FOB/TRF/HP Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A rapid, Immunochromatographic rapid test for the qualitative detection of human hemoglobin, transferrin and Helicobacter Pylori antigen 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/TRF/HP Rapid Test Cassette（Colloidal Gold） is a lateral flow immunochromatographic assay for the qualitative detection of human hemoglobin , transferrin and Helicobacter Pylori antigen in feces.

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/TRF/HP 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, transferrin or Helicobacter Pylori antigen. 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 monoclonal reagent. If hemoglobin (transferrin or Helicobacter Pylori antigen) is present in the sample, it is blocked and immunoreaction appears as a red-pink line. Then migrate to the non specific anti-mouse IgG which gives rise to a red-pink line.This line indicates that the chromatography has been developed without hindrance.It appears also with negative samples.If the control line dose not developed, the test is invalid.

MATERIALS

Materials Provided:
Test devices. Each cassette is pouched with a package of desiccant.
Extraction diluents (1.5mL/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.

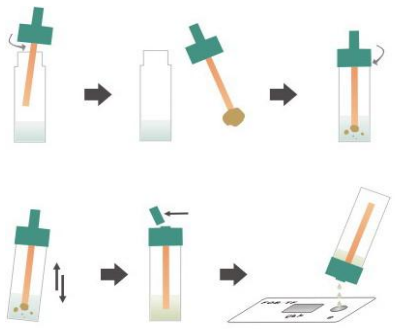
STORAGE AND STABILITY

The FOB/TRF/HP 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: Only the C line appears, and no T line developed.
POSITIVE: Both C and T lines appear, the result is positive.
The intensity of the test line ("T") may be less than that of the control line ("C"); this still means positive result.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.
INVALID: No C line appears, regardless the color of T line. The assay is invalid. Repeat the assay with a new device. If the problem persists, contact your local distributor.

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. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single result, but should only be made by the physician after evaluate all clinical and laboratory evidences.
5. Failure to follow the procedures of assay and test result interpretation may give inaccurate results.
6. A negative result can occur if the FOB/TRF/HP present in the specimen is below the detection limits of the assay, or that are detected are not present during the stage of disease in which a sample is collected.

PERFORMANCE

The FOB/TF/HP 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/TRF/HP 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/TRF /HP 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%

HP Results

Product		Other Rapid Test		Total Results
FOB/TRF /HP Rapid Test Cassette（Colloidal Gold）	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative specificity :98.8% Relative sensitivity :100%
Accuracy : 98.9%

BIBLIOGRAPHY

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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		

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