

Faecal Occult Blood (FOB) Rapid Test

Catalogue Number: RAPG-FOB-001

TEST KIT DESCRIPTION

The Biopanda Faecal Occult Blood Rapid Test detects the presence of human faecal occult blood in human faecal samples. This test applies lateral flow immuno-chromatography.

SUMMARY

Many diseases can cause hidden blood in the faeces. This is also known as Faecal Occult Blood (FOB), Human Occult Blood, or Human Haemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.

The Biopanda FOB Rapid Test qualitatively detects low levels of Faecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Faecal Occult Blood at 40ng/ml or higher, or 4.8 µg/g faeces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The Biopanda FOB Rapid Test is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in faeces. The membrane is precoated with anti-haemoglobin antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates laterally along the membrane chromatographically by capillary action to react with anti-haemoglobin antibody on the membrane and generates a coloured line. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 10 x foil wrapped cassette with desiccant
- 10 x Specimen collection tubes with extraction buffer
- 1 x product insert

STORAGE AND STABILITY

Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

PRECAUTIONS

Follow these instructions for the best results:

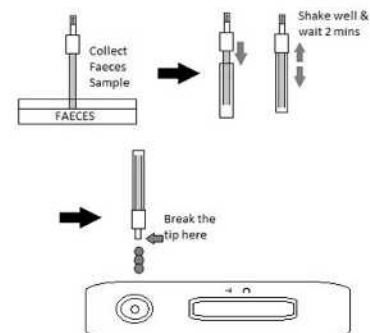
- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- Samples may be potentially infectious and should be handled with standard biosafety procedures.
- Ensure the test kit is at room temperature before running the test.
- Keep the cassette inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Tests that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test to ensure quality controlled testing.

SAMPLE COLLECTION AND PREPARATION

- Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- No dietary restrictions are necessary before using the FOB Rapid Test Cassette.

TEST PROCEDURE

1. To collect faecal specimens:
Collect faeces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.
2. To process faecal specimens:
Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the faecal specimen in at least 3 different sites. Do not scoop the faecal specimen.
Screw on and tighten the cap onto the specimen collection tube, then 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.
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and unscrew the top cap of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µl) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
5. Read results at 5 minutes. Results read after 10 minutes are considered invalid.



TEST RESULTS

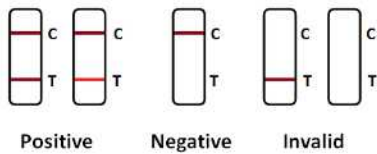
POSITIVE:* Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of Faecal Occult Blood present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No 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.



Thank you for purchasing Biopanda's FOB Rapid Test kit. Please read this manual carefully before operating to ensure proper use.



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LIMITATIONS OF THE PROCEDURE

Revision date: 15/10/2020

1. The FOB Rapid Test is for *in vitro* diagnostic use only.
2. This tests will only indicate the presence of Faecal Occult Blood, the presence of blood in faeces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

SENSITIVITY AND SPECIFICITY

The Biopanda FOB Rapid Test has been compared with another leading commercial FOB rapid test demonstrating an overall correlation of 98.6%.

Method	Other Rapid Test		Total Result	
	Results	Positive		Negative
Biopanda FOB Rapid Test	Positive	189	4	193
	Negative	10	802	812
Total Result		199	806	1005

Relative Sensitivity: 95.0% (95%CI*: 91.0%-97.6%) *Confidence Interval

Relative Specificity: 99.5% (95%CI: 98.7%-99.9%)

Accuracy: 98.6% (95%CI: 97.7%-99.2%)

LIMIT OF DETECTION

The Biopanda FOB Rapid Test can detect levels of Faecal Occult Blood as low as 50 ng/ml or 6 µg/g in faeces.

INTRA-ASSAY VARIATION

Within-run precision has been determined by using 15 replicates of three specimens: 50 ng/ml, 100 ng/ml and 10 µg/ml positive specimens. The specimens were correctly identified >99% of the time.

INTER-ASSAY VARIATION

Between-run precision has been determined by 15 independent assays on the same three specimens: 50 ng/ml, 100 ng/ml and 10 µg/ml positive specimens. Three different lots of the Biopanda FOB Rapid Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS-REACTIVITY

The Biopanda FOB Rapid Test is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

REFERENCES

1. Simon JB. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, *Gastroenterology*, 1985; 88: 820.
2. Blebea J, Mcpherson RA. False-Positive Guaiac Testing With Iodine, *Arch Pathol Lab Med*, 1985;109:437-40.