Ferritin FIA Rapid Test Device
(Whole Blood/Serum/Plasma)

Catalogue No.: FI2-FER-001

A Fluorescence Immunoassay for the quantitative detection of Ferritin in whole blood, serum or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE
The Biopanda Ferritin FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of ferritin in whole blood, serum or plasma.

BACKGROUND
Iron is one of the important trace metal elements necessary for the body. More than 90% of the iron in the body is combined with protein, and iron-containing protein has many important biological functions in the body.
Ferritin is the protein with the most iron content in the body, mainly found in the spleen, liver, and bone marrow. About 66% of the body's ferritin is synthesized by hepatocytes. Ferritin is a globular protein that can be expressed in almost all types of cells, soluble in water, cytoplasm or plasma, and stable in both intracellular and extracellular fluids. There are two physiological types of ferritin, one is serum ferritin (SF); the other is intracellular ferritin.
Serum ferritin (SF) is an important clinical indicator that reflects the body's iron storage. Decreased serum ferritin concentrations of < 15 ng/mL always indicate iron deficiency and can be the result of prior blood loss, pregnancy. It is also an acute phase reactant and marker of a variety of inflammations in the body, and can increase non-specifically (values> 400 ng/mL) in a variety of inflammatory states, including chronic kidney disease, rheumatoid arthritis, other autoimmune diseases, as well as acute infections and malignant tumours.

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

REAGENTS
The test includes anti-ferritin antibody conjugated fluorescent particles for detection and another anti-ferritin antibody coated on the membrane for capture.

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. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. Do not eat, drink or smoke in the area where the specimens and tests are handled. 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. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extreme humidity and temperatures can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. The Biopanda Ferritin FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Analyzer 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. 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 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 ferritin test devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (Ferritin)
- 1 x Package Insert

EQUIPMENT REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION
1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days; for long term storage, store below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger-prick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeat freeze-thaw cycles.
5. EDTA K2, heparin lithium and citrate sodium can be used as the anticoagulant for collecting the specimen.

***For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information*.**

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 device, specimen, and buffer tube to reach room temperature (15-30°C) prior to testing.

1. Turn on the analyzer and insert the ID card into the analyzer 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Remove the test device from the sealed foil pouch and place on a clean, level surface.
3. Follow the appropriate steps below for the prepared specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **20 µL of whole blood/serum/plasma** into the buffer tube.
      ii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
      iii. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test device.
   b. **<u>For finger-prick whole blood specimens:</u>**
      i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
      ii. Massage the hand without touching the puncture site by applying

pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.

iii. Use a sterile lancet (not provided) to puncture the skin and wipe away the first sign of blood.

iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.

v. Using the capillary dropper provided and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. **The dropper will automatically collect the correct volume of blood (approx. 20 µL),** *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µL), then add to the specimen well (S) of the test device.

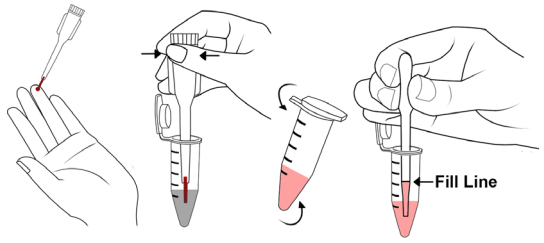

Figure 1

4. Insert the test device into the analyzer test device slot. According to user requirements, select either 'Standard test' or 'Quick test' mode.
5. **Test results should be interpreted 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.

QUALITY CONTROL

Each Biopanda Ferritin 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 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

Normal Reference Range		Clinical Reference
Men	20-60 years old: 30-400 ng/mL	Healthy
Women	17-60 years old: 13-150 ng/mL	

Note: 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

Accuracy

The product was evaluated with 135 clinical specimens in comparison with a commercial CLIA test kit. The correlation coefficient (r) was 0.990.

Analytical sensitivity

The test can detect levels of ferritin as low as 1.0 ng/ml.

Detection range

1.0–2,000.0 ng/mL

Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 30 ng/ml and 350 ng/ml of ferritin. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 30 ng/ml and 350 ng/ml of ferritin. C.V. is ≤ 15%.

Interfering substances

The following substances do not interfere with the test results at the indicated concentrations:

Ascorbic Acid at 200 mg/L, Haemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1,000 mg/dL, Uric Acid at 200 mg/L.

LIMITATIONS OF THE TEST

1. The Biopanda Ferritin FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of ferritin.
2. The test will only indicate the presence of ferritin in the specimen and should not be used as the sole criterion for clinical decisions.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. In addition to infections and tumours, patients with hemochromatosis caused by long-term repeated blood transfusions, and some patients with connective tissue diseases, such as lupus erythematous and rheumatoid arthritis, have significantly increased ferritin levels. In the diagnosis of tumours, ferritin, like other tumour markers, is a non-specific indicator. The detection of serum ferritin levels alone cannot diagnose malignant tumours.
5. The results are based on measuring the levels of ferritin in a specimen. If the result is below or above normal, other clinical findings need to be considered before making an accurate medical diagnosis.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

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

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