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## Human FOB+Tf( transferrin ) Rapid test

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*Cat.No: DTSXY-Z7*

*Lot. No. (See product label)*

### Size

20T

### Intended use

The FOB+Tf ( transferrin ) Rapid test is a rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of human haemoglobin (hHb) and human transferrin (hTf) in human feces specimens which might be useful for the diagnosis of bleeding gastrointestinal disorders. Only for laboratory use.

### General Description

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 haemoglobin in feces is inadequate as a screening test for stomach cancer (upper gastrointestinal disorders), because of human haemoglobin 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 haemoglobin, 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 antiinflammatory drugs (NSAIDs).

### Principle Of The Test

The FOB+Tf ( transferrin ) Rapid test is a qualitative lateral flow immunoassay for the detection of human haemoglobin and human transferrin in human feces samples. The membrane is pre-coated with monoclonal antibodies against human haemoglobin and human transferrin on the test line region. During testing, the sample reacts with the particles coated with antihuman haemoglobin antibodies and/or with anti-human transferrin antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugates and generate one or two coloured lines. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

### Reagents And Materials Provided

1. Card tests
2. Instructions for use
3. Specimen collection vial with buffer

## Materials Required But Not Supplied

1. Specimen collection container
2. Disposable gloves
3. Timer

## Specimen Collection And Preparation

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C /36-46.4°F) for 7 days prior to testing (maximum 6 months) the specimen must be kept frozen at -20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

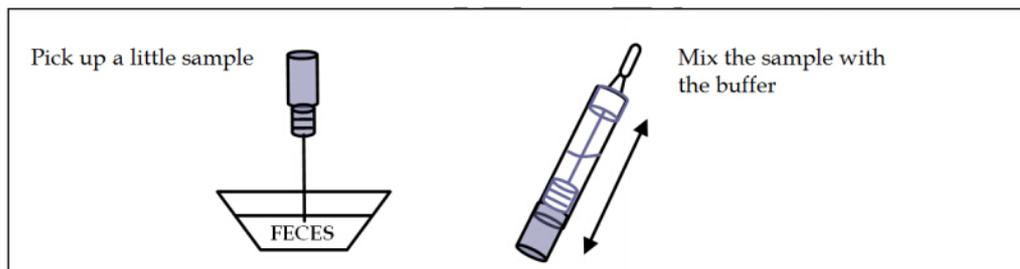
## Reconstitution And Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

## Assay Procedure

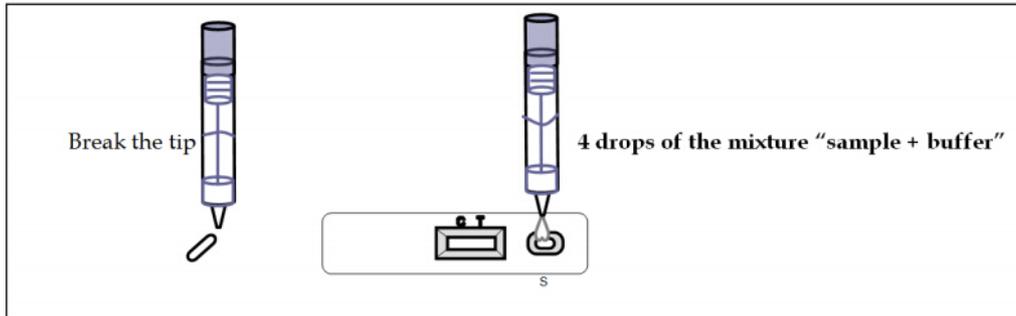
### To process the collected stool samples:

Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times in different parts of the fecal specimen to pick up the sample. Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 15 µL into the specimen collection vial with buffer.



**Test Procedure:** Allow the tests, stool samples and buffer to reach the room temperature (15-30°C /59-86°F) prior to testing. Do not open the pouches until ready to perform the assay.

1. Remove the test from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate card for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

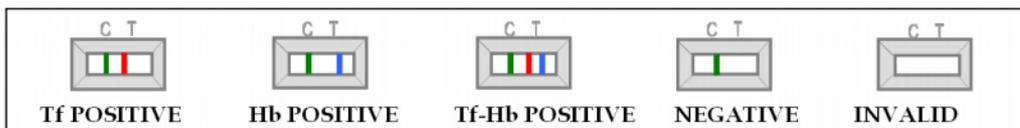


## Quality Control

Internal procedural controls are included in the test:

A GREEN line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

## Interpretation Of Results



**Tf POSITIVE:** Two lines appear across the central window, a **red** test line marked with the letter T and a **green** control line marked with the letter C. A Transferrin (Tf) positive result could be indicative of upper gastrointestinal bleeding.

**Hb POSITIVE:** Two lines appear across the central window, a **blue** test line marked with the letter T and a **green** control line marked with the letter C. The result Haemoglobin (Hb) positive is indicative of little blood in faeces; transferrin exists in only trace amounts in blood and could be not detected.

**Tf-Hb POSITIVE:** Three lines appear across the central window, a **red** test line and **blue** test line marked with the letter T, and a **green** control line marked with the letter C. Transferrin (Tf) and Haemoglobin (Hb) positive result could be indicative of lower gastrointestinal bleeding disorders.

**NEGATIVE:** Only one **green** line appears across the control line region marked with the letter C (control line). Not occult blood in feces.

**INVALID:** Total absence of the green control coloured line regardless the appearance or not of the red and blue test lines. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

### NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the blue or red coloured test lines in the result line region (T) will vary depending on the concentration of human haemoglobin or human transferrin in the specimen. However, neither the quantitative value, nor the rate of increase in haemoglobin and/or transferrin can be determined by this qualitative test.

## Performance Characteristics

### Cut-off value

Cut-off value of Rapid-VIDITEST FOB-Transferrin Card is 50ng/mL (5.1 µg hHb/g feces) for human haemoglobin and 4ng/mL (0.4 µg hTf/g feces) for human transferrin.

### Sensitivity and Specificity

It was performed an evaluation using this Card with fecal samples obtained from patients. The Card was evaluated compared with others commercial immunoassays (ImmunoTech OcculTech YD Diagnostics, and Human Hexagon, OBTI). Sensitivity: >99% and specificity 99% compared with ImmunoTech OcculTech (haemoglobin test line) Sensitivity: >99% and specificity >99% compared with Human Hexagon (transferrin test line)

### Cross-Reactivity

It was performed an evaluation to determine the cross reactivity and interferences of this Card. There is not cross reactivity against other fecal markers occasionally present in feces (Bovine and pig haemoglobin, Bovine and pig transferrin, Human calprotectin, Human lactoferrin).

## Precautions

1. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not use the test if pouch is damaged.
4. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
5. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. The test should be discarded in a proper biohazard container after testing.
7. The test must be carried out within 2 hours of opening the sealed bag.

## Limitations

1. The test will only indicate the presence of human haemoglobin or/and transferrin in the specimen (qualitative detection) and should be used for the detection of haemoglobin and transferrin in feces specimens only. Neither the quantitative value nor the rate of increase in haemoglobin or transferrin concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. In the case of patients have bleeding haemorrhoids, blood in urine, strained during bowel movement or women during their menstrual period, should be not collect samples.
5. Positive results confirm the presence of occult blood in fecal samples; nevertheless, it can be due to several causes, besides colorectal bleeding, such as haemorrhoids, anal fissures, colon polyps, peptic ulcers, ulcerative colitis, gastroesophageal reflux disease (GERD), Crohn's disease. Positive results should be followed up with additional diagnostic procedures by a physician to determine the exact cause and source of the blood in the stool. Endoscopy is the method of choice in diagnosing the cause of upper and lower gastrointestinal bleeding.
6. Negative results do not exclude bleeding since some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. Additionally, blood may not be uniformly distributed in stool samples.

## References

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.