

PUBLICATION SPOTLIGHT

FOB Gold FIT solutions

FIT performance in CRC symptomatic testing

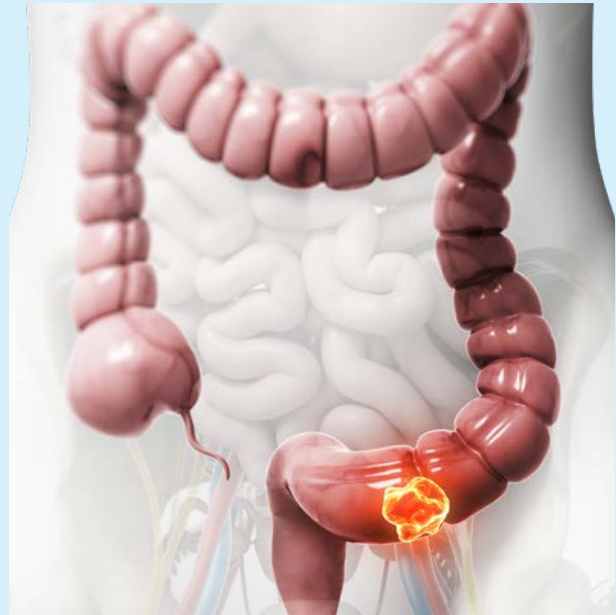
CRC is one of the most common malignancies and a leading cause of cancer-related mortality. FIT is widely applied in national CRC screening programmes and as rule-out test in symptomatic patients to support decision if further invasive investigation is needed. Most people with symptoms associated with bowel disease do not have CRC but are often referred directly to secondary care for invasive investigation. With the limited colonoscopy resources available in many countries, FIT can effectively support ruling-out CRC in symptomatic patients, and thus avoiding unnecessary colonoscopies. On the other hand, FIT can also detect CRC in people with symptoms who have been seeking medical advice.

NICE Diagnostic Guidance DG30 [6] advises FOB Gold to guide referral for CRC in primary care (see NICE DG30 facts below). FOB Gold is recommended for adoption in primary care to guide referral for suspected CRC in patients without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral [6].

FOB Gold helps to rule-out CRC in patients with lower abdominal symptoms

NICE DG30 facts

- ✓ recommends using a cut-off of 10 µg Hb/g faeces in symptomatic populations
- ✓ concluded that when using the cut-off of 10 µg Hb/g faeces, the FIT provides enough sensitivity to reliably rule out CRC in primary care
- ✓ noted that FOB Gold is compatible with a range of clinical chemistry analysers which may be an advantage for laboratories
- ✓ stated that FOB Gold has potential to be a cost-effective option for triaging referrals to secondary care for people with symptoms but at low risk of CRC



List of references

Symptomatic

[1] Navarro M. et al.: Reducing the Cut-Off Value of the Faecal Immunochemical Test for Symptomatic Patients does not Improve Diagnostic Performance. *Frontiers in Medicine* (2020) 7(410):1–9.

Key message: FOB Gold was evaluated in 727 patients with 'red flag' symptoms showing a high NPV for cancer (99.4%) at 20 µg/g cut-off which was similar to the NPV (99.6%) reached at the NICE DG30 recommended cut-off at 10 µg/g, thus can be used to avoid or prioritize colonoscopy procedures in symptomatic.



[2] Lué A. et al.: The combination of quantitative faecal occult blood test and faecal calprotectin is a cost-effective strategy to avoid colonoscopies in symptomatic patients without relevant pathology. *Ther Adv Gastroenterol* (2020) 13:1–15.

Key message: FOB Gold applied in the population-based Aragon CRC screening programme (cut-off 20 µg Hb/g) was used with the same cut-off combined with a calprotectin assay to improve the overall diagnostic accuracy for the detection of significant colonic pathology in prospectively enrolled symptomatic patients referred to colonoscopy.

[3] Navarro M et al.: Faecal Hemoglobin Concentration, a Good Predictor of Risk of Advanced Colorectal Neoplasia in Symptomatic and Asymptomatic Patients. *Frontiers in Medicine* (2019) 6(91): 1–10 and AGA congress (2017) Poster 2678674.

Key message: Male gender, age and Hb concentration (FIT) can be used as predictors of risk of advanced neoplasia and CRC to triage colonoscopy in symptomatic population based on the results of using FOB Gold at a cut-off of 20 µg/g in 1227 symptomatic patients.



[4] De Klerk C.M. et al.: A large proportion of faecal immunochemical test-positive participants in colorectal cancer screening is symptomatic. *United European Gastroenterology Journal* (2018) 6(3):471–479.

Key message: By using FOB Gold in the Dutch CRC screening programme a large proportion (47%) of the FIT-positive participants reported CRC-related symptoms and showed an association between visible rectal blood loss and a change in bowel habits with the presence of CRC.

[5] Augé J.M. et al.: An evaluation of the SENTIFIT 270 analyser for quantitation of faecal haemoglobin in the investigation of patients with suspected colorectal cancer. *Clin Chem Lab Med* (2018) 56(4):625–633.

Key message: The sensitivity and the specificity of FOB Gold for detecting advanced neoplasia (CRC + advanced adenoma) were judged to be accurate for the application in a symptomatic patient population and those undergoing surveillance.



[6] NICE Diagnostics guidance: Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care (DG30). National Institute for Health and Care Excellence (2017).

Key message: The FOB Gold quantitative FIT is recommended for adoption in primary care in order to guide referral for suspected CRC in people who have unexplained symptoms and no rectal bleeding, but do not meet the criteria for a suspected cancer pathway referral.

[7] Augé J.M. et al.: FIT performance in surveillance and symptomatic patients. The same test but different interpretation. EML Athens (2017) Poster.

Key message: FOB Gold clinical performance was assessed on SENTIFIT 270 analyzer in symptomatic patients (520) in relation to colonoscopy findings showing a NPV of 88.9% at a cut-off of 10 µg/g for advanced neoplasia (CRC + high risk adenoma).



[8] Krivec S. et al.: Assessment of the diagnostic applicability of quantitative immunochemical faecal occult blood (iFOB) test. EML Berlin (2011) Poster.

Key message: FOB Gold revealed a sensitivity of 45.2% and specificity of 92.3% for significant bowel disease (cancer, polyps or bleeding) using a threshold of 9.35 micrograms Hb/g faeces (55 ng/mL) in a symptomatic patient cohort.

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