Ferritin FIA Rapid Test Device

(Serum/Plasma)

FI2-FER-001

A rapid test for detecting Ferritin in serum or plasma with the use of 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 serum or plasma.

SUMMARY

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. [1]
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 [1]. There are two physiological types of ferritin, one is serum ferritin (SF); the other is intracellular ferritin. [2]
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. [3,4]

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. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. 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 eye protection when specimens are assayed.
5. Do not interchange or mix reagents 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 Ferritin FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Analyser 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

- 25 x foil wrapped Ferritin test devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (Ferritin)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 1 day, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **75 µL of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature.
Allow the test, specimen, 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. Transfer **75 µl of serum/plasma** into the buffer tube, mix the specimen and the buffer well by shaking the tube before leaving it to sit for 1 minute.
4. Using a Pipette, **transfer 75 µl of diluted specimen** into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; 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 cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
“Standard test” mode: Insert the test cassette into the Analyser immediately

after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for ferritin is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda Ferritin FIA Rapid Test Device is 1.0 ~500.0 ng/ml.

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.

LIMITATIONS

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 Biopanda Ferritin FIA Rapid Test Device 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 of the Biopanda Ferritin FIA Rapid Test Device 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 combined to achieve an accurate medical diagnosis.

EXPECTED RESULTS

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

PERFORMANCE CHARACTERISTICS

ACCURACY: The product was evaluated with 98 clinical specimens compared with a commercial CLIA test kit. The correlation coefficient (r) was 0.984.

ANALYTICAL SENSITIVITY

The Biopanda Ferritin FIA Rapid Test Device can detect levels of ferritin as low as 1.0 ng/ml in serum and plasma.

LINEARITY RANGE: 1.0-500.0 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, Hemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1,000 mg/dL, Uric Acid at 200 mg/L.

REFERENCES

1. Elizabeth C. Theil , Rabindra K. Behera , Takehiko Tosha．Ferritins for chemistry and for life．Coordination Chemistry Reviews，2013，257：579-586．
2. LeviS.A human mitochondrial ferritin encoded by anIntronless gene．J Biolo Chem，2001，276：24437—24440．
3. Daru J, Colman K, Stanworth SJ, et al. Serum ferritin as an indicator of iron status: what do we need to know?[J]. Am J Clin Nutr, 2017, 106(Suppl 6): 1634S-1639S.
4. Mizuta M, Shimizu M, Inoue N, et al. Serum ferritin levels as a useful diagnostic marker for the distinction of systemic juvenile idiopathic arthritis and Kawasaki disease[J]. Mod Rheumatol,2016, 26(6): 929-932.

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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