

High Accuracy FOB Rapid Test Cassette Plays an Important Role in the Diagnosis of Colorectal Cancer

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Abstract

Background: The FOB Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces. It plays an important role in the preliminary diagnosis of Colorectal Cancer. In 2020, colorectal cancer was the third most common cancer and cancer-related death in the United States [1]. Many new treatment methods have been developed and their use in combination with advances in diagnostic methods has led to improvement in treatment results [1]. Therefore, FOB Rapid Test Cassette has an important effect in early diagnosis of Colorectal Cancer. Before accessing medical treatment in the hospital, patients can use FOB Rapid Test Cassette to detect colorectal cancer so that it can be detected and treated early.

Many factors may cause colorectal cancer. Obesity is an established risk factor for colorectal cancer development and is invariably characterized by deregulated metabolism, such as insulin resistance, hyperinsulinemia, hyperglycaemia, and Type 2 diabetes [2]. To analyse the factors that cause colorectal cancer, there are methods to help prevent colon cancer at its root.

Objective: To evaluate the significance of the CITEST FOB Rapid Test Cassette in early diagnosis of colorectal cancer.

Method: Run a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in feces and compare with a leading commercial FOB test using clinical specimens for validation of performance.

Results: The compared test results show that the overall relative sensitivity of CITEST FOB Rapid Test Cassette is 95%, relative specificity is 99.5% and accuracy is 98.6%.

Conclusion: In conclusion, the CITEST FOB Rapid Test Cassette has high sensitivity, high specificity and high accuracy which play an important role in early diagnosis of colorectal cancer.

This product is easy to operate and gives results within 5 minutes. Patients can use this test for earlier detection of colorectal cancer.

Keywords: Colorectal Cancer; FOB Rapid Test Cassette; Chromatographic Immunoassay

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Introduction

Background of Colorectal Cancer

According to the World Digestive Endoscopy Organization, in 2019 the incidence rate of colorectal was only lower than that of breast cancer, accounting for the second position in malignant cancers. Colorectal cancer is the third most diagnosed cancer in men and the second most in women, with 1.65 million new cases and almost 835,000 deaths in 2015. Inherited genetic susceptibility contributes significantly to the etiology of colorectal cancer [3]. Improving the

early diagnosis rate of colorectal is the key to decreasing the case fatality rate and improving patients' quality of life.

Currently, surgical resection, chemotherapy, and radiotherapy are the main treatment options for colorectal cancer, among which patients with early cancer are given priority to surgical resection, while those with advanced colorectal cancer commonly receive radiotherapy and chemotherapy [4].

Risk of Colorectal Cancer

Colon cancer as a malignant tumor is very harmful. Incidence of

colon cancer is very high and once it enters the advanced stage, the survival rate within five years can be as low as 10% [5]. Moreover, colon cancer case fatality rates are high and occupy more medical resources than most other cancers. If the patient's lesion stage is above early cancer, endoscopic treatment can obtain a more satisfactory treatment effect.

Effects of colon cancer can cause anemia, repeated and long-term persistent gastrointestinal bleeding resulting in a deficiency of hematopoietic factors in patients, which causes iron deficiency anemia in patients. Patients typically present with clinical symptoms such as dizziness, fatigue, decreased activity tolerance, and pale lips. After the tumor tissue grows, it can also lead to local blockage symptoms, and patients can develop abdominal distension, abdominal pain, decreased diet and other gastrointestinal blockage symptoms. In severe cases, relatively complete intestinal obstruction symptoms can occur, resulting in clinical symptoms like blood collapse.

Prevention of Colorectal Cancer

Prevention Method

Prevention methods can include avoiding a high-fat diet. Diets containing fibre can help accelerate the peristalsis of the intestine and promote healthy bowel movements.

Patients with a family history of Tumors should routinely go to the Department of Gastroenterology or Gastrointestinal Surgery after the age of 40 for fecal occult blood. Fecal occult blood is a small amount of blood in the stool and an early sign of colon Tumors. The tumor ruptures and causes bleeding and mixes into the stool indicating a positive for fecal occult blood. Once the fecal occult blood is present, it is recommended that patients undergo a colonoscopy as soon as possible. Colonoscopies can observe whether there are lesions in each intestinal tube. Help additionally, a biopsy can obtain a specimen sample and send to pathology for further diagnosis.

Colorectal Cancer Diagnostic Methods

Patients can use the CITEST FOB Rapid Test Cassette to detect colorectal cancer in the early stage. Fecal routine plus occult blood testing can determine whether there is a small amount of bleeding in the stool and do a preliminary screening.

Screening and diagnosis of colon cancer currently rely heavily on colonoscopy. Colonoscopy is done from the anus into a mirror, and the endoscope can travel up through the intestine and finally reach the area between the large intestine and the small intestine, that is, above the ileocecal valve. However, colonoscopy is too painful for patients. The FOB Rapid Test can help patients to detect colorectal cancer in a relatively easy way and decrease the painfulness of patients.

Evaluation of CITEST FOB Rapid Test Cassette

Materials and Directions for Use help

Materials include test cassettes, specimen collection tubes with extraction buffer and package insert.

The FOB Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50ng/ml or higher, or 6µg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the patient's diet.

There are two specimen types with different operation methods. The specimens are both fecal specimens. In both tests, a clean, dry specimen of 1-2 mL or 1-2 g should be collected.

For Solid Specimens

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

For Liquid Specimens

Hold the dropper vertically to aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S) and read the result after 5 minutes.

Performance Characteristics

The FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test using clinical specimens (Table 1).

Expected Values

The FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between the two systems is 98.6%

Summary

FOB Rapid Test Cassette is the most general method to for screen colorectal cancer. The fecal occult blood test has a very important diagnostic and differential diagnostic value for gastrointestinal

Table 1. Compared with another leading commercial rapid test.

Method	Other Rapid Test		Total Result
	Result	Positive Negative	
FOB Rapid Test Cassette (Feces)	Positive	189 4	193
	Negative	10 802	812
Total Results		199 806	1005

Relative sensitivity: 189/199=95% (95%CI*: 91%~97.6%);

Relative specificity: 802/806=99.5% (95%CI*: 98.7%~99.9%);

Accuracy: (189+802)/(189+10+4+802) =98.6% (95%CI*: 97.7%~99.2%).

*Confidence Intervals

bleeding diseases. The fecal occult blood test must have high sensitivity and specificity.

The fecal occult blood test has important diagnostic significance for all types of gastrointestinal bleeding, especially for patients with gastric cancer, typhoid fever, or mild bleeding from gastric and duodenal ulcers, as well as anemia with unknown causes, and those suspected of gastrointestinal bleeding. The positive rate of peptic ulcer and fecal occult blood test was reported differently by different families. Fecal occult blood changed from positive to negative, and then continued to be negative, indicating that the ulcer was healing.

Furthermore, the Fecal occult blood test has a certain clinical significance. It is a method to determine gastrointestinal bleeding, which is mainly used to detect small amounts of bleeding invisible

to the naked eye, also called the o-tolidine method (OB). The fecal occult blood test is still the most widely used and evaluated test in colorectal cancer screening. The test is fast, simple to use and painless.

The FOB Rapid Test Cassette of this evaluation performed satisfactorily in standard experimental conditions. The tests showed both excellent accuracy and specificity.

The results of tested samples demonstrate that the FOB Rapid Test Cassette developed by CITEST Diagnostics Inc. meets the requirements of professional in vitro diagnostic intended use. Thus, a conclusion can be drawn that CITEST FOB Rapid Test Cassette can be used in the early diagnosis of colorectal cancer and has a certain clinical significance.

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