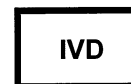




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## **Rapid-VIDITEST**

### **FOB+Tf Card**

*One step Faecal Occult Blood and Transferrin Card Test*

#### **Instruction manual**

#### **INTENDED USE:**

The Rapid-VIDITEST FOB+Tf Card is a one step coloured chromatographic immunoassay for the qualitative determination of human haemoglobin (Hb) and human transferrin (Tf) in stool samples to detect gastrointestinal bleeding.

#### **INTRODUCTION:**

Colorectal cancer is a leading cause of illness and death in the Western world. Screening with faecal occult blood tests is based on the concept that important target colonic neoplasm, such as early-stage cancer and large adenomatous polyps, will bleed, for which may be detected by an occult blood test. When gastrointestinal blood is lost, the stool will contain a combination of intact or nearly intact haemoglobin, intact heme, and heme-derived porphyrins in amounts that depend on the site, the amount of bleeding and the transit time through the gut. Immunochemical tests detect intact or nearly intact human haemoglobin, being a very specific technique to detect the loss of blood from the lower intestine, because blood from lower sites is less degraded during transit. The haemoglobin is unstable in feces, leading to false negative results. The detection of faecal transferrin, which is more stable than haemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract. Transferrin is a blood-derived component that may be leaked into gastrointestinal tract and then discharged with the feces in gastrointestinal bleeding diseases. Transferrin is stable in feces and a good marker to detect loss of blood from the upper and lower intestine (gastrointestinal bleeding). This immunochromatographic assay detects human haemoglobin and human transferrin in stool samples simultaneously, by obtaining more accurate testing results.

#### **PRINCIPLE:**

The Rapid-VIDITEST FOB+Tf Card is a qualitative immunochromatographic assay for the determination of human haemoglobin and human transferrin in stool samples. The membrane is pre-coated with mouse monoclonal antibodies on both test bands (result region), against human haemoglobin and human transferrin.

During testing, the sample is allowed to react with coloured conjugates (anti-human haemoglobin antibodies-blue microspheres and anti-human transferrin antibodies-red microspheres) pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will

capture the coloured conjugate. Different coloured bands will be visible, depending upon the haemoglobin or the transferrin content of the sample. These bands are used to interpret the result.

The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as verification that sufficient volume is added, that proper flow is obtained and as an internal control for the reagents.

#### **MATERIALS PROVIDED:**

- Rapid-VIDITEST FOB+Tf Card tests
- Instructions for use
- Specimen collection tubes-sample diluent

#### **MATERIALS REQUIRED BUT NO PROVIDED:**

- Specimen collection container
- Disposable gloves
- Timer

#### **SPECIMEN COLLECTION AND PREPARATION:**

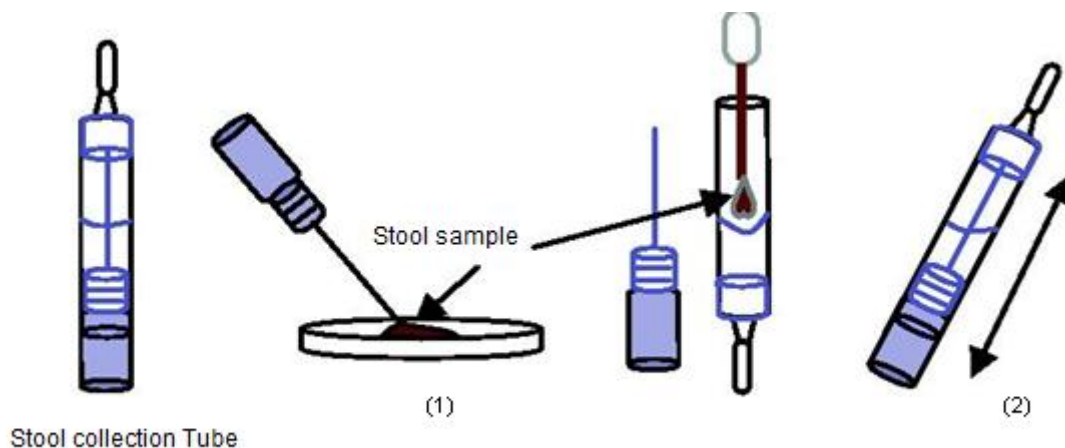
Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4°C/36-40°F) for 1-2 days prior to testing. For longer storage, maximum 1 year, 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.

#### **PROCEDURES:**

##### **To process the collected stool samples:**

Use a separate vial for each sample.

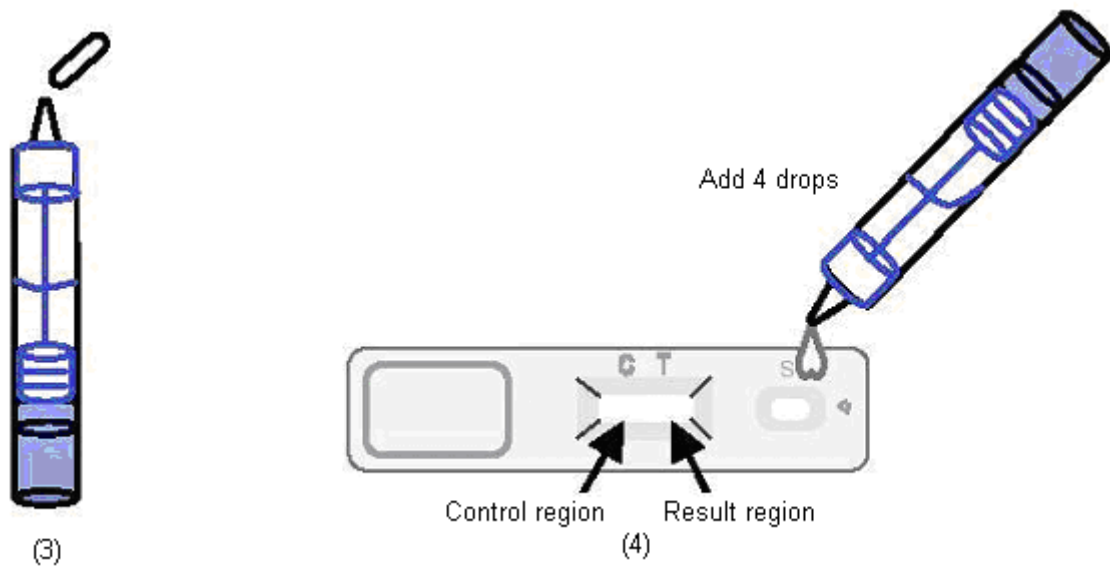
- (1) Unscrew the tap and use the stick by introducing four times into the faecal specimen to pick up a little sample (approx. 150mg), if the stool sample were liquid take 150 µl by using a pipette and adding the sample into the stool collection tube.
- (2) Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.



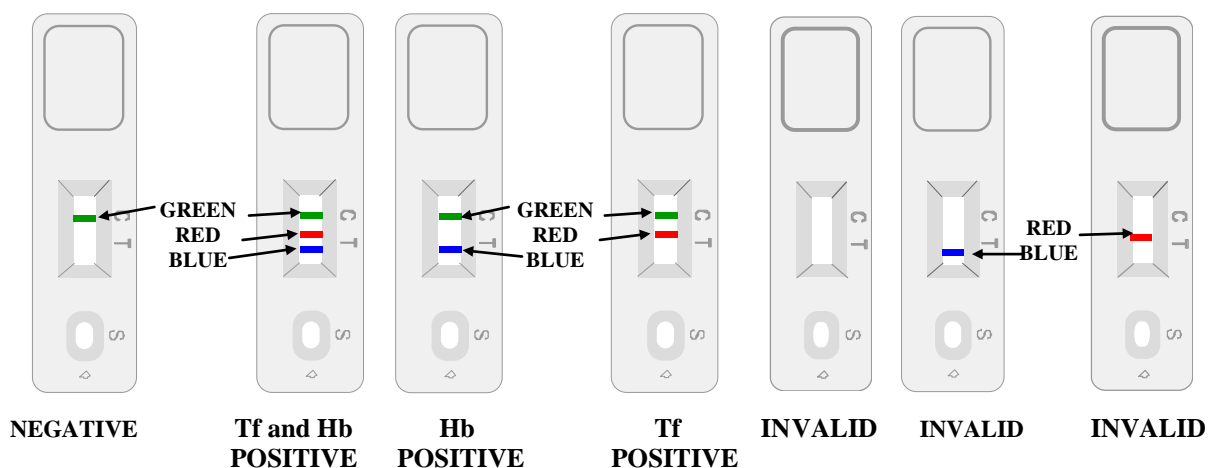
### Test Procedure:

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

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the tube (3).
2. Remove the Rapid-VIDITEST FOB+Tf Card from its sealed bag before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense 4 drops or 100 µl into the circular window marked with an arrow (4).
4. Read the result at **10 minutes** after dispensing the sample.



### INTERPRETATION OF RESULTS:



**NEGATIVE:** Only one GREEN band appears across the central window in the site marked with the letter C (control line). No Occult blood presents: neither human haemoglobin nor human transferrin.

**Tf and Hb POSITIVE:** In addition to the GREEN control band, a RED band (Tf test line) and a BLUE one (Hb test line) also appear in the site marked with the letter T (result region). That probably would mean a lower gastrointestinal bleeding disease (colorectal cancer).

**Tf POSITIVE:** In addition to the GREEN control band, a RED band (Tf test line) also appears in the site marked with the letter T (result region). That probably would mean an upper gastrointestinal bleeding disease (the human haemoglobin was probably degraded in the gastrointestinal tract).

**Hb POSITIVE:** In addition to the GREEN control band, a BLUE one (Hb test line) also appear in the site marked with the letter T (result region). That probably would mean a lower gastrointestinal bleeding disease (the concentration of human transferrin in blood is 100 times less than human haemoglobin, therefore, Hb positive means not much blood present in feces).

**INVALID:** A total absence of the control coloured band (GREEN) regardless the appearance or not of the result lines (RED or BLUE). Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely reasons for control line failure. Review the procedure and repeat the tests using a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

#### **NOTES ON THE INTERPRETATION OF RESULTS:**

The intensity of the RED/BLUE coloured band 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 or transferrin can be determined by this qualitative test.

#### **QUALITY CONTROL:**

Internal procedural controls are included in the test:

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

**LIMITATIONS:**

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of stool sample could result in wrong results (brown bands appear or absence of the control coloured band).
3. Patients suffering from menstrual period, bleeding haemorrhoids, blood in urine or strain during bowel movement should not collect samples.
4. Positive results confirm the presence of human haemoglobin or/and human transferrin in faecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as haemorrhoids, 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 cancer may bleed intermittently or not during certain stages of the disease. Moreover, blood may not be uniformly distributed in stool samples.

**PERFORMANCE CHARACTERISTICS:****Sensitivity**

A sample containing human haemoglobin at concentration equal to or higher than 50 ng/ml and human transferrin at concentration equal to or higher than 4 ng/ml produces positive results when using Rapid-VIDITEST FOB+Tf Card.

Different haemoglobin and transferrin dilutions were tested directly in the extraction buffer or spiked in a negative stool sample in accordance with the kit instructions to determinate the detection limit of the test.

The detection of human haemoglobin with Rapid-VIDITEST FOB+Tf Card showed >99% of sensitivity compared to a commercial guaiac assay.

The detection of human haemoglobin in stool samples with Rapid-VIDITEST FOB+Tf Card showed >99% of sensitivity compared with others commercial rapid tests (ImmunTech OccultTech (YD Diagnostics) and Human Hexagon OBTI).

**Specificity**

The Rapid-VIDITEST FOB+Tf Card is specific for human haemoglobin and human transferrin, showing no cross-reaction with haemoglobin or transferrin from bovine and pig.

The detection of human haemoglobin with Rapid-VIDITEST FOB+Tf Card showed >99% of specificity compared to a commercial guaiac assay, >99% compared with other commercial rapid tests (ImmunTech OccultTech (YD Diagnostics) and Human Hexagon OBTI).

The use of monoclonal antibodies in the elaboration of Rapid-VIDITEST FOB+Tf Card assures high degree of specificity to detect human haemoglobin and transferrin.

**STORAGE AND STABILITY:**

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.

## PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered as potentially hazardous and handled as if they were infectious agents.
- The tests should be discarded in a proper biohazard container after testing.

## REFERENCES:

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## SYMBOLS FOR IVD COMPONENTS AND REAGENTS:



*In vitro* diagnostic device



Batch code



Use by



Manufacturer