FOB Rapid Test
Package Insert

REF VTFO-U602	English

INTENDED USE

VivaDiag™ FOB Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human hemoglobin in human feces samples. The test is used to aid diagnosis of bleeding caused by a number of gastrointestinal disorders, such as diverticulitis, colitis, polyps, and colorectal cancer. The test is recommended for use in routine physical examinations, monitoring any bleeding in patients, and screening for colorectal cancer or gastrointestinal bleeding. The test is intended to be used by healthcare professionals in laboratories. Not for near-patient use. For *in vitro* diagnostic use only.

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 utilized 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 hemoglobin 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 anti-human hemoglobin monoclonal antibody 1 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 anti-human hemoglobin monoclonal antibody 2, and the C line is pre-coated with goat anti-mouse IgG antibody.
During testing, the specimen reacts with antibodies to human hemoglobin 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 hemoglobin 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 professional *in vitro* diagnostic use only.
- For single use. Do not reuse tests.
- Do not interchange or mix reagents from different lots.
- Do not use the test if its foil pouch is damaged.
- Do not use the test after the expiration date.
- This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled by observing usual safety precautions (e.g. do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not eat, drink or smoke in the area where the specimens or kits are handled. Protective clothing such as laboratory coats, disposable gloves and eye protection are recommended. Observe established precautions against microbiological hazards throughout testing. Follow standard procedures for proper disposal of specimens in accordance with local regulations.
- Humidity and temperature can adversely affect results.
- The components of the test (e.g. antibodies/chemicals) do not cause any danger if the test is used according to the instructions.
- Follow the instructions for use carefully. Inform the patients of the procedures of the collection and dilution of the stool sample.
- 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 hemoglobin 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.
- Used testing materials should be discarded according to local regulations.

COMPOSITION

Materials provided and available for purchase:

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

Materials required but not provided:

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

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 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 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).
- Do not remove the test device from the pouch until ready to use. The test device should be used within 1 hour once opened.

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

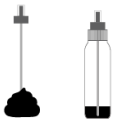
SPECIMEN COLLECTION AND HANDLING

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

1) Specimen collection

Specimen collection and pre-treatment:
Use the specimen collection tube for specimen collection. Best results will be obtained if the assay is performed within 1 hour after collection.

1. 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).
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 buffer.



2) Specimen handling

Perform the test as soon as possible after specimen collection. If it is not possible for the patient to bring the specimen collection tube to the doctor immediately, the specimen can be stored in buffer and refrigerated at 2-8°C for a maximum of 3 days. During transportation of the specimen to the doctor, uninterrupted cooling is not required. However, transportation should be carried out quickly, as a slow degradation of hemoglobin may occur at warm temperatures. At temperatures up to a maximum of 25°C, transportation should not exceed 48 hours. If testing is not carried out in the doctor's practice/laboratory immediately after receiving of the specimen, it can be stored refrigerated there for a maximum of 3 more days. If testing is delayed, faecal specimens in buffer can be frozen at -20°C for up to 2 months. Avoid repeated freeze-thaw cycles.

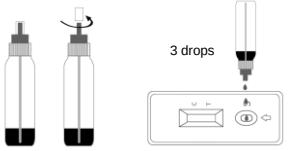
Note:

- *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.*

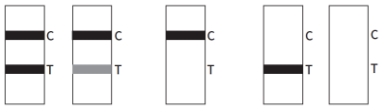
TEST PROCEDURE

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. Hold the specimen collection tube upright and open the cap onto the specimen collection 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 **Negative** **Invalid**

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 hemoglobin 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.
- The performance of this product has been established for human feces only. Other specimen types have not been evaluated.
- These assays are chromatographic immunoassay and may be affected by environmental conditions.
- There is a possibility that substances and/or factors may interfere with the test and cause false results. Technical or procedural errors can also contribute to erroneous results.
- Refer to the WARNINGS AND PRECAUTIONS in this Package Insert for requirements of training and qualifications required by the users.
- The false results may be caused by unstable or degraded antigens are not recognized by antibodies as a result of analyte changes with time and temperature.
- The false results may be caused by the cross-reactions or other non-specific antibody in the sample. The false results may be caused by the reaction of unknown components shielding the antigens and antibodies.

PERFORMANCE

1. Sensitivity

Limit of detection: The test kit has a sensitivity of 40 ng/mL, when detecting Hb quality control samples.

2. Cross-Reactivity

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

3. Clinical Sensitivity/Clinical Specificity

The result of the 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%~97.3%)		
Specificity	99.1% (1024/1033, 95%CI, 98.4%~99.6%)		
Accuracy	98.2% (1349/1374, 95%CI, 97.3%~98.8%)		

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	20 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

The tests do not show a Hook or Prozone Effect up to the maximal observed physiological concentration (10 μg/mL). And sample containing as high as 2000 μg/mL hemoglobin can still test positive.Thus, the working range is 40ng/ml up to 2000μg/mL (= 1.6μg/g to 80mg/g faeces).

REFERENCES

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8. Yamamoto M., Nakama H., Cost-effectiveness analysis of immunochemical occult blood screening for colorectal cancer among three feces sampling methods: Hepatogastroenterology, 2000 Mar-Apr, 47 (32) 396-399.

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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