



Ferritin Fast Test Kit

(Immunofluorescence Assay)

User Manual



IF1077 for Getein1100
IF3077 for Getein1180
IF2077 for Getein1600

INTENDED USE

Ferritin Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of ferritin in human serum and plasma samples. It can be used as an aid in the quantification of human ferritin and the diagnosis of iron deficiency anemia or iron overload related diseases.

SUMMARY

Ferritin has a molecular weight of 440 kD, depending on the iron content, and consists of a protein shell (apoferritin) that is composed of 24 subunits and an iron core containing an average of 2500 Fe³⁺ ions.

Latent iron deficiency is defined as a fall below the 12 ng/mL ferritin threshold. The two values are diagnostic even when the blood picture is still morphologically normal. A depressed ferritin level accompanied by hypochromic, microcytic anemia indicates manifest iron deficiency.

Elevated ferritin values are also encountered with the following tumors: acute leukemia, Hodgkin's disease and carcinoma of the lung, colon, liver, and prostate. Ferritin determinations have also proved to be of value in liver metastasis. Reasons for the elevated values could be cell necrosis, blocked erythropoiesis or increased synthesis in tumor tissue.

PRINCIPLE

The test uses an anti-human ferritin monoclonal antibody I conjugated with fluorescence latex coated on the sample pad and another anti-human ferritin monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human ferritin antibody I binds with the ferritin in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human ferritin

antibody II. The fluorescence intensity of test line increases in proportion to the amount of ferritin in sample.

Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of ferritin in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/1180 contains:

Package specifications: 25 tests/box, 10 tests/box

- 1) Getein Ferritin test card in a sealed pouch with desiccant
- 2) Capillary pipet
- 3) Sample diluent
- 4) User manual: 1 piece/box
- 5) SD card: 1 piece/box

2. A kit for Getein1600 contains:

Package specifications: 2x24 tests/box, 2x48 tests/box

Sealed cartridge with 24/48 Getein Ferritin test cards

User manual: 1 piece/box

Materials required for Getein1600:

- 1) Sample diluent: 1 bottle/box
- 2) Box with pipette tips: 96 tips/box
- 3) Mixing plate: 1 piece/box

3. Sample diluent composition:

Phosphate buffered saline, protein stabilizer and surfactant.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad (the end of pad is coated with fluorescence latex-labelled anti-human Ferritin monoclonal antibody I), nitrocellulose membrane (test line is coated with another Ferritin monoclonal antibody II and the control line C is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1180 within 1 hour on-

ce the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent at 0~30°C with a valid period of 24 months.

Store the sample diluent at 2~8°C for better results.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**. **Heparin, EDTA and sodium citrate** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (for Getein1100/Getein1180): **10 µL**.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

- Put the test card on a clean table, horizontally placed.
- Using disposable pipet, deliver **10 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample port on the test card.
- Reaction time: 15 minutes.** Insert the test card into Getein-1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

- Confirm SD card lot No.in accordance with test kit lot No..Perform "SD card" calibration when necessary.
- Enter testing interface of Getein1180.
- Remove the test card form the sealed pouch immediately before use.Label the test card with patient or control identification.
- Put the test card on a clean table,horizontally placed.
- Using disposable pipet, deliver **10 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample port on the test card.
- Reaction time: 15 minutes.** Insert the test card into Getein-1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

NOTES

- It is required to perform "SD card" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein1100/Getein1180.
- Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1180/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 50 times.

EXPECTED VALUE

The expected normal value for ferritin was determined by testing samples from apparently healthy male and women.

Group	Age	N	95% Reference Interval(ng/mL)
Male	20-60	254	30.00-400.00
Female	17-60	205	13.00-150.00

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50 ~1000.00 ng/mL
Lower Detection Limit	≤0.50 ng/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.














Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

REFERENCES

- Torti F M , Torti S V . Regulation of ferritin genes and protein.[J]. Blood, 2002, 99(10):3505.
- Theil E C . Ferritin: Structure, Gene Regulation, and Cellular Function in Animals, Plants, and Microorganisms[J]. Annual Review of Biochemistry, 2003, 56(1):289-315.
- Kell D B , Pretorius E . Serum ferritin is an important inflammatory disease marker, as it is mainly a leakage product from damaged cells[J]. Metallomics,
- Cho M R , Park J K , Choi W J , et al. Serum ferritin level is positively associated with insulin resistance and metabolic syndrome in postmenopausal women: A nationwide population-based study[J]. Maturitas, 2017, 103:3.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Ferritin Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community
	CE mark		Do not use if package is damaged
	Catalogue number		

Thank you for purchasing Ferritin Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF84-S-05



Getein Biotech, Inc.
 Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
 Tel: +86-25-68568508
 Fax: +86-25-68568500
 E-mail: tech@getein.com.cn
 overseas@getein.com.cn
 Website: en.bio-gp.com.cn



Lotus NL B.V.
 Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
 E-mail: peter@lotusnl.com
 Tel: +31644168999