



Topic Exploration Report ¹

CanSense - Raman spectroscopy blood test combined with machine learning to identify colorectal cancer (CRC)

What is a Topic Exploration Report?

Topic Exploration Reports are not health technology assessments. These reports provide a high-level briefing on new topics submitted to Health Technology Wales and are not based on exhaustive or systematic literature searches. Instead, they rely on a focussed scan of key resources.

What evidence is used in a Topic Exploration Report?

Priority is given to summarising the most relevant or useful evidence, rather than covering all possible evidence. Information reported is typically based on abstracts and study authors' own conclusions, rather than detailed scrutiny of full texts.

What are the aims of a Topic Exploration Report?

Topic Exploration Reports offer an overview of the available evidence on a topic and aim to highlight any uncertainties or gaps in the evidence. These reports outline the quantity and type of evidence found, but no critical appraisal or formal evidence synthesis is conducted.

How should a Topic Exploration Report be used?

Topic Exploration Reports can be used to indicate what evidence may be available for a topic, and do not provide definitive guidance on how a technology should be used. The evidence presented within the reports should be interpreted with caution.

¹ [Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg](#)
Translation of published technical HTW documents from English into Welsh

Topic exploration report number	TER 584
Topic	Raman spectroscopy blood test combined with machine learning to identify colorectal cancer (CRC)
Summary of findings	CanSense is a new blood test, incorporating Raman spectroscopy and machine learning analysis and can be used after faecal immunochemical testing (FIT) for the detection of colorectal cancer. With increasing demand on cancer pathways, this technology has the potential to triage people who present with lower gastrointestinal (GI) symptoms within primary care. HTW researchers identified one NICE guideline on the recognition and referral of suspected cancer, one NICE diagnostic guidance on quantitative FIT, one guideline on the diagnosis and management of colorectal cancer, one systematic review on the diagnostic accuracy of Raman spectroscopy, two primary studies and two ongoing studies. Outcomes include diagnostic accuracy, and perceptions on the proposed care pathway. We did not identify any studies that evaluated the cost-effectiveness of CanSense-CRC when compared with standard procedures. There is lack of evidence about the impact on patient management decisions and other clinical outcomes, e.g. time to diagnosis and mortality, as well as resource use, a reduction in waiting times and reduced burden on colonoscopy waiting lists. Information from the topic proposer suggests CA-UK regulation is due for approval by the first quarter of 2025.

Introduction and aims

Colorectal cancer is the fourth most common cancer in Wales (Bowel Cancer UK 2024), and more than 2,000 people diagnosed every year (Welsh Government 2024). It can be treatable, curable and survival chances increase significantly when it is caught early enough (Welsh Government 2024). However, five out of seven health boards in Wales currently breach waiting times for diagnostic tests (Bowel Cancer UK 2024) and a late diagnosis can negatively affect survival rates. The increasing demand for endoscopy and a lack of capacity in hospitals is the root cause of long waiting times for appointments (Bowel Cancer UK 2024).

FIT for CRC was recommended by NICE diagnostics guidance (DG30) in 2017 for low-risk symptom triage in primary care, however, FIT samples have a low return rate (Jenkins et al. 2023). A paper about high-throughput serum Raman spectroscopy platform was published by (Jenkins et al. 2018), highlighting that there have only been few studies of vibrational spectroscopic techniques based on the analysis of blood serum for colorectal cancer diagnostics, rather than tissue samples. With increasing demand on endoscopies, blood tests analysed with Raman Spectroscopy, incorporating machine learning, have the potential to triage people who present with lower gastrointestinal (GI) symptoms within primary care. The test could help clinicians identify and prioritise patients with suspected cancer for further investigation. Raman spectroscopy measures proteins, nucleic acids, and lipids in serum to produce a 'biochemical fingerprint' (Jenkins et al 2023). Using AI algorithm, people are classified into high or low likelihood of CRC.

CanSense-CRC by CanSense Ltd, combines blood sample analysis using Raman spectroscopy with machine learning for those with positive FIT results, but can also be used on its own. This product is not yet CE or UK-CA marked, although UK-CA marking is expected by the first quarter of 2025.

Health Technology Wales researchers searched for evidence on blood tests utilising Raman spectroscopy with machine learning, including CanSense, for the detection and triage of colorectal cancer.

Evidence overview

HTW researchers identified one systematic review on the diagnostic accuracy of Raman spectroscopy, two additional primary studies, two guidelines, and one diagnostic guidance. Information from the topic proposer suggested there is an ongoing study due to complete in the first quarter of 2025, and another ongoing study due to complete in July 2025.

Guidelines

A NICE guideline on the recognition and referral of suspected cancer [NG12] recommends FIT testing using HM-JACKarc or OC-Sensor to guide referral for suspected colorectal cancer in some adults [recommendation 1.3.1] (NICE 2015) and adults with a FIT test of 10 micrograms of haemoglobin per gram of faeces or more should be referred using a suspected cancer pathway referral [recommendation 1.3.2] (NICE 2015). Recommendations from this section of the guideline are from diagnostic guidance [DG56] on the quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care (NICE 2023).

Healthcare Improvement Scotland published a national clinical guideline on the diagnosis and management of colorectal cancer, revised in 2016 (SIGN 2011). Under the key recommendations, colonoscopy is recommended as a sensitive method of diagnosing colorectal cancer, enabling biopsy and polypectomy. CT colonography is also recommended as an alternative. The guideline makes no reference to CanSense or Raman spectroscopy (SIGN 2011).

Evidence overview

Secondary research

Zheng et al. (2019) conducted a systematic review with meta-analysis on the diagnostic accuracy of Raman spectroscopy in participants without prior FIT testing in the care pathway (13 studies, 679 patients: 186 with premalignant lesions, 493 with malignant lesions-confirmed with histopathology). The review included studies on both tissue (n=9) and serum (n=4) samples. Further details about the study design of included studies were unclear from the study characteristics table in the review, e.g. it is unclear whether studies included in the review incorporated automated analysis via machine learning. The pooled sensitivity, specificity, diagnostic accuracy, positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio and positive post-test probability for CRC using Raman spectroscopy were 0.94 (0.92–0.96), 0.94 (0.88–0.97), 0.96 (0.94–0.98), 16.44 (7.80–34.63), 0.062 (0.043–0.090), 263.65 (99.03–701.96) and 86%, respectively.

Primary studies

Jenkins et al. (2023) conducted a mixed-methods prospective cohort pilot study which aimed to evaluate the performance of CanSense (Raman spectroscopy with machine learning analysis), along with the FIT test, to triage CRC patients in primary care settings across South Wales who had been referred to the urgent suspected cancer pathway. 532 patients were recruited from 27 GP practices. The results found that Raman-CRC identified CRC with a sensitivity of 95.7%, specificity of 69.3% with area under curve (AUC) of 0.80 compared with colonoscopy as the reference test (248 patients). Stage I and II cancers were detected with 78.6% sensitivity. Authors conclude that using Raman spectroscopy, with automated analysis via machine learning algorithms, in sequence with FIT to prioritise patients may speed up diagnosis and improve cancer outcomes.

Nelson et al. (2023) reported the qualitative component of the above study. Interviews with 23 patients and 12 healthcare professionals were conducted to gather their perceptions on a dual-triage approach, combining FIT and Raman spectroscopy. The study found that both patients and healthcare professionals agree that combining FIT and Raman spectroscopy with machine learning is a simple test, and it aligned with routine practice.

Ongoing research

There are two ongoing studies. One study on CAN-FIT is due to complete by the end of March 2025, and another study about understanding Raman signatures in CRC is due to complete in July 2025. For further details, see page 5.

Areas of uncertainty

Current guidelines make no reference to the use of blood samples using Raman spectroscopy alone, or the use of this with machine learning.

There is lack of evidence of what difference the current findings would make to patient management decisions i.e., other outcomes such as resource use, a reduction in waiting times and reduced burden on colonoscopy waiting lists. We did not identify any studies that evaluated the cost-effectiveness of CanSense-CRC- when compared with standard procedures.

Further details on the artificial intelligence component of the technology would be useful, such as what type of machine learning is used.

Literature search results

Health technology assessments and guidance

NICE. (2015). Suspected cancer: recognition and referral. NICE Guideline [NG12]. National Institute for Health and Care Excellence. Available at: <https://www.nice.org.uk/guidance/ng12/> [Accessed 29 January 2025].

NICE. (2023). Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care. Diagnostics guidance [DG56]. National Institute for Health and Care Excellence. Available at: <https://www.nice.org.uk/guidance/dg56/> [Accessed 29 January 2025].

SIGN. (2011). Diagnosis and management of colorectal cancer. A national clinical guideline. Healthcare Improvement Scotland. Available at: <https://www.sign.ac.uk/our-guidelines/diagnosis-and-management-of-colorectal-cancer/> [Accessed 3 January 2025].

Evidence reviews and economic evaluations

Zheng Q, Kang W, Chen C, et al. (2019). Diagnosis accuracy of Raman spectroscopy in colorectal cancer: A PRISMA-compliant systematic review and meta-analysis. *Medicine (Baltimore)*. 98(34): e16940. doi: 10.1097/md.00000000000016940. Available at: <https://pubmed.ncbi.nlm.nih.gov/31441886/>

Individual studies

Jenkins C, Woods F, Chandler S, et al. (2023). A novel blood based triage test for colorectal cancer in primary care: a pilot study. *BJGP Open*. 7(1). doi: 10.3399/bjgpo.2022.0077. Available at: <https://pubmed.ncbi.nlm.nih.gov/36332909/>

Nelson K, Carter K, Hepburn J, et al. (2023). Patient and healthcare professionals' perceptions of a combined blood and faecal immunochemical test for excluding colorectal cancer diagnosis in primary care. *Health Expect*. 26(6): 2655-65. doi: 10.1111/hex.13796. Available at: <https://pubmed.ncbi.nlm.nih.gov/37697688/>

Ongoing research

1. Information from the topic proposer suggests there is an ongoing study, CAN-FIT due to complete by the end of March 2025. UK-CA marking for CanSense is expected by the first quarter of 2025. Outcomes will include, but not limited to, resource use and reduced waiting times, earlier detection within pathway timescales and service improvement.
2. There is an ongoing observational study about understanding Raman signatures in colorectal cancer: ISRCTN13189452 with an estimated completion date of 2 July 2025. The study is currently recruiting and will only be including adults. The primary outcome is the analysis of spectral signatures defining CRC and polyp/adenoma detection measured using Raman spectroscopy of study samples. Available at: <https://scanmedicine.com/clinicaltrials/ISRCTN13189452>

Background references

Bowel Cancer UK. (2024). A Spotlight on Bowel Cancer in Wales. Available at: <https://www.bowelcanceruk.org.uk/news-and-blogs/research-blog/a-spotlight-on-bowel-cancer-in-wales/> [Accessed 10 January 2025].

Welsh Government. (2024). Bowel screening age lowered to 50 in Wales. Welsh Government. [Accessed 10 January 2025] Available at: <https://www.gov.wales/bowel-screening-age-lowered-50-wales>.

Jenkins CA, Jenkins RA, Pryse MM, et al. (2018). A high-throughput serum Raman spectroscopy platform and methodology for colorectal cancer diagnostics. *Analyst*. 143(24): 6014-24. doi: 10.1039/c8an01323c. Available at: <https://pubmed.ncbi.nlm.nih.gov/30398225/>

Date of search	2 January 2025
Concepts used	Raman spectroscopy; CanSense; Raman-CRC; colorectal cancer.

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	What is the clinical and cost effectiveness of blood tests utilising Raman spectroscopy with machine learning to identify colorectal cancer (CRC) in symptomatic primary care patients?
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	Inclusion criteria	Exclusion criteria
Population	Patients with suspected CRC	General population
Intervention	Blood tests utilising Raman spectroscopy and machine learning analysis	FIT alone
Comparison/Comparators	Colonoscopy	
Outcome measures	Diagnostic accuracy outcomes Resource use e.g., reduction in appointments, patient waiting times Health related QoL Resource use Economic outcomes PPI outcomes	

Proposed speciality	Cancer
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