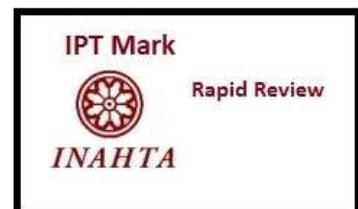




**INFORMATION BRIEF (RAPID REVIEW)**

**SELF EZ DETECT FOR  
COLORECTAL CANCER  
SCREENING**

Malaysian Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia  
004/2025



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**SUGGESTED CITATION:** Tengku Noor Farhana TK and Izzuna MMG. Self EZ DETECT for Colorectal Cancer Screening. Ministry of Health Malaysia: Malaysian Health Technology Assessment Section (MaHTAS); 2025. 10 p. Report No.: 004/2025

**DISCLOSURE:** The author of this report has no competing interest in this subject and the preparation of this report is entirely funded by the Ministry of Health Malaysia.

## TITLE: SELF EZ DETECT AS FOR COLORECTAL CANCER SCREENING

### PURPOSE

To provide brief information on the efficacy/effectiveness, safety and cost-effectiveness of one type of faecal occult blood test called self EZ DETECT for screening of colorectal cancer (CRC) following a request by the Disease Control Division and Family Health Development Division.

### BACKGROUND

Colorectal cancer is an abnormal cell growth in the colon (large intestine) or rectum.<sup>1</sup> The development of CRC consists of multiple stages: initiation, promotion and progression. The first stage involves genetics predisposing the affected epithelial cell of intestinal mucosa to subsequent neoplastic transformation. Then, the initiated cells multiply and generate abnormal cell growth which develops into cancer in the promotion phase. In the progression phase, the benign cancer cells become malignant by acquiring aggressive and metastatic potential features.<sup>2</sup> There are many precursors to CRC e.g. adenoma, serrated lesions and polyps. Each of the precursors has a different risk of developing CRC, particularly colorectal carcinoma. The most common subtype of CRC is adenocarcinoma which accounts for 85% of CRC globally. It is followed by mucinous carcinoma which accounts for another 5 to 20% of CRC cases worldwide.<sup>3</sup>

Colorectal cancer is the third most common cancer which affects people aged 50 years and above predominantly.<sup>1</sup> The incidence of CRC has varied considerably according to different countries. In 2020, it was estimated that 19.3 million cases were newly diagnosed with CRC worldwide where the incidence rates were highest in Europe, Australia and New Zealand. The age-standardised incidence rate per 100,000 population of CRC was 19.8. Males had a higher incidence rate than females (23.4 per 100,000 population vs 16.2 per 100,000 population). This cancer also accounts for about 10 million cancer deaths. It is about 2.5 times higher in high-income nations than in low-income countries. Among the CRC, colon cancer was the most common subtype of CRC accounting for 59.5% of new cases and 61.9% of deaths while rectum cancer, another subtype of CRC, accounts for 37.9% of new cases and 36.3% of deaths for both genders and throughout all ages.<sup>4</sup> Based on the Malaysia National Cancer Registry Report 2017 - 2021, CRC has become the second most common cancer accounting for 14.1% of all cancers. It is the most common cancer in males with an age-standardised rate (ASR) of 18.8 per 100,000 population while the ASR in females was 13.7 per 100,000 population.<sup>5</sup>

The diagnosis of CRC is crucial to determine the patient's prognosis and survival. Patients may have better survival and outcomes when diagnosed early, especially for those who have risk factors for CRC e.g. family history, previous history of CRC or polyps or other related diseases, diet, lack of physical activity, tobacco smoking, being a male, older age

and use of medications. Therefore, many CRC screening programmes were established in many countries due to the high incidence rate of CRC especially in the higher income countries. Guaiac faecal occult blood test (gFOBT) and faecal immunochemical test (FIT) have been recommended as the first-line screening test for those 50 years and older. Those who were positive for gFOBT or FIT will be referred for a confirmation test which is a colonoscopy. However, participation in both tests was still low compared with the national standard.<sup>6</sup> Hence, there is a growing interest to explore the alternative method of screening to increase people's willingness to be screened for CRC.

### **Technical features**

The self EZ DETECT test is manufactured to detect bleeding in the gastrointestinal (GI) tract using its ability to analyse the presence of a small amount of blood in the stool. The biodegradable test pad is coated with tetramethylbenzidine and hydrogen peroxide colour dye. The haemoglobin of the blood (as small as 10 µg/ml) crystallises the oxygen from the hydrogen peroxide solution and turns the colourless dye tetramethylbenzidine into green. The test comprises an In Vitro Diagnostic Medical Device test pad and manufactured through aluminium pouch packaging (**Figure 1**). The size of the test pad is 55 mm (height) X 75 mm (length) X 0.17 mm (thickness). Each of the packages usually contains five test pads.<sup>7</sup>

To use the product, the patient has to flush the toilet first and remove any residue. Then, the patient may proceed with bowel movement while preventing other substances from entering toilet. One test pad can be removed from of the aluminium pouch and dropped into the toilet. It is not critical that the pad touch the stool but must touch the water in the toilet bowl. The test results may appear within two minutes. The dye on the test pad will turn green if it is positive for blood (**Figure 3a**) and light off-white if it is negative (**Figure 3b**). Once the test has been completed, the test pad can be disposed of when flushing together with stool in the toilet.<sup>7</sup> The test should be repeated at least two times. It is considered positive if any test pads give a positive result and the patient should be referred for further management with the specialist.<sup>8</sup>



Figure 1: The packaging of the test pad

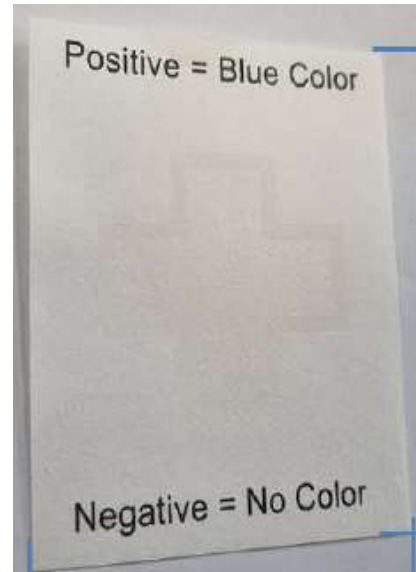


Figure 2: The test pad before the procedure



Figure 3a: The positive test pad



Figure 3b: The negative test pad

## EVIDENCE SUMMARY

A total of 86 titles were retrieved from scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and general search engines [Google Scholar and US Food and Drug Administration (USFDA)], using the search term; EZ Detect or EZ-Detect or EZDetect and colorectal cancer or carcinoma. The last search was conducted on 17 February 2025. Four articles were found to be relevant and included in this review which was comprised of three diagnostic and one cross-sectional studies. These studies assessed the diagnostic accuracy, perceived acceptance and difficulty level of self EZ DETECT as a

screening tool for CRC. Information on the registration and cost of self EZ DETECT were also included in this review.

## **EFFICACY/ EFFECTIVENESS**

### **Accuracy of Self EZ DETECT**

A diagnostic study was conducted by Lohsiriwat V in 2014 to determine the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of this test for detection of CRC. Ninety-six CRC patients and 101 healthy individuals with normal colonoscopic findings were included in the study. They had an average age of 65 years (range 33 - 93). However, the setting for the study was not mentioned. Participants were selected based on their colonoscopic findings before they were enrolled in the study. The overall accuracy of detecting CRC was 70.0% using self EZ DETECT. There were no significant differences in detecting proximal colon cancer compared with distal CRC, and also when detecting infiltrative tumours compared with non-infiltrative tumours.<sup>8</sup>

Another diagnostic study on self EZ DETECT was conducted by Cruz-Correa M et al. in 2007 comparing the diagnostic accuracy of the intervention with Hemoccult (HO) II among patients referred to an academic GI practice. Most of the patients were female with a mean age of 65.5 years (standard deviation, SD=11.2). Out of 207 patients, 30.4% had adenomatous polyps and 11% were diagnosed with advanced adenomas. There was no significant difference between the two tests in the accuracy of detecting adenomas among the screening cohort that underwent colonoscopy post-test. However, the self EZ DETECT was less effective in detecting advanced adenomas than HO II (84.9% vs 94.4%,  $p=0.03$ ).<sup>9</sup>

The self EZ DETECT had also been studied by Tate JJT et al. previously in 1989 among patients with symptoms of large bowel disease in a surgical out-patients clinic evaluating the intervention with the HO test. The total number of patients who completed self EZ DETECT alone was 404 (88%) while only 275 (60%) patients completed additional HO tests. The median age of the patients was 65 years old. There was a statistically significant difference in sensitivity, specificity and PPV between the two tests in detecting CRC ( $p<0.005$ ), however there was no significant difference in detecting all neoplasia including adenomatous polyps.<sup>10</sup>

The comparison of sensitivity, specificity, PPV and NPV out of the three studies are as follows:

| Study           | Lohsiriwat V, 2014 <sup>a</sup>   |      |        | Cruz-Correa M et al., 2007    |              | Tate JJT et al., 1989                                     |           |
|-----------------|-----------------------------------|------|--------|-------------------------------|--------------|---|-----------|
| Test            | Self EZ DETECT                    |      |        | Self EZ DETECT                | Hemoccult II | Self EZ DETECT  | Hemoccult |
|                 | According to staging <sup>b</sup> |      |        | Detection of adenoma          |              | Detection of all neoplasia (including adenomatous polyps) |           |
|                 | I                                 | II   | III-IV |                               |              |   |           |
| Sensitivity (%) | 29.0                              | 32.0 | 50.0   | 17.6                          | 8.8          | 25.9  | 46.2      |
| Specificity (%) | -                                 | -    | -      | 88.0                          | 100.0        | -   | -         |
| PPV (%)         | -                                 | -    | -      | 35.3                          | 100.0        | 28.6  | 42.9      |
| NPV (%)         | -                                 | -    | -      | 74.3                          | 74.8         | -   | -         |
|                 | Overall CRC detection             |      |        | Detection of advanced adenoma |              | Detection of CRC  |           |
| Sensitivity (%) | 41.0                              |      |        | 25.0                          | 0.0          | 36.4  | 80.0      |
| Specificity (%) | 97.0                              |      |        | 86.5                          | 97.5         | 89.3  | 88.5      |
| PPV (%)         | 93.0                              |      |        | 5.9                           | 0.0          | 16.3  | 28.6      |
| NPV (%)         | 63.0                              |      |        | 97.2                          | 96.7         | -   | -         |

<sup>a</sup>No comparison in this study

<sup>b</sup>CRC detection based on 7<sup>th</sup> American Joint Committee for Cancer (AJCC) staging. There was no significant difference in sensitivity to detect CRC when compared with other staging (p=0.19).

Abbreviation: NPV = negative predictive value; PPV = positive predictive value, - = no data

## Societal

Cruz-Correa M et al. also reported that the majority of the patients in the endoscopy unit preferred self EZ DETECT compared with HO II (81.0% vs 8.0%, p<0.001). They also mentioned that the intervention was more straightforward and more hygienic, easier to conduct and they could get faster results. However, some also reported that the instructions given by self EZ DETECT are less understandable than HO II.<sup>9</sup>

In 2004, Hou SI et al. also conducted a pre-post study to assess the perceived acceptance, difficulty level and screening efficacy of the self EZ DETECT test compared with a traditional faecal occult blood test (FOBT) among Chinese workers in Taiwan. About 375 participants completed the pre-test questionnaire and 81% of them completed the post-test questionnaire during two to four weeks of follow-up, however only 74% of them completed the screening test. The mean age of the population was 48.18 years (SD=8.79). After using the intervention, the number of people intended to perform self EZ DETECT was significantly higher (p=0.000). Other than that, the participants' perceived acceptance (73.4% vs 10.0%) and screening efficacy (82.3% vs 22.9%) were higher for self EZ DETECT (p=0.000). In contrast, the participants scored the perceived difficulty higher in traditional

FOBT than in self EZ DETECT (49.7% vs 5.7%,  $p=0.000$ ). After performing the self EZ DETECT test, the participants' scores for the acceptance level (2.60 vs 2.19,  $p=0.000$ ) and perceived completion efficacy (2.79 vs 2.33,  $p=0.000$ ) of traditional FOBT reduced significantly. In contrast, the acceptance level for self EZ DETECT remains high even though there was no significant difference before and after the test (3.98 vs 3.96,  $p=0.846$ ). Some patients also expressed concern about interpreting the results themselves as they felt more assured if the result was analysed by a professional using traditional FOBT.<sup>11</sup>

The earlier study by Tate JJT et al. in 1989 reported that 98% of the patients preferred to repeat self EZ DETECT test if they were to repeat the screening test.<sup>10</sup>

## **SAFETY**

None of the studies reported any adverse events after performing the self EZ DETECT test.

The self EZ DETECT has been approved by the United States Food and Drug Administration (U.S. FDA)<sup>12</sup>, however it is still not registered with the Medical Device Authority in Malaysia.

## **COST-EFFECTIVENESS**

There was no evidence assessing the cost-effectiveness of self EZ DETECT test. Generally, the cost for one pad test is around [REDACTED]

## **ORGANISATIONAL**

Compared with traditional FOBT, the preparation for self EZ DETECT is much easier as it does not require any diet restriction before it is performed. This is because other sources of haemoglobin from the diet e.g. raw meat and some vegetables will not cause any false positive result when performing the test.<sup>8, 9</sup>

Regardless of how easy the new FOBT test is, participants among Chinese workers still stated the need for explanations and demonstrations before it is introduced to the population. This can be an effort to create awareness and increase the willingness of the population to undergo FOBT using this new kit, self EZ DETECT.<sup>11</sup> Furthermore, as the self EZ DETECT result is based on the change of the colour on the test pad, it is not suitable for patients who have a problem interpreting the results and those with colour-blindness.<sup>10</sup>

Other than that, reporting the results using the self EZ DETECT test also needs to be addressed. Some participants were motivated to send their results due to active participation from their supervisors. Thus, it should be monitored properly as some patients

may not report their results using self EZ DETECT as it is a self-test kit that differs from the traditional FOBT where the stool is analysed by a professional. Therefore, the test findings were automatically collected by the professionals.<sup>11</sup>

## CONCLUSION

Based on the above review, there was limited evidence retrieved demonstrated the performance of self EZ DETECT in screening for CRC. The latest evidence on self EZ DETECT in 2014 showed its sensitivity to detect CRC slightly improved with highest sensitivity of 50% in detecting stage III - IV CRC compared with the earlier study in 1989. The specificity and PPV have remarkably improved since then. The self EZ DETECT had comparable accuracy in detecting adenoma or all neoplasia compared with traditional FOBT but less accurate in detecting advanced adenoma. Additionally, it is unable to reliably distinguish between infiltrative and non-infiltrative tumours or between proximal and distal tumours. Nevertheless, patients reported that the new FOBT is much easier, simpler and more hygienic than traditional FOBT. Patients can also know their test results faster without sending the stool to the laboratory for testing.

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**10 March 2025**