

Folate FIA Rapid Test Device (Serum/Plasma)

Catalogue Number: FI2-FOL-001

A Fluorescence Immunoassay for the quantitative detection of Folate in human serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

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 CONTENTS

- 25 x Foil wrapped Folate rapid test devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (Folate)
- 1 x Package Insert

EQUIPMENT REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

1. Collect the specimens according to standard procedures. Only use clear, non-haemolysed samples.
2. EDTA K2 can be used as the anticoagulant for collecting the plasma specimens.
3. A clean tube without anticoagulants can be used to collect serum specimens.

Specimen Storage and Shipping

1. Do not leave specimens at room temperature for prolonged periods.
2. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, and -20°C for long term storage. Frozen specimens should be thawed and mixed before testing. Avoid repeat freeze-thaw cycles.
3. Bring specimens to room temperature (15-30°C) prior to testing.
4. If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on operating the device. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: *Standard Test* mode and *Quick Test* mode.

Standard Test mode is a 'set and forget' method where the test will automatically be read after 15 minutes.

Quick Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests simultaneously.

Refer to the user manual for further details.

Allow the test cassette, specimen, and buffer to reach room temperature (15-30°C) prior to testing.

1. Turn on the analyzer and insert the ID card into the 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. **Pipette 10 µl of serum/plasma** into the buffer tube. Mix the sample and the buffer well using the pipette and allow the tube to sit for 10 minutes.
3. Remove the test device from the foil pouch and place it on a clean, level surface.
4. After 10 minutes, pipette **75 µl of diluted specimen** into the sample well of the test device.
5. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
6. Test results should be read at **15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The test results are calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyzer screen after testing is complete. For additional information, please refer to the user manual.

Assay range of the test device is 1-20 ng/mL.

QUALITY CONTROL

Each Biopanda Folate FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is

INTENDED USE

The Biopanda Folate FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Folate in human serum or plasma.

BACKGROUND

Folate is a water-soluble chemical compound in the vitamin B group. Folate is beneficial to the production and maintenance of new cells, is conducive to the synthesis of DNA and RNA, and prevents changes to DNA, thus preventing cancer. Folate deficiency can cause megaloblastic anaemia, and it disturbs the synthesis of DNA and cell division, which affects hematopoietic cells and neoplasms. In addition, serum folate deficiency in pregnant women can lead to neural tube defects in foetuses, affecting their normal development.

Folate cannot be synthesized by the human body and needs to be obtained through the diet, such as fresh fruits and vegetables, and other foods rich in folate. Unbalanced diet or poor absorption is the main causes of folate deficiency.

TEST PRINCIPLE

The Folate FIA Rapid Test Device detects folate based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains folate, it attaches to the fluorescent microspheres-conjugated folate binding protein. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of folate in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of folate in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show Folate concentration in specimen.

REAGENTS

The test includes folate binding protein coated on fluorescent microspheres and anti-folate 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens.
7. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
8. Do not interchange or mix reagents from different lots.
9. Extreme humidity and temperatures can adversely affect results.
10. Used testing materials should be discarded in accordance with local regulations.
11. The Biopanda Folate FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by healthcare professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch. Do not freeze.
2. The test must remain in the sealed pouch until use.
3. Care should be taken to protect the components of the kit from

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 error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. Insufficient specimen 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.

EXPECTED RESULTS

Research has shown that when the concentration of folate is $\leq 3\text{ng/mL}$, it is considered folate deficiency.

Each laboratory should determine the applicability of the reference range through experiments, and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

PERFORMANCE CHARACTERISTICS

1. Accuracy

The deviation is $\leq 15\%$.

2. Analytical sensitivity

The Folate FIA Rapid Test Device can detect levels of folate as low as 1 ng/mL in serum or plasma specimens.

3. Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 2 different concentrations of folate control. C.V. is $\leq 15\%$.

Inter-Assay

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of folate control. C.V. is $\leq 15\%$.

4. Interfering Substances

The following compounds have been tested using the Folate FIA Rapid Test Device and no interference was observed.

Triglyceride: 100 mg/dL Total cholesterol: 15 mmol/L

Haemoglobin: 1000 mg/dL Bilirubin: 33 mg/dL

5. Detection Range

The detection range is 1-20 ng/mL.

6. Method comparison

The product was evaluated with 102 clinical samples compared with commercial CLIA test kit. The correlation coefficient(r) is 0.9568.

LIMITATIONS OF THE TEST

- The Folate FIA Rapid Test Device should be used only with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
- The test should preferably be performed with freshly collected samples. For stored specimens, please refer to specimen storage.
- The test is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of folate.
- The test may yield low results due to folate epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of folate antigen with time and temperature.
- Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
- The test will only indicate the presence of folate in the specimen and should not be used as the sole criteria for diagnosis.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Only clear, non-haemolysed specimens can be used. Folate levels will significantly increase in haemolysed specimens.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Storage temperature		Lot Number		Consult instructions for use
	Do not use if package is damaged				

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



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