IVD solutions through partnership

Mast Group

OC-Sensor

The World's No.1 FIT

FIT in Symptomatic Pathways

For more information visit our **NEW FIT website** FIT-Screening.co.uk

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

Getting to the bottom of NICE Guidelines...

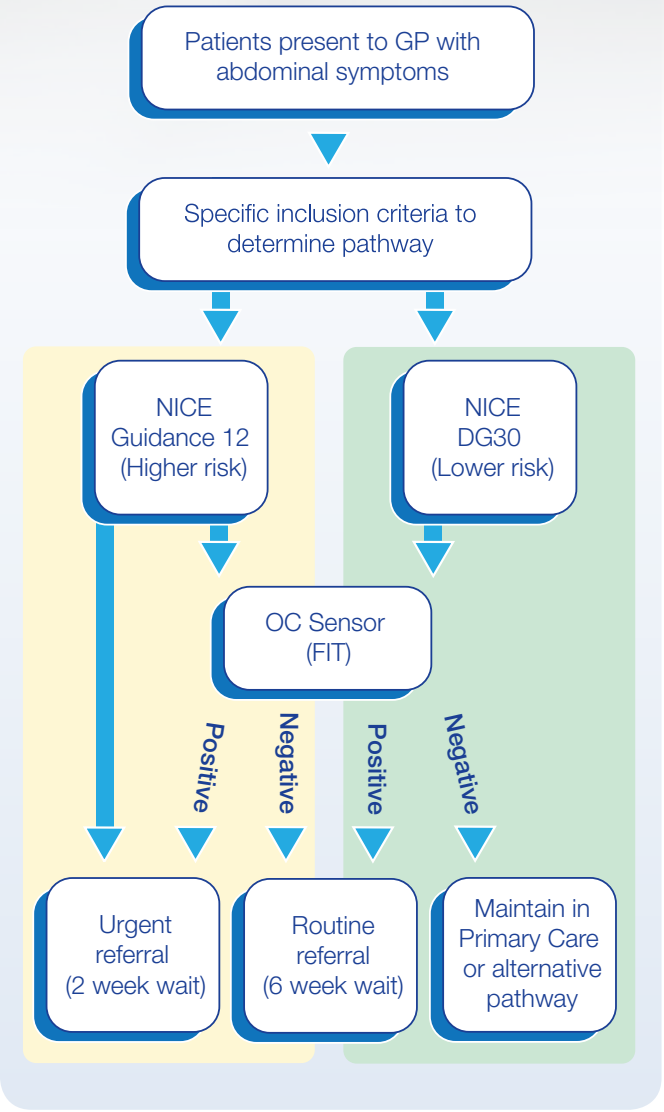
A major challenge facing clinicians is to identify patients suspected of colorectal cancer in primary care. The waiting times published by NHS England is further evidence that demand for diagnostics tests is outstripping capacity.

"Every month during the whole of 2017, approximately 3,000 patients (2,889) on average were waiting more than six weeks for endoscopy tests at their local hospital in England,whilst every month on average over 2,000 patients (2,379) with suspected cancer are waiting longer than two weeks for an urgent referral".

Bowel Cancer UK, Feb 2018.

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, changes in bowel habits, perianal symptoms and rectal bleeding.

The National Institute of Health and Care Excellence (NICE) has revised NG12 to include the use of FIT testing to 'rule in' patients for the 2-week-wait pathway. More recently Diagnostic Guidance 30 has endorsed OC-Sensor, proving it cost effective to 'rule out' patients with more generic symptoms from being referred to secondary care.



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.**

NICE Diagnostic Guidance 30

Using FIT to triage low risk patients that do not meet the criteria for NG12:

- **OC Sensor is proven cost effective for use.**
- **increased specificity results in 32% less unnecessary referrals than other brands.**
- **cut off should be 10ug/g.**

Primary Care Triage with OC Sensor - putting FIT first!

Making a pathway decision based on clinical presentation and patient demographics alone is difficult, results in many unnecessary referrals and subsequent colonoscopies. NICE have endorsed OC Sensor for use and introduced FIT as part of NG12 and DG30 in a bid to improve the situation.

But is the use and interpretation of FIT following medium or low risk categorisation based on age and traditional symptoms the most effective strategy? The Spanish Colon Predict study compared the use of FIT against both NG12 (pre 2015) and SIGN guidelines in symptomatic patients. The outcome clearly demonstrates the superior performance of OC Sensor compared to existing guidance criteria.

Colon Predict Study

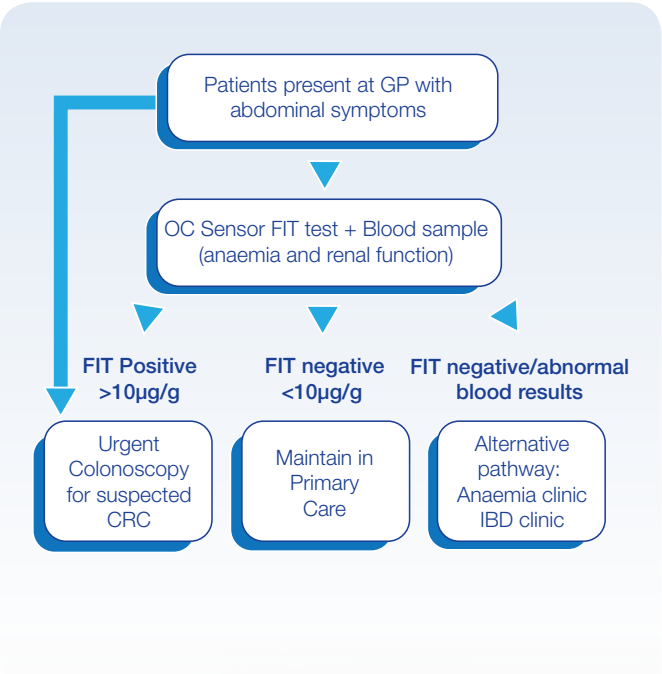
CRC and HRA in Symptomatic Patients Cut Off 20µg/g

CRC	Sensitivity	Specificity	No of Scope for CRC	Odds ratio for CRC
FIT (OC Sensor)	87.6%	77.4%	2.83 (95% CI 2.4-3.41)	24.23 (95% CI 12.91-45.93)
NICE NG12 (pre 2015)	61.9%	62.5%	5 (95% CI 3.98-6.37)	3.04 (95% CI 1.96-4.71)
SIGN	82.5%	42.7%	5.93 (95% CI 4.85-7.35)	3.51 (95% CI 2.03-6.06)

FIT (20µg/g) would have resulted in 19.6% less colonscopies and found 42% more CRC's compared to NICE and SIGN Cubiella et al. Colorectal Disease, 2014.

Colonoscopy capacity is a scarce resource. Including laboratory tests at the start of the decision making pathway would refine GP referral practices and reduce pressure on 2ww and colonoscopy lists in Secondary Care. With improved agility within the pathway, you can demonstrate a reduced the diagnostic window for positive patients, a reduction in overall waiting times and a much improved yield at colonoscopy. Collecting a blood sample for anaemia and renal function alongside FIT, is a streamlined and efficient use of resources. Results can then be interpreted alongside clinical symptoms to best guide patient referral practice.

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.



> "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]

> "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]

OC-Sensor
The World's No.1 FIT

OC Sensor is the leading quantitative FIT product, used worldwide in over 46 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 30 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. 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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