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CE

IVD

Rapid-VIDITEST

FOB Card

One step Fecal Occult Blood Card Test

Instruction manual

INTENDED USE:

The Rapid-VIDITEST FOB Card is a one step coloured chromatographic immunoassay for the qualitative detection of human hemoglobin (Hb) in stool samples.

INTRODUCTION:

Colorectal cancer is a leading cause of illness and death in the Western world. Screening with fecal occult blood tests is based on the concept that important target colonic neoplasm, such as early-stage cancer and large adenomatous polyps, will bleed and may be detected by an occult blood test. When gastrointestinal blood is lost, the stool will contain a combination of intact or nearly intact hemoglobin, intact heme, and heme-derived porphyrins in amounts that depend on the site and amount of bleeding and the transit time through the gut. Immunochemical tests detect intact or nearly intact human hemoglobin, being a very specific technique for detecting loss of blood from the lower intestine, because blood from lower sites is less degraded during transit.

PRINCIPLE:

The Rapid-VIDITEST FOB Card is a qualitative immunochromatografic assay for the determination of human hemoglobin in stool samples. The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, against human hemoglobin.
During testing, the sample is allowed to react with the coloured conjugates (anti-human hemoglobin mouse monoclonal antibodies-red microspheres) which was 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.
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.

MATERALS PROVIDED:

- Rapid-VIDITEST FOB Card tests
- Instructions for use
- Stool collection tubes-sample diluent

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

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.

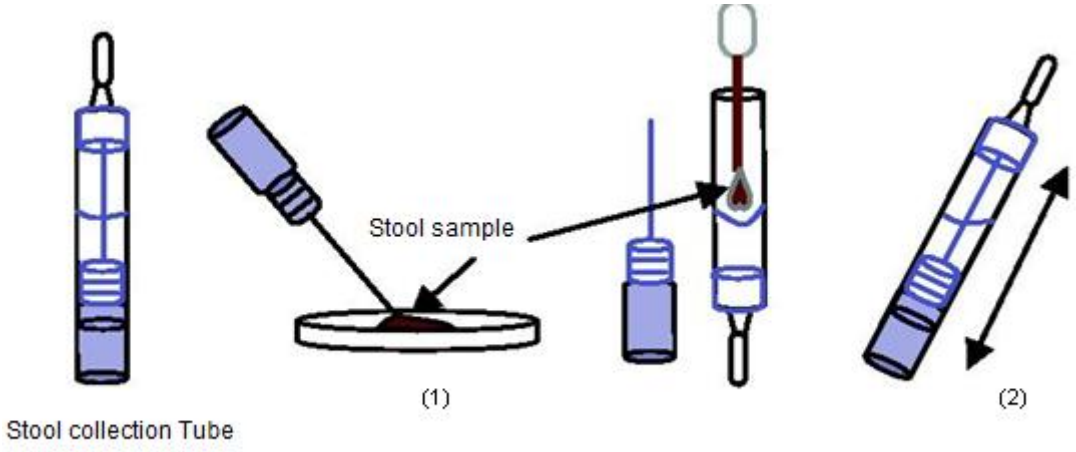
PROCEDURES:

Specimen preparation:

Use a separate vial for each sample.

(1) Unscrew the tap and use the stick to pick up a little sample,if the stool sample was liquid take 100 µl using a pipette and add 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.

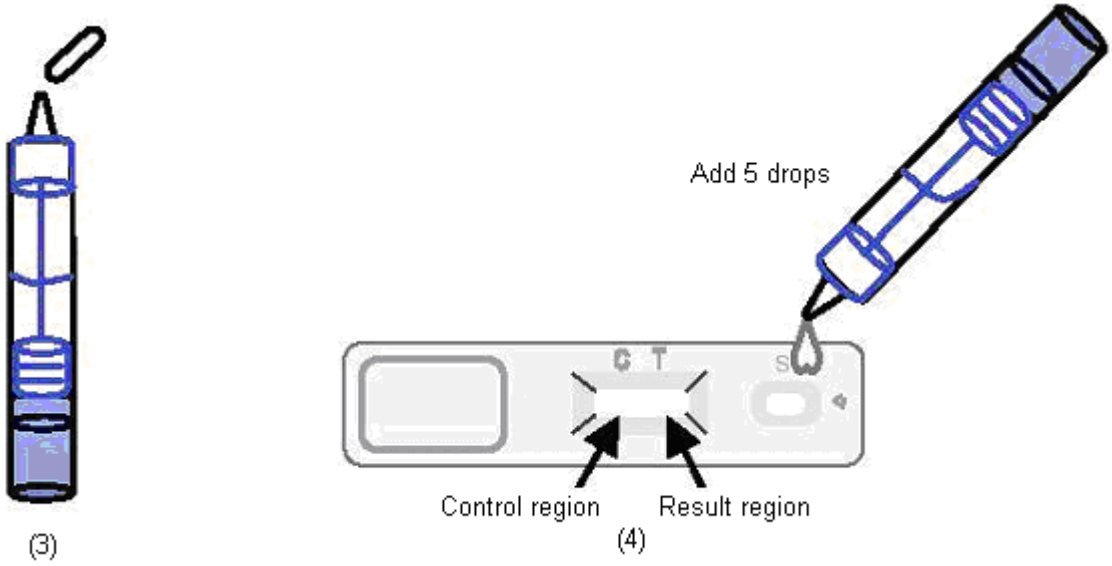


Precautions: Patients should not collect samples during their menstrual period, if they have bleeding haemorrhoids, blood in urine, or if they have strained during bowel movement.

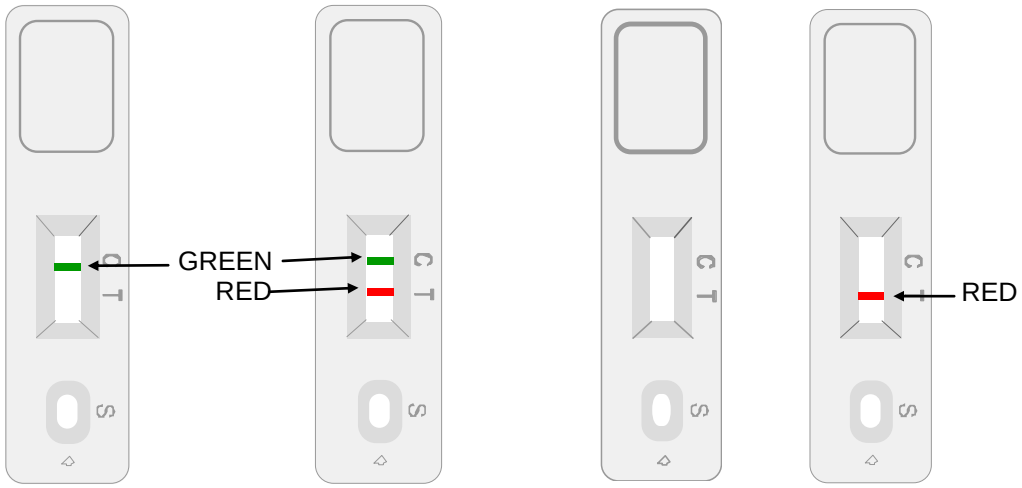
Test Procedure:

Allow the tests, stool samples and controls to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches 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 top (3).
2. Remove the Rapid-VIDITEST FOB Card from its sealed bag before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow (4).
4. Read the result at **5 minutes** (the coloured bands appear). Do not read a test result after more than 10 minutes.



INTERPRETATION OF RESULTS:



NEGATIVE: Only one GREEN band appears across the central window in the site marked with the letter C (control line).

POSITIVE: In addition to the GREEN control band, a RED band (test line) also appears in the site marked with the letter T (result region).

INVALID: A total absence of the control coloured band (GREEN) regardless the appearance or not of the result lines (RED). 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 with 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 coloured band in the result line region (T) will vary depending on the concentration of human hemoglobin in the specimen. However, neither the quantitative value, nor the rate of increase in haemoglobin 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 cause wrong results (brown bands appear or absence of the control coloured band).
3. The intensity of the lines may vary from very strong at high hemoglobin concentrations to faint when the hemoglobin concentration is close to the sensitivity limit of the test.
4. Patients should not collect samples during their menstrual period, if they have bleeding haemorrhoids, blood in urine, or if they have strained during bowel movement.
5. Positive results confirm the presence of human hemoglobin in fecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as haemorrhoids, blood in urine or stomach irritations. A possitive results should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
6. Negative results do not exclude bleeding, as 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.
7. This test may be less sensitive for detecting upper gastrointestinal bleeding because blood degrades as it passes through the gastrointestinal track.

PERFORMANCE CHARACTERISTICS:

Sensitivity

A sample containing human hemoglobin at concentration equal to or higher than 50 ng/mL produces a positive result using Rapid-VIDITEST FOB Card. In some cases sample containing human hemoglobin at concentrations less than 50 ng/mL can also be tested as positive.
Different hemoglobin dilutions were tested directly in the extraction buffer or spiked in a negative stool sample in accordance with the kit instructions.
The detection of human hemoglobin with Rapid-VIDITEST FOB Card showed >99% of sensitivity compared to a commercial guaiac assay.

Specificity

The Rapid-VIDITEST FOB Card is specifics for human hemoglobin and do not show any cross reaction with hemoglobin from bovine and pig.

The detection of human hemoglobin with Rapid-VIDITEST FOB Card showed >99% of specificity compared to a commercial guaiac assay.

The use of mouse monoclonal antibodies in the elaboration of Rapid-VIDITEST FOB Card assures high degree of specificity for the detection of human hemoglobin.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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 in the same manner as an infectious agent.
- The tests should be discarded in a proper biohazard container after testing.

REFERENCES:

1. Towler BP, Irwig L, Glasziou P, Weller D, Kewenter J. Screening for colorectal cancer using the faecal occult blood test, Hemoccult. Cochrane Database Syst Rev. 2000;(2): CD001216.
2. Ransohoff DF and Lang CA. Sceening for colorectal cancer with the Fecal Occult Blood Test a background paper. Ann Intern Med. 1997; 126: 811-822.
3. Ransohoff DF and Lang CA. Suggested technique for Fecal Occult Blood testing and interpretation in colorectal cancer screening. Ann Intern Med. 1997; 126: 808-810

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer