

FOB FIA Rapid Test Device

Catalogue No.: F12-FOB-001

For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda FOB FIA Rapid Test Device is intended for *in vitro* quantitative detection of Human Faecal Occult Blood.

SUMMARY

Many diseases can cause hidden blood in the faeces. This is known as Faecal Occult Blood (FOB), Human Occult Blood, or Human Haemoglobin. During the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood, making it vital to detect FOB for early diagnosis. Traditional guaiac based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.^{1,2}

The Biopanda Faecal Occult Blood (FOB) FIA Rapid Test Device quantitatively detects low levels of FOB. The test uses a double antibody sandwich assay to selectively detect FOB at 10-1000 ng/ml. Unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The Biopanda FOB FIA Rapid Test Device detects Human Occult Blood in faeces based on Fluorescence Immunoassay. The sample moves through the strip from the sample pad to the absorbent pad. If the sample contains haemoglobin, it attaches to the fluorescent microspheres-conjugated anti-haemoglobin antibodies. Any complexes will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of haemoglobin in the sample correlates with the intensity of the fluorescence signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of haemoglobin in the sample can be calculated by the Analyser.

REAGENTS

The test kit includes anti-haemoglobin antibody coated fluorophores and anti-haemoglobin antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
4. Do not eat, drink or smoke in the area where the samples and tests are handled. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of samples. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. Do not interchange or mix reagents or ID cards from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda FOB FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

Materials Provided:

- 25 x foil wrapped FOB Rapid Test Device
- 25 x Sample collection tubes with buffer solution
- 1 x ID card (FOB)
- Package Insert

Materials required but not provided:

- Sample Collection Containers
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SAMPLE COLLECTION AND PREPARATION

1. Samples should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding haemorrhoids or blood in the urine.
2. 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.
3. No dietary restrictions are necessary before using the Biopanda FOB FIA Rapid Test Device.
4. Collect sufficient quantity of faeces (1-2 mL or 1-2 g) in a clean, dry sample collection container to obtain maximum antigens (if present). Perform the assay within 6 hours after collection for the best results. Sample collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, samples should be kept below -20°C.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. To process faecal samples:
 - For Solid Samples:
Unscrew the cap of the sample collection tube, then randomly stab the sample collection applicator into the faecal sample in **at least 3 different sites** to collect approximately 50 mg of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal sample.
 - For Liquid Samples:
Hold the dropper vertically, aspirate faecal samples, and then transfer 2 drops (approximately 80 µL) into the sample collection tube containing the extraction buffer.
4. Tighten the cap onto the sample collection tube, and then shake the sample collection tube vigorously to mix the sample and the extraction buffer. Let the tube sit for 2 minutes.
5. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. The Device should be used within one hour of opening.
6. Hold the sample collection tube upright and open the cap onto the sample collection tube. Invert the sample collection tube and transfer **2 full drops of the extracted sample (approximately 80 µL)** to the sample well of the test Device, and then start the timer. Avoid trapping air bubbles in the sample well.
7. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.
 - 'Quick test'** mode: Insert the test Device into the Analyser at **15 minutes** after sample application and click **'QUICK TEST'**, fill the test information and click **'NEW TEST'** immediately. The Analyser will automatically give the test result after a few seconds.
 - 'Standard test'** mode: Insert the test Device into the Analyser immediately after sample application, click **'STANDARD TEST'**, fill in the test information and click **'NEW TEST'** at the same time. The Analyser will automatically count down the 15 minutes. The Analyser will produce a result after the countdown.

INTERPRETATION OF RESULTS

The result of tests for FOB is calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyser screen. For additional

information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda FOB FIA Rapid Test Device is 10-1000 ng/mL.

QUALITY CONTROL

Each FOB FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an "N/A" message on the Analyser. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control 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.

LIMITATIONS OF THE TEST

1. The Biopanda FOB FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of FOB.
2. The test will only indicate the presence of Faecal Occult Blood, the presence of blood in faeces does not necessarily indicate colorectal bleeding.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of FOB may produce a dose hook effect, resulting in incorrect interpretation of FOB levels. High dose hook effect has not been observed with this test up to 1000 ng/mL of FOB.
5. The results of the Biopanda FOB FIA Rapid Test Device are based on measuring the levels of FOB in a sample. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 50 ng/mL	Negative result
≥ 50 ng/mL	Positive result

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation is $\leq \pm 15\%$.

2. Sensitivity

The Biopanda FOB FIA Rapid Test Device can detect levels of FOB as low as 10 ng/mL in faeces.

3. Detection range

10-1000 ng/mL

4. Linearity range

10-1000 ng/mL, $R \geq 0.990$

5. Cross-reactivity

The Biopanda FOB FIA Rapid Test Device is specific to human haemoglobin. Samples 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 haemoglobin, Chicken haemoglobin, Pork haemoglobin, Goat haemoglobin, Horse haemoglobin, Rabbit haemoglobin and Turkey haemoglobin.

REFERENCES

1. Simon, J. B. (1985). *Occult blood screening for colorectal carcinoma: a critical review*. *Gastroenterology*, 88(3), 820-837.
2. Blebea, J., & McPherson, R. A. (1985). *False-positive guaiac testing with iodine*. *Archives of Pathology & Laboratory Medicine*, 109(5), 437-440.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test		<i>in vitro</i> diagnostic medical device
	Consult instructions for use		Batch code
	Storage temperature		Contains sufficient for <n> tests
	Catalogue number		Do not use if package is damaged

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



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