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FIT performance in CRC symptomatic testing

FOB Gold® FIT solutions

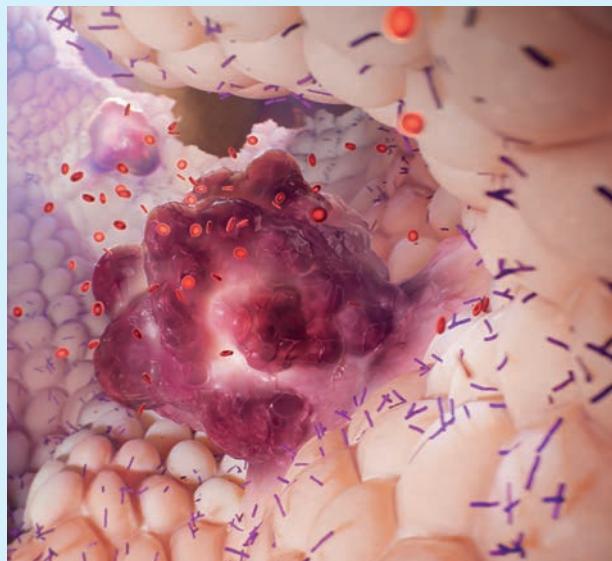
CRC is one of the most common malignancies and a leading cause of cancer-related mortality. FIT is widely applied in national CRC screening programmes and as rule-out test in symptomatic patients to support decision if further invasive investigation is needed. Most people with symptoms associated with 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.

Several studies using FOB Gold® in symptomatic patients have demonstrated its value as a tool for prioritising patients for referral to endoscopy services. Recent results have shown that combining FOB Gold® and CALiaGold® results for identifying symptomatic patients at high risk of CRC can increase the sensitivity for detection of CRC [1]. In general FOB Gold® has proven to provide high negative predictive values for CRC [2, 5, 6] which represents an important prerequisite for FIT in the symptomatic population.

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

FIT symptomatic testing workflow

- ✓ FIT can be offered to patients who present with symptoms as a test to guide their further management
- ✓ The FIT result provides a numerical value to the patient followed by a doctor's consultation
- ✓ If the FIT result is negative, there will be additional examinations depending on the persisting symptoms, if it is positive, the patient will be triaged to further investigations, mainly to endoscopy services
- ✓ 'Safety netting' (a strategy that aims to ensure patients are monitored throughout the diagnostic process, e.g. a repeated FIT) is important until symptoms are explained or resolved



List of references

Symptomatic

-  [1] Lanas A. et al. (2023): Fecal occult blood and calprotectin testing to prioritize primary care patients for colonoscopy referral: The advantage study. *United European Gastroenterol J* (2023) 11(7): 692–699.
Key message: FOB Gold® (hemoglobin, fHb) and CALiaGold® (calprotectin, FC) results were used to develop a tool for identifying symptomatic patients at high risk for CRC who need urgent referral to colonoscopy, thus adding a cut-off of 150 µg/g of FC to both fHb thresholds (> 0 and ≥ 10), the sensitivity of fecal tests could be improved (to 97.1% and 95.6%).
-  [2] Maclean W. et al. (2023): Efficacy and accuracy of faecal sampling by a digital rectal examination for FIT. *Annals of Clinical Biochemistry* (2023) 60(3): 169–176.
Key message: In a prospective study with FOB Gold®, digital rectal examination FIT results were comparable to the home-sampling ones if the clinician was able to obtain good samples in which the FOB Gold® sensitivity and negative predictive value for colorectal cancer were 100% based on the results of 553 samples.
-  [3] Benton S. et al. (2022): A comparison of the faecal haemoglobin concentrations and diagnostic accuracy in patients suspected with colorectal cancer and serious bowel disease as reported on four different faecal immunochemical test systems. *Clin Chem Lab Med* aop: 1–9.
Key message: Samples of the symptomatic NICE FIT study were analysed on four different FIT systems and compared based on 3 different thresholds (LoD, 10 and 100 µg/g) at which at 100 µg/g the sensitivity was similar for all methods, whereas at the lower cut-offs differences were observed apparently due to the lack of harmonization of FITs.
-  [4] Schwettmann L. et al. (2022): Evaluation of the SENTiFIT-FOB gold faecal immunochemical test for the presence of haemoglobin using the automated Roche Cobas 8000 system. *Practical Laboratory Medicine* 29: 1–8.
Key message: The FOB Gold® assay was judged to be appropriate for application on the Roche Cobas 8000 analyser which showed good analytical performance with regard to early detection of significant colorectal diseases at a cut-off of 10 µg/g.
-  [5] Maclean W. et al. (2022): Comparison of the QuikRead go® point-of-care faecal immunochemical test for haemoglobin with the FOB Gold Wide® laboratory analyser to diagnose colorectal cancer in symptomatic patients. *Clin Chem Lab Med* 60(1): 101–108.
Key message: Both FITs (POC and FOB Gold®) were accurate in their ability to detect CRC in symptomatic population (FOB Gold's® sensitivity 100% at 10 µg/g cut-off), concluding that the laboratory-based FOB Gold® assay showed better diagnostic accuracy data compared to the POC test.
-  [6] Navarro M. et al. (2020): Reducing the Cut-Off Value of the Faecal Immunochemical Test for Symptomatic Patients does not Improve Diagnostic Performance. *Frontiers in Medicine* 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.
-  [7] Lué A. et al. (2020): 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.
-  [8] Navarro M. et al. (2019): Fecal Hemoglobin Concentration, a Good Predictor of Risk of Advanced Colorectal Neoplasia in Symptomatic and Asymptomatic Patients. *Frontiers in Medicine* 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.
-  [9] De Klerk C.M. et al. (2017): A large proportion of fecal 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.
-  [10] Augé J.M. et al. (2017): 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.

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