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Ferritin
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

Ferritin Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of ferritin in human serum, plasma and whole blood samples. It can be used as an aid in the diagnosis of iron deficiency anemia or iron overload related diseases. For professional and laboratory use only.

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 Fe^{3+} 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

Ferritin Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay with a sandwich design. After the sample is applied to the test strip, the fluorescence-labelled ferritin monoclonal antibody binds to the ferritin in the sample, forming a marked antigen-antibody complex. This complex then moves to the test zone on the test card by capillary action. In the test zone, the marked antigen-antibody complex is captured by another ferritin monoclonal antibody on the test zone. The fluorescence intensity of the test zone increases in proportion to the amount of ferritin in sample. Fluorescent signals intensity can be analyzed by applicable device thus the ferritin in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
Ferritin test card*	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Sample diluent**	10 tubes	25 tubes	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

*Ferritin test card

A test card consists of: Fluorescence-labelled Ferritin monoclonal antibody, Ferritin monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer, NaN_3 (< 0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer, NaN_3 (< 0.1%) (25 mL/bottle for Getein 1200, 4*6 mL/tube for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

1. The SD card, also known as the standard curve data card, stores standard curve data for specific test items and uses RFID technology to transfer the data to analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. Do not mix or interchange different batches of kits.

APPLICABLE ANALYZER

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: 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.

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. Due to the high Ferritin content within red blood cells, hemolyzed specimens should not be used.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma and whole blood. 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 (whole blood sample may be stored up to 3 days at 2–8°C).
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 Getein 1100/Getein 1160/Getein 1180): 10 μL.***

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Using disposable pipet or pipette, 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 well on the test card.
5) ***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 Getein 1160/Getein 1180:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Using disposable pipet or pipette, 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 well on the test card.
5) Insert the test card into Getein 1160/Getein 1180 ***immediately*** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code **(On the outer packaging box)** to complete calibration as prompted by the instrument.
2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).

3) Using disposable pipet or pipette, deliver 10 μL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
4) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

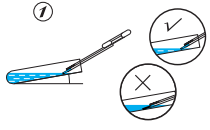
For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2) Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3) Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Note:

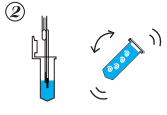
1. It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
2. It is required to scan the QR code to complete calibration when using a new batch of kits for Getein 1150.
3. The directions for using disposable pipet are as follows:

Directions to use disposable pipet

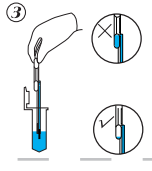


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

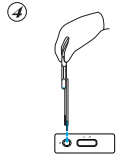
Note: Do not immerse the exhaust pipe below the liquid level.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

TEST RESULTS

Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Dilute the sample which concentration is higher than the upper limit with calf serum, 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	30.0-400.0
Female	17-60	205	13.0-150.0

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
Limit of Detection	≤ 0.50 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

LIMITATIONS

1. 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.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

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

REFERENCES

1. Torti F M, Torti S V. Regulation of ferritin genes and protein. [J]. Blood, 2002, 99(10):3505.
2. 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.
3. 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, 2014, 6(4):748-773.
4. 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 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	Unique device identifier		

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

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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: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF1077-10T	Getein 1100	10 T/kit
IF1077	Getein 1100	25 T/kit
IF8077-10T	Getein 1150	10 T/kit
IF8077	Getein 1150	25 T/kit
IF5077-10T	Getein 1160	10 T/kit
IF5077	Getein 1160	25 T/kit
IF3077-10T	Getein 1180	10 T/kit
IF3077	Getein 1180	25 T/kit
IF4077-24T	Getein 1200	2×12 T/kit
IF4077	Getein 1200	2×24 T/kit
IF4077-96T	Getein 1200	2×48 T/kit
IF2077-24T	Getein 1600	2×12 T/kit
IF2077	Getein 1600	2×24 T/kit
IF2077-96T	Getein 1600	2×48 T/kit