

List of Publications on the *HM-JACKarc* Faecal Immunochemical Test for Haemoglobin (FIT) Analytical System: March 2021

***HM-JACKarc* in Asymptomatic Population Screening**

Passamonti B, Malaspina M, Fraser CG, et al. A comparative effectiveness trial of two faecal immunochemical tests for haemoglobin (FIT). Assessment of test performance and adherence in a single round of a population-based screening programme for colorectal cancer. *Gut* 2018;67:485-96.

Rubeca T, Cellai F, Confortini M, Fraser CG, Rapi S. Impact of pre-analytical factors on fecal immunochemical tests: need for new strategies in comparison of methods. *Int J Biol Markers* 2015;30:e269-74.

Results from the Scottish Bowel Screening Programme. See the full details of the results of introduction of FIT as a first-line test at: <https://www.isdscotland.org/Health-Topics/Cancer/Bowel-Screening/> A summary of the findings is available at: <https://www.isdscotland.org/Health-Topics/Cancer/Publications/2019-02-05/2019-02-05-Bowel-Screening-Publication-Summary.pdf>

Clark G, Strachan JA, Carey FA, et L. Transition to quantitative faecal immunochemical testing from guaiac faecal occult blood testing in a fully rolled-out population-based national bowel screening programme. *Gut* 2021;70:106-13.

Clark GRC, Strachan JA, McPherson A, et al. Faecal haemoglobin distributions by sex, age, deprivation and geographical region: consequences for colorectal cancer screening strategies. *Clin Chem Lab Med* 2020;58:2073-80.

***HM-JACKarc* in Assessment of Symptomatic Patients**

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* 2016;54:125-32.

Godber IM, Todd LM, Fraser CG, MacDonald LR, Ben Younes H. Use of a faecal immunochemical test for haemoglobin can aid in the investigation of patients with lower abdominal symptoms. *Clin Chem Lab Med* 2016;54:595-602.

Widlak MM, Thomas CL, Thomas MG, et al. Diagnostic accuracy of faecal biomarkers in detecting colorectal cancer and adenoma in symptomatic patients. *Aliment Pharmacol Ther* 2017;45:354-363.

Cubiella J, Digby J, Rodríguez-Alonso L, et al. The fecal hemoglobin concentration, age and sex test score: Development and external validation of a simple prediction tool for colorectal cancer detection in symptomatic patients. *Int J Cancer* 2017;140:2201-11.

Quyn AJ, Steele RJ, Digby J, et al Application of NICE guideline NG12 to the initial assessment of patients with lower gastrointestinal symptoms: not FIT for purpose? *Ann Clin Biochem* 2018;55:69-76.

Widlak MM, Neal M, Daulton E, et al. Risk stratification of symptomatic patients suspected of colorectal cancer using faecal and urinary markers. *Colorectal Dis* 2018;20:O335-42.

Turvill J, Mellen S, Jeffery L, et al. Diagnostic accuracy of one or two faecal haemoglobin and calprotectin measurements in patients with suspected colorectal cancer. *Scand J Gastroenterol* 2018;53:1526-34.

Digby J, Steele RJ, Strachan JA, et al. Do other variables add value to assessment of the risk of colorectal disease using faecal immunochemical tests for haemoglobin? *Ann Clin Biochem* 2019;56:472-9,

Mowat C, Digby J, Strachan JA, et al. Impact of introducing a faecal immunochemical test (FIT) for haemoglobin into primary care on the outcome of patients with new bowel symptoms: a prospective cohort study. *BMJ Open Gastroenterol* 2019;6:e000293.

Nicholson BD, James T, East JE, et al. Experience of adopting faecal immunochemical testing to meet the NICE colorectal cancer referral criteria for low-risk symptomatic primary care patients in Oxfordshire, UK. *Frontline Gastroenterology* 2019;10:347-55.

Farrugia A, Widlak M, Evans C, et al. Faecal immunochemical testing (FIT) in symptomatic patients: what are we missing? *Frontline Gastroenterology* 2020;11:28-33.

D'Souza N, Hicks G, Benton SC, Abulafi M. The diagnostic accuracy of the faecal immunochemical test for colorectal cancer in risk-stratified symptomatic patients. *Ann R Coll Surg Engl* 2020;102:174-9.

Nicholson BD, James T, Paddon M, et al. Faecal immunochemical testing for adults with symptoms of colorectal cancer attending English primary care: a retrospective cohort study of 14 487 consecutive test requests. *Aliment Pharmacol Ther* 2020;6.1031-41.

Digby J, Strachan JA, McCann R, Steele RJ, Fraser CG, Mowat C. Measurement of faecal haemoglobin with a faecal immunochemical test can assist in defining which patients attending primary care with rectal bleeding require urgent referral. *Ann Clin Biochem* 2020;57:325-7.

Khan AA, Klimovskij M, Harshen R. Accuracy of faecal immunochemical testing in patients with symptomatic colorectal cancer. *Br J Surg Open* 2020;4:1180-8

McSorley ST, Digby J, Clyde D, et al. Yield of colorectal cancer at colonoscopy according to faecal haemoglobin concentration in symptomatic patients referred from primary care. *Colorectal Dis* 2020 Oct 16. doi: 10.1111/codi.15405. Epub ahead of print.

Chapman CJ, Banerjea A, Humes DJ, et al. Choice of faecal immunochemical test matters: comparison of OC-Sensor and HM-JACKarc, in the assessment of patients at high risk of colorectal cancer. *Clin Chem Lab Med* 2020 Oct 29:/j/cclm.ahead-of-print/cclm-2020-1170/cclm-2020-1170.xml.

D'Souza N, Georgiou Delisle T, Chen M, Benton S, Abulafi M; NICE FIT Steering Group. Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms referred on a 2WW pathway: a diagnostic accuracy study. *Gut* 2020 Oct 21:gutjnl-2020-321956. doi: 10.1136/gutjnl-2020-321956. Epub ahead of print.

Mowat C, Digby J, Strachan JA, et al. Faecal haemoglobin concentration thresholds for reassurance and urgent investigation for colorectal cancer based on a faecal

immunochemical test in symptomatic patients in primary care. *Ann Clin Biochem*. 2021 Jan 21:4563220985547. Epub ahead of print.

Bailey SER, Abel GA, Atkins A, et al. Diagnostic performance of a faecal immunochemical test for patients with low-risk symptoms of colorectal cancer in primary care: an evaluation in the South West of England. *Br J Cancer* 2021 Jan 19. Epub ahead of print.

Logan RPH, Hamilton W. Delivering better value colonoscopy: bridging the gap with FIT. *Gut*. 2020 Nov 24:gutjnl-2020-323118. Epub ahead of print.

Hicks G, D'Souza N, Georgiou Delisle T, Chen M, Benton SC, Abulafi M; NICE FIT Steering Group. Using the faecal immunochemical test in patients with rectal bleeding: Evidence from the NICE FIT Study. *Colorectal Dis* 2021 Feb 19.

Strachan JA, Mowat C. The use of faecal haemoglobin in deciding which patients presenting to primary care require further investigation (and how quickly) – the FIT approach *eJIFCC* 2021;32:52-60.

Miller J, Maeda Y, Au S, et al. Short-term outcomes of a COVID-adapted triage pathway for colorectal cancer detection. *Colorectal Dis* 2021 Mar 7. Epub ahead of print.

National Guidelines

National Institute for Health and Clinical Excellence (NICE) Diagnostic Guidance DG30 - <https://www.nice.org.uk/guidance/dg30> - Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care. 2017

Reviews

Westwood M, Corro Ramos I, Lang S, et al. Faecal immunochemical tests to triage patients with lower abdominal symptoms for suspected colorectal cancer referrals in primary care: a systematic review and cost-effectiveness analysis. *Health Technol Assess* 2017;21:1-234.

Westwood M, Lang S, Armstrong N, et al. Faecal immunochemical tests (FIT) can help to rule out colorectal cancer in patients presenting in primary care with lower abdominal symptoms: a systematic review conducted to inform new NICE DG30 diagnostic guidance. *BMC Med* 2017;15:189.

Senore C, Haug U. Faecal immunochemical tests have the potential for correctly ruling out colorectal cancer in symptomatic patients. *BMJ Evid Based Med* 2018;23:113-4.

Godber IM, Benton SC, Fraser CG. Setting up a service for a faecal immunochemical test for haemoglobin (FIT): a review of considerations, challenges and constraints. *J Clin Pathol* 2018;71:1041-5.

Fraser CG. Faecal immunochemical tests for haemoglobin (FIT) in the assessment of patients with lower abdominal symptoms: current controversies. *Gastroenterol Hepatol* 2019;42:263-70.

D'Souza N, Abulafi M. The faecal immunochemical test in low risk patients with suspected bowel cancer. *Br J Hosp Med (Lond)* 2019;80:22-6.

Pin Vieito N, Zarracquiños S, Cubiella J. High-risk symptoms and quantitative faecal immunochemical test accuracy: Systematic review and meta-analysis. *World J Gastroenterol* 2019;25:2383-401.

Stonestreet J, Chandrapalan S, Woolley D, Uthman U, Arasaradnam RP. Systematic review and meta-analysis : diagnostic accuracy of faecal immunochemical testing for haemoglobin (FIT) in detecting colorectal cancer for both symptomatic and screening population. *Acta Gastroenterol Belg* 2019;82:291-9.

Conference report

Mole G, Withington J, Logan R. From FOBt to FIT: making it work for patients and populations. *Clin Med (London)* 2019;19:196–9. Erratum in: *Clin Med (Lond)* 2019;19:360.

Book Chapter

Steele RJC, Fraser CG. Haemoglobin for Timely Assessment of Patients with Symptoms of Colorectal Disease in Olsen Timely Diagnosis of Colorectal Disease, Olson L, ed. Springer, 2018.

Evaluations of the HM-JACKarc

Itoh M, Fukada M, Nagai G. Evaluation of the Extel “Hemo Auto” HS and the Hemo Auto MC Feces Collection Container Using the HM-JACKarc Fully Automated Faecal Occult Human Hemoglobin Analyzer. *J Clin Lab Inst Reagents* 2011;34:387-92.

Carroll MRR, Piggott C, Pearson S, Seaman HE, Halloran SP. Evaluation of quantitative faecal immunochemical tests for haemoglobin. Guildford Medical Device Evaluation Centre (GMEC), Guildford, UK, 2013.

Rapi S, Rubeca T, Fraser CG. How to improve the performances of Faecal Immunological Tests (FIT): Need for standardization of the sampling and pre-analytical phases and revision of the procedures for comparison of methods. *Int J Biol Markers* 2015;30:e127-31.

Rapi S, Berardi M, Cellai F, et al. Effects of fecal sampling on preanalytical and analytical phases in quantitative faecal immunochemical tests for hemoglobin. *Int J Biol Markers* 2017;32:e261-6.

Fraser CG. Comparison of quantitative faecal immunochemical tests for haemoglobin (FIT) for asymptomatic population screening. *Transl Cancer Res* 2016;5(Suppl 4):S916-9.

Park Y, Choi Q, Kwon GC, Koo SH. Performance evaluation of the HM-JACKarc analyser for faecal occult blood test. *J Lab Med Qual Assur* 2016;38:137-42.

Piggott C, Carroll MRR, John C, O'Driscoll S, Benton SC. Analytical evaluation of four faecal immunochemistry tests for haemoglobin. *Clin Chem Lab Med* 2020;59:173-8.

James T, Nicholson BD, Marr R, et al. Faecal immunochemical testing (FIT): Sources of result variation based on three years of routine testing of symptomatic patients in English primary care. Br J Biomed Sci 2021 Feb 25. Epub ahead of print.

Stability of faecal haemoglobin

Mellen S, de Ferrars M, Chapman CL, et al. Evaluation of sample stability for a quantitative faecal immunochemical test and comparison of two sample collection approaches. Ann Clin Biochem 2018;55: 657-64.

Haemoglobin variants

Carroll MR, John C, Mantio D, Djedovic NK, Benton SC. An assessment of the effect of haemoglobin variants on detection by faecal immunochemical tests. Ann Clin Biochem 2018;55:706-9.

Sampling of faeces

Piggott C, John C, Bruce H, Benton SC. Does the mass of sample loaded affect faecal haemoglobin concentration using the faecal immunochemical test? Ann Clin Biochem 2018;55:702-5.

Zahida Z, Carolyn P, Benton SC. Does visually over-loaded HM-JACKarc collection device impact faecal haemoglobin results? Ann Clin Biochem 2020 Dec 3:4563220976749. Epub ahead of print.

Faecal haemoglobin in adenoma

Mowat C, Digby J, Strachan JA, Steele RJC, Fraser CG. Low sensitivity of fecal immunochemical tests (FIT) for detection of sessile serrated adenomas/polyps confirmed over clinical setting, geography, and FIT system. Dig Dis Sci 2019;64:3024-6.

Faecal haemoglobin in ulcerative colitis – application of HM-JACKarc

Ryu DG, Kim HW, Park SB, et al. Clinical implications of fecal calprotectin and fecal immunochemical test on mucosal status in patients with ulcerative colitis. Medicine (Baltimore) 2019;98:e17080.

Other publications

Allison JE, Fraser CG. The importance of comparing quantitative faecal immunochemical tests (FIT) before selecting one for a population-based colorectal cancer screening programme. *J Lab Precis Med* 2018;3:7.

Piggott C, Shugaa Z, Benton SC. Independent internal quality control (IQC) for faecal immunochemical tests (FIT) for haemoglobin: use of FIT manufacturers' IQC for other FIT systems. *Clin Chem Lab Med* 2020;59:e41-3

O'Driscoll S, Piggott C, Bruce H, Benton SC. An evaluation of ten external quality assurance scheme (EQAS) materials for the faecal immunochemical test (FIT) for haemoglobin. *Clin Chem Lab Med* 2020;59:307-13.

Benton SC, Symonds E, Djedovic N, et al; International Federation of Clinical Chemistry Faecal Immunochemical Test Working Group (IFCC FIT-WG). Faecal immunochemical tests for haemoglobin: analytical challenges and potential solutions. *Clin Chim Acta* 2021 Feb 8:S0009-8981(21)00040-1. Epub ahead of print.