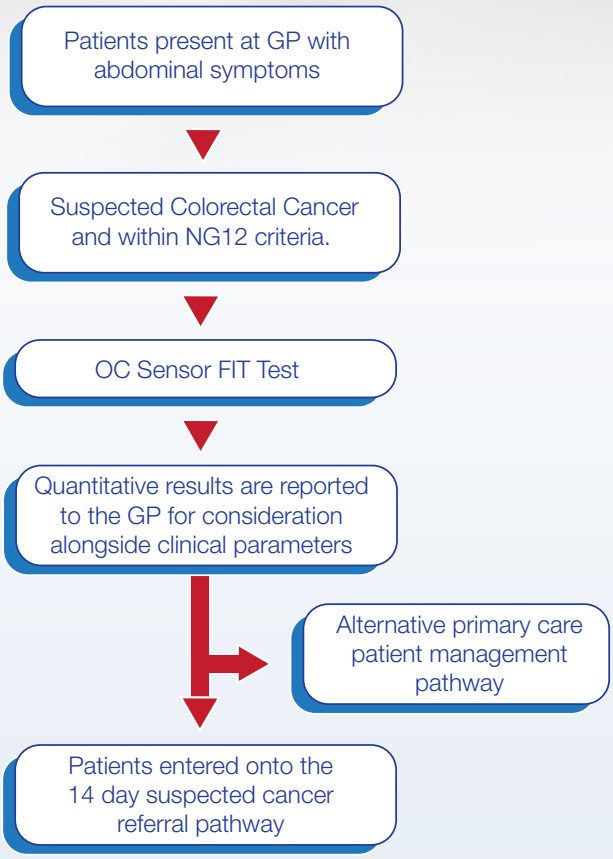
- Simple, hygienic and fully automated
- Quantitative, sensitive and specific
- Positive impact on endoscopy resources

Urgent cancer referral – how does your laboratory FIT in?

A major challenge facing clinicians is to identify patients suspected of colorectal cancer in primary care. In 2013-14, only 9% of all urgent '14 day' suspected cancer referrals resulted in a diagnosis and treatment for cancer[1]. In the same year 94% of NHS trusts met the 14 day target, but the 62 day target was met by only 74% of trusts[2] incurring penalties for breached deadlines.

Patients can sometimes present to GP's with anaemia, palpable abdominal or rectal masses which would always require further investigation. However, the majority of patients present with a range of non-specific symptoms including abdominal pain, weight loss, anaemia, changes in bowel habits, perianal symptoms and rectal bleeding. All these symptoms can usually be explained by more common conditions hence their low predictive value[3].

Recently the National Institute of Health and Care Excellence (NICE) issued a revised NG12 'Suspected Cancer: Recognition and Referral' guideline, which now includes the use of Faecal Occult Blood testing in the patient diagnostic pathway prior to enrolment on the '14 day' pathway for specific patient cohorts. Unfortunately it did not differentiate between the traditional Guaiac FOBT which is both analytically and clinically inferior to the newer innovative Quantitative Faecal Immunochemical Tests (FIT).



NICE Guidance 12

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.**
- **are aged under 60 with: changes in their bowel habit or iron-deficiency anaemia.**
- **are aged 60 and over and have anaemia even in the absence of iron deficiency.**

Sample collection using quantitative FIT is simple and hygienic. A single sample is sufficient to rule out the presence of detectable haemoglobin and provide reassurance to the patient and clinician.

The use of quantitative FIT within the NG12 detection and referral pathway will help to define those patients in need of an urgent '14 day' referral. Quantitative FIT is approximately 100 x more sensitive that traditional guaiac tests, detecting more early stage cancers and advanced adenomas. While clinical judgement should always prevail, a benefit of quantitative FIT could be the added confidence to not enrol a patient on the urgent referral pathway following a negative result. This saves both patient inconvenience and pressure on already scarce endoscopy resources.

> 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 2015[1]

> The negative predictive values of FHb for colorectal cancer, higher-risk adenoma and IBD were **100%, 97.8%** and **98.4%**, respectively
>
> Mowat et al. BMJ August 2015[1]

Triage with Quantitative FIT

Alternative innovative research is underway to incorporate quantitative FIT as a triage tool to 'rule out' significant bowel disease in secondary care. Research under taken by *Mowat et al*. 2015[4] demonstrated that the OC Sensor has a negative predictive value of 100% for CRC and 97.8% for other significant bowel disease[3] at a cut off of 10µg/g (50 ng/ml).

Currently there is immense pressure on endoscopy resources. With limited time, capacity and financial support, the ability to be able to offer a 14 day outpatient appointment is extremely challenging.

Mowet et al. 2015[4] demonstrated that if FIT is used to triage all patients in their cohort approximately a third will have negative tests and do not require immediate investigation.

Following a negative test, patients could be reassured that they are very unlikely to have cancer without the need for a disruptive and invasive investigation, improving compliance and the overall patient experience.

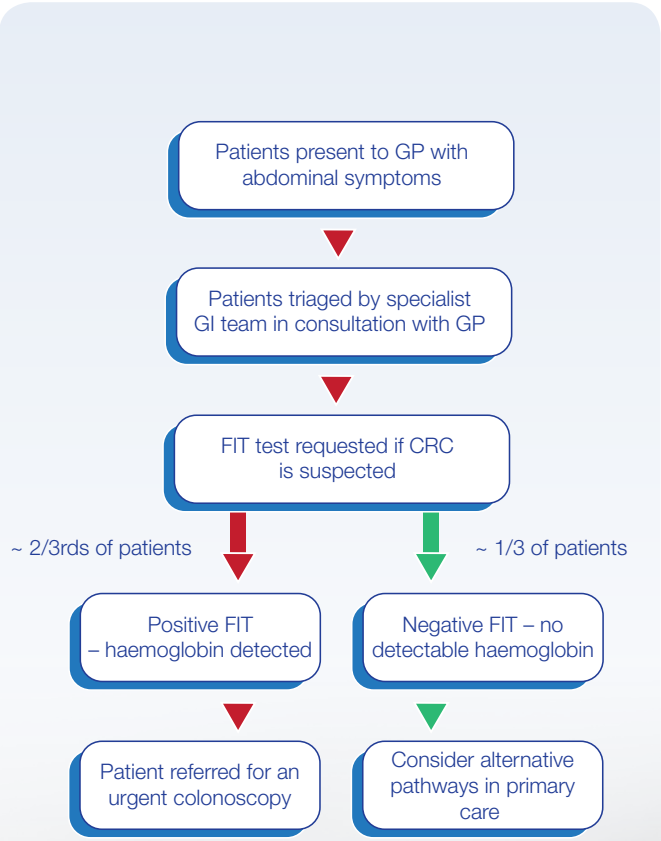


Diagram developed from *Mowat et al.* 2015.

OC-SENSOR

OC Sensor is the leading quantitative FIT product, used worldwide in over 42 countries. Manufactured by Eiken Chemical Co. since 1989, OC Sensor is the primary choice for both national bowel cancer screening programs and routine laboratories.

Building on over 20 years of experience, the OC Sensor platform features a unique sample collection device, compatible with a choice of dedicated analysers ensuring the optimum solution for your laboratory.

OC Sensor Sample Collection Device Innovative design, ease of use and high quality manufacturing ensure that sampling for FIT analysis could not be simpler or more reliable.

Features include:

- **Durable design – prevents accidental damage and reduces repeat sampling**
- **Flat surface – easy to write on surface for patient data**
- **Integrated scraper – ensures accurate/ reproducible stool volume for quantitative measurement.**
- **Unique Integrated filter – removes the potential of faecal matter contaminating and blocking the automation.**
- **Unique Sample buffer – provides market leading stability for faecal haemoglobin.**

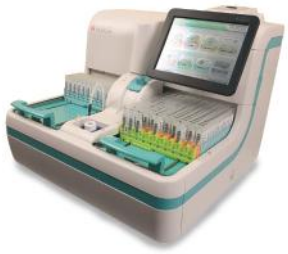
The OC Sensor Analysers offer all the routine features you would expect and a lot more:

- **One touch, walk away operation.**
- **Simple to use software via the onboard touch screen.**
- **Ready to use reagents to reduce hands on time, pipetting errors and improved reproducibility**
- **Fully automated calibration curve generation, daily controls, primary tube retesting and prozone check function**

OC-SENSOR iO

– small to medium throughput

OC-SENSOR PLEDIA



– medium to high throughput

1. Health Services Management Centre at the University of Birmingham, ICF GHK Consulting. Measuring up? The health of NHS cancer services. London: Cancer Research UK, 2014.
2. NHS England. Provider-based Cancer Waiting Times for Q3 2014–15. Secondary Provider-based Cancer Waiting Times for Q3 2014–15. 18 February 2015. 2015. http://www.england.nhs.uk/ statistics/2015/02/18/provider-based-cancer-waiting-times-for-q3-2014-15/
3. Hamilton W, Coleman MG, Rubin G. Colorectal cancer. BMJ 2013;346:f3172.
4. Faecal haemoglobin and faecal calprotectin as indicators of bowel disease in patients presenting to primary care with bowel symptoms. Mowat et al. 2015 BMJ August 20, 2015 as 10.1136/gutjnl-2015-309579

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