FOB/TF Rapid Test Cassette(Colloidal Gold)

Cassette

Instruction for Use

A rapid, Immunochromatographic rapid test for the qualitative detection of human hemoglobin and transferrin in human feces.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PROUDCT SPECIFICATION

1T/BOX,10T/BOX,20T/BOX,25T/BOX,40T/BOX，50T/BOX

INTENDED USE

The FOB/TF Rapid Test Cassette （Colloidal Gold） is a lateral flow immunochromatographic assay for the qualitative detection of human hemoglobin and transferrin in feces. It is intended to be used in as a useful aid to detect gastrointestinal bleeding caused by a number of gastrointestinal disorders, e.g.,diverticulitis, colitis, polyps, and colorectal cancer.This test is recommended for professional use only and all results must be interpreted together with other clinical information or other diagnosis methods available to the physicians.

SUMMARY

Colorectal cancer is cancer that occurs in the colon or rectum, and affects both men and women of all racial and ethnic groups, and is most often found in people aged 50 years or older. For men, colorectal cancer is the third most common cancer after prostate and lung cancers. For women, colorectal cancer is the third most common cancer after breast and lung cancers. Fecal occult blood should be an important indicator in the diagnostic evaluation of patients with suspected gastrointestinal bleeding of any etiology,not just as an indication of colorectal cancer. The presence of human hemoglobin in feces is inadequate as a screening test for stomach cancer(upper gastrointestinal disorders), because of human hemoglobin derived from the upper digestive tract is broken down in the intestinal tract (the antigenicity is lost). Detection of fecal transferrin, which is more stable in stool than hemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract. Blood in the stool may be the only symptom of cancer, but not all blood in the stool is caused by cancer. Other conditions that can cause blood in the stool include: Haemorrhoids, Anal fissures, Colon polyps, Peptic ulcers, Ulcerative colitis. Gastroesophageal reflux disease (GERD). Crohn's disease, use of non-steroidal anti-inflammatory drugs (NSAIDs).

PRINCIPLE

The FOB/TF Rapid Test Cassette（Colloidal Gold） uses new homogenous immunochromatographic system with gold particules. It is a ready to use test which only needs a faecal sample dilution with the supplied ready to use dilution buffer. Specificity is ensured by using a monoclonal antibody conjugated with gold particules and directed against specific human hemoglobin or transferrin. The immunochromatographic test is coated with a monoclonal immunoreagent specific for human hemoglobin and transferrin.Liquid sample and gold conjugate both migrate by capillarity and reach the first specific anti-hemoglobin monoclonal reagent. If hemoglobin is present in the sample, it is blocked and immunoreaction appears as a red-pink line. As sample still migrates, it reaches the second specific reagent line against transferrin, then migrate to the non specific anti-mouse IgG which gives rise to a third red-pink line. This line indicates that the chromatography has been developed without hindrance. It appears also with negative samples.

MATERIALS

Materials Provided:

Test devices. Each cassette is pouched with a package of desiccant.
Extraction diluents (1.5 mL/bottle)
Instruction for use.

Materials Required but Not Provided

Timer
An absorbent disposable tissue or a clean disposable cup

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

Stool samples must be taken as soon as the symptoms appear. The samples can be stored in the refrigerator for 1 to 2 days. For longer storage they must be kept frozen at -20ºC. In this case, the sample should be totally thawed, and brought to room temperature and homogenised before testing.

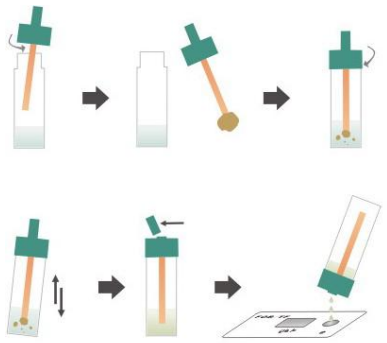
STORAGE AND STABILITY

The FOB/TF Rapid Test Cassette （Colloidal Gold） can be stored at any temperature between 2-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

SPECIMEN COLLECTION AND HANDLING

1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the specimen collection tube and remove the applicator stick. Be careful not to spill or spatter solution from container. (Please refer to below illustration)
3. Insert the stick into fecal specimen at several different sites.
4. Collect a thin smear of specimen on the probe tip only. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely.

The specimen is now ready for testing, transportation or storage.

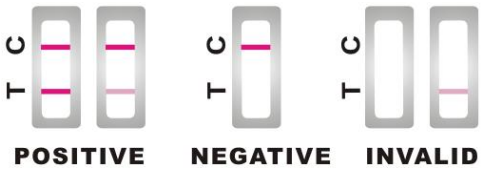


TEST PROCEDURE

Test device, patient's specimens, and controls should be brought to room temperature (10-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from the foil pouch, and label the device with patient or specimen ID number.
2. Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction diluents.
3. Holding the tube vertically, carefully break the tip of the purple cap. Invert the collection tube and carefully dispense 2-3 drops of the liquid into the sample well of the testing device. (Please refer to above illustration)
4. Observe the result in 5-10minutes. Strong positive results may be observed sooner.**Don't read result after 10 minutes.**

INTERPRETATION OF RESULTS



Negative:
One red line appears in the control line region (C). No line appears in the test line region (T).
Positive: Two distinct red lines appear. One red line should be in the control line region (C) and another apparent red line should be in the test line region (T).

Invalid: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Note: The shade of color in the region of the detection line (T) depends on the concentration of FOB/TF antigen in the specimen. Therefore, any shade of color in the region of the detection line (T) should be considered positive.

LIMITATIONS OF THE ASSAY

1. The test must be carried out within 1 hours of opening the sealed bag.
2. An excess of stool sample could result in wrong results.
3. Patients suffering from menstrual period, bleeding hemorrhoids, blood in urine or strain during bowel movement should not collect samples.
4. Positive results confirm the presence of human hemoglobin or/and human transferrin in fecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritations. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
5. Negative results do not exclude bleeding, as some polyps and colorectal cancers may bleed intermittently or not during certain.

PERFORMANCE

Sensitivity

The FOB/TF Rapid Test Cassette(Colloidal Gold) can detect hemoglobin at 200ng/ml and transferrin at 10ng/ml diluted in extraction buffer provided.

Cross-reactivity

The FOB/TF Rapid Test Cassette(Colloidal Gold) is specific for human hemoglobin and human transferring, showing no cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces.

Accuracy

The FOB/TF Rapid Test Cassette(Colloidal Gold) has been compared with another leading commercial rapid test using clinical specimens.

FOB Results

Method	Other Rapid Test			Total Result
FOB/TF Rapid Test Cassette（Colloidal Gold）	Results	Positive	Negative	
	Positive	143	1	144
	Negative	3	289	292
Total Result	146		290	436

Relative sensitivity: 97.9% Relative specificity: 99.7%
Accuracy: 99.1%

Transferrin Results

Method	Other Rapid Test			Total Result
FOB/TF Rapid Test Cassette（Colloidal Gold）	Results	Positive	Negative	
	Positive	91	2	93
	Negative	1	342	343
Total Result	92		344	436

Relative sensitivity: 98.9% Relative specificity: 99.4%
Accuracy: 99.3%

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 200ng/mL, 400ng/mL and 10μg/mL FOB positive specimens.The specimens were correctly identified >99% of the time.
Within-run precision has been determined by using 15 replicates of three specimens: 10ng/mL, 80ng/mL and 1μg/mL Transferrin positive specimens.The specimens were correctly identified >99% of the time

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same 6 specimens:200ng/mL hemoglobin, 400ng/mL hemoglobin, 10μg/mL hemoglobin, 10ng/mL transferrin, 80ng/mL transferrin and 1ug/mL transferrin standard sample. Three different lots of the FOB/TF Rapid Test Cassette（Colloidal Gold）have been tested using these specimens. The specimens were correctly identified >99% of the time.

【BIBLIOGRAPHY】

1. WALKER C.W., "Fecal occult blood tests reduce colorectal cancer mortality.", Am Fam Physician. 2007 Jun 1;75(11):1652-3.
2. CHIEN-HUA CHIANG, et al. «A comparative study of three fecal occult blood tests in upper gastrointestinal bleeding»; Kaohsiung J. Med. Sci May 2006, Vol 22, No 5: 223-228
3. HIROFUMI MIYOSHI, et al. «Accuracy of Detection of Colorectal Neoplasia using an Immunochemical Occult Blood Test in Symptomatic Referred Patients: Comparison of Retrospective and Prospective Studies. Internal Medicine Sept. 2000 Vol. 39, No. 9: 701-706

Code:GKPD045-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
Dezhou Guoke Medical Technology Co., Ltd
Add.: 28-31 axis,1 and 2 span, No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No. 6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province,China
E-mail: office@guoke-medical.com

European Authorized Representative:
Riomavix S.L.
Add.: Calle de Almansa 55,1D, Madrid 28039 Spain
E-mail: riomavix@gmail.com