Ferritin Test Kit User Manual(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

Ferritin Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit

5 tests/kit

25 tests/kit

50 tests/kit

100 tests/kit

[INTENDED USE]

Ferritin Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of Ferr (Ferritin) in serum and plasma.

Iron protein molecular weight is 45000, is composed of 24 polypeptide subunits a middle hollow spherical protein Ferritin exists in various tissues and cells in the body, and keep the balance of iron metabolism, when the body requirements increase, ferritin can release of the iron in the body of the activity of serum ferritin content is his judgment under the heavy load iron deficiency and iron in the body of the effective indicators. It has early auxiliary diagnostic value for iron deficiency anemia and malnutrition, and is also related to the degree of liver function damage. The commonly used FERR detection methods in clinical and laboratory mainly include immunoturbidimetry, immunofluorescence and chemiluminescence.

[TEST PRINCIPLE]

Ferritin Test Kit (Dry Fluorescence Immunoassay) uses immunofluorescence double antibody sandwich method quantitatively detect Ferr content.

Two highly specific and highly sensitive monoclonal antibodies were used, of which Ferr mouse monoclonal antibody 1 was used as the capture antibody, which was coated in the test area on nitric fiber membrane. Ferr mouse monoclonal antibody 2 was labeled into fluorescent microspheres and fixed on the binding pad. The diluent was mixed with the sample, and the antigen in the sample was bound to Ferr mouse monoclonal antibody 2-labeled fluorescent microspheres in the binding pad. The complexes were then captured by Ferr mouse monoclonal antibody 1 immobilized on the test site to form a fluorescent microsphere sandwich structure. The fluorescent particle complex labeled with chicken IgY in the binding pad was bonded with the goat anti-chicken IgY fixed on the quality control area of nitrocellulose membrane to form the quality control area. The content of ferritin in human blood can be determined by matching analyzer.

[MAIN COMPONENTS]

1. Ferritin test strip in a sealed pouch with desiccant.....25 tests
2.Sample diluent.....25 pieces
3.QR code card for calibration.....1 piece
4.User Manual.....1 piece
5.Quantitative suction and dropping tube (Optional).

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

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-1100 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-3000 Automatic Fluorescence Immunoassay Analyzer

[**SAMPLE REQUIREMENT]**

1. Used for human serum and plasma. Other bodily fluids and samples may not get the accurate result.
2. Plasma can be anticoagulant with heparin, EDTA and sodium citrate under aseptic conditions.
3. Clinical blood samples should be tested within 6 hours at room temperature (15℃~30℃) after collection.Serum and plasma samples can be stored for 6 months at -20℃ and for 6 days at 2℃-8℃.
4.Avoid using microbial contamination samples.
5.The frozen samples shall be completely melted, reheated and mixed before being used. Repeated freeze-thaw should be avoided. It is recommended that samples be freeze-thaw not more than once. If there are sediments in thawed samples, centrifuge the samples before testing them.

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15℃-30℃).
3.Perform QR code calibration when necessary (Details refer to User Manual)
4. On the main interface of analyzer, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to User Manual)
5.Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6.Using pipette to drop 5μL sample into the tube of the sample diluent. Mix gently and thoroughly. And then drop 100μL of mixed fluid into the sample port in the test strip.
7. **Reaction Time: 15 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.

For panel outside: After reaction time 15 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.

7. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Reference Range:

Male : 16-220 ng/mL

Female :10-125 ng/mL

Through the determination of Human Ferr content in the whole blood, serum and plasma samples of 180 healthy people, the following reference interval was obtained after the statistical analysis of 95% distribution range.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1.If the test result of the sample is more than 1000ng/ml, the analyzer displays “>1000ng/ml”, and if the result is less than 5ng/ml, the analyzer displays “＜5ng/ml”. Specific data can be exported through related software as needed.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.

2. Samples containing interfering substances can affect test results. The maximum allowable concentration is: hemoglobin 3 mg/ mL bilirubin 0.25 mg/ mL and triglyceride 10 mg/ mL.

[PRODUCT PERFORMANCE]

1. Lower Detection Limit:5ng/ml.

2.Measuring Range:10-1000ng/ml, r≥0.990

3. Accuracy: the relative deviation is within the range of ±15%.

4. Within-Run Precision: ≤15%.

5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. IVD: In vitro diagnostic medical device.

2.After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.

4. The damaged test strip or package cannot be used.

5.All sample from patients should be treated as potential sources of infection.

6. Used strips should be properly disposed according to local regulations to avoid contaminnation.

[REFERENCES]

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Revision Date: January 4, 2021

Version Number: 0.2

Production date and expiration see the label.

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store between 4-30℃
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion