FOB Rapid Test
Package Insert

REF VTFO-A602	English

INTENDED USE

The VivaDiag™ FOB Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of human haemoglobin in feces samples. It is intended to be used by professionals as a preliminary test result to aid in diagnosis of lower gastrointestinal (g. i.) pathologies. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY

Colorectal cancer is one of the most commonly diagnosed types of cancer and a leading cause of cancer-related deaths. Screening for occult blood in feces is likely to improve the odds of the detection of colorectal cancer at an early stage, thus reducing mortality.
Previously, commercially available FOB test is utilised the Guaiac Method, which requires a special diet prior to testing in order to avoid false positive and false negative results. The FOB Rapid Test is designed to detect human haemoglobin in feces samples. The test is based on an immunochemical method that improves specificity of detection of lower gastrointestinal disorders including colorectal cancers and adenomas without any dietary restrictions.

PRINCIPLE

The VivaDiag™ FOB Rapid Test is a lateral flow chromatographic immunoassay. The test device consists of: 1) a burgundy colored conjugate pad containing Antibodies to human haemoglobin conjugated with colloidal gold (antibody conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with Antibodies to human haemoglobin, and the C line is pre-coated with goat anti-mouse IgG antibody.
During testing, the specimen reacts with antibodies to human haemoglobin conjugated with coloured particles and pre-coated on the sample pad of the test. The mixture then migrates along the membrane by capillary action and interacts with components on the membrane. If there is sufficient human haemoglobin in the specimen, a coloured line will form in the test line region of the membrane. The presence of this coloured line indicates a positive test result, while its absence indicates a negative test result. The appearance of a coloured line in the control line region serves as a procedural control indicating that the proper volume of specimen has been added and membrane wicking has occurred.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test result is invalid over 5 minutes.
- The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
- Positive results may occur due to the gastrointestinal tract bleeding caused by taking drugs (such as aspirin).
- A small amount of digestive tract bleeding cannot mix with feces evenly in the process of feces formation. To obtain accurate results, it is necessary to detect three times for hemorrhage of digestive tract is discontinuous process. One time of positive result can indicate the existence of hidden bleeding.
- Positive result may occur according to menstrual period, hematuria and nasal bleeding.
- Weakly positive or negative results may occur for the long time stay of Hb in digestive tract, and the enzyme may be secreted by the intestinal enzymes of the degradation. Another detection should be taken for 2~3 times to judge with clinical symptoms.
- Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results

COMPOSITION

Materials provided and available for purchase

1. Test device in foil pouch
2. Specimen collection tube with buffer
3. Package insert

Materials required but not provided:

1. Specimen collection container
2. Timer
3. Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
4. Appropriate biohazardous waste containers and disinfectants.
5. Dropper

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 36-86°F(2-30°C). Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 59-86°F(15-30°C).
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

SPECIMEN COLLECTION AND HANDLING

The FOB Rapid Test is intended only for use with human feces specimens.

1) Specimen collection

Specimen collection and pre-treatment:

1. Use the specimen collection tube for specimen collection. Best results will be obtained if the assay is performed within 2 hours after collection.

For solid specimens:

Unscrew and remove the applicator stick attached on the cap. Be careful not to spill or spatter solution from the tube. Collect specimen by inserting the applicator stick into at least 6 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).

For liquid specimens:

Hold the pipette vertically, aspirate feces specimens, and then transfer 2 drops (approximately 50 µL) into the specimen collection tube containing the extraction buffer.
2. Place the applicator back into the tube and screw the cap tightly.
3. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.

Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.

2) Specimen handling

Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours.

Note:

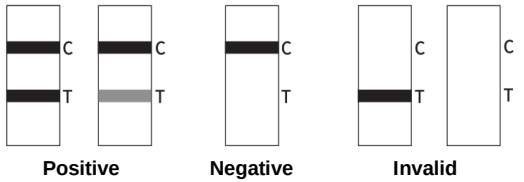
- *Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.*
- *A sample must be collected in a clean and dry container.*

TEST PROCEDURE

Please read the instructions carefully before testing. Allow equipment, buffers, and samples to equilibrate to room temperature (15°C to 30°C) prior to testing.

1. Take out a test device from sealed foil pouch and put it on a clean and level surface.
2. Break off the tip of the buffer tube. Apply 3 drops of the extracted specimen into the specimen well. Please avoid bubbles during applying.
3. Wait for the red line(s) to appear. Read the test result at **5 minutes**. Don't read the result after 10 minutes.

INTERPRETATION OF TEST RESULTS



Positive*: Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

*NOTE: The intensity of the color in the test line region (T) may vary depending on the concentration of haemoglobin present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Negative: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

Invalid: Control line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Limited by the detection method, the experimental personnel should pay more attention to the negative results. If fecal occult blood is still suspected, the sample should be collected later and carry the detection with other methods.
- Negative result may occur when detecting samples with concentration exceed 2000µg /mL indicate that the sample should be diluted (50~100 times) before tested again.

PERFORMANCE

1. Accuracy

The result of VivaDiag™ FOB Rapid Test compared to Other rapid test using 1374 specimens was shown as below:

VivaDiag™ FOB Rapid Test	Other rapid test		
	Positive	Negative	Total
Positive	325	9	334
Negative	16	1024	1040
Total	341	1033	1374
Sensitivity	95.3%(325/341, 95%CI, 92.5%~97.1%)		
Specificity	99.1%(1024/1033, 95%CI, 98.4%~99.5%)		
Accuracy	98.2%(1349/1374, 95%CI, 97.3%~98.8%)		

2. Sensitivity

Limit of detection: The test kit has a sensitivity of 50ng/mL, when detecting Hb quality control samples.

3. Cross-Reactivity

FOB Test is specific for human haemoglobin and shows no cross-reaction with haemoglobin from bovine, pig, chicken and goat blood at concentrations up to 0.5 mg/mL.Hemoglobin from polecat may cause cross reactions.

4. Interfering Substances

There was no interference for potential interfering substances listed below.

Interfering substance	Concentration in specimen	Interfering substance	Concentration in specimen
Ascorbic acid	20 mg/dL	Urea	2000 mg/mL
Oxalic acid	60 mg/dL	Glucose	2000 mg/dL
Acetylsalicylic acid	20 mg/dL	Albumin	2000 mg/dL
Bilirubin	100 mg/dL	Caffeine	40 mg/dL
Uric acid	60 mg/dL	/	/

5. Reproducibility

The reproducibility study was conducted at three sites by three Technicians using three different lots of product to demonstrate the within run, between run and between operator precision. The intra-assay agreements were 100%. The inter-site agreement was 100%.

6. Hook Effect

Sample containing as high as 0.5 mg/mL hemoglobin can still test positive. The tests do not show a Hook or Prozone Effect up to the maximal observed physiological concentration (0.5 mg/mL). Thus, the working range is 50 ng/ml up to 0.5 mg/ml (=2.5 µg/g to 250 µg/g faeces).

REFERENCES

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INDEX OF SYMBOLS

	Consult instructions for use		Use by		Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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CE IVD

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