

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, plasma, whole blood and fingertip blood.

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 desiccant25 tests
2. Sample diluent 25 pieces
3. QR code card for calibration1 piece
4. User manual 1 piece
5. Plastic transfer pipette (Optional).
6. Alcohol pad (Optional).
7. Safety Blood Lancet (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]

The test can be analyzed on Dx365 Igloo Reader Pro device.

[SAMPLE REQUIREMENT]

1. Used for human serum, plasma, whole blood and fingertip blood . Other bodily fluids and samples may not get the accurate result. Use the materials in accessory kit B for fingertip blood sampling.
2. Plasma and whole blood can be anticoagulant with heparin, EDTA and sodium citrate under aseptic conditions.
3. Clinical blood sample must be performed by within 4 hours after the sample collection. Serum or plasma sample can be stored at 2°C-8°C for 7days and -20°C for 6 months. Whole blood should not be frozen and can be stored at 2°C-8°C for 3 days.
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°C-30°C).
3. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
4. 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
5. **Reaction Time: 15 minutes**
See Reader Instructions on following page.

[EXPECTED VALUE]

Reference Range:

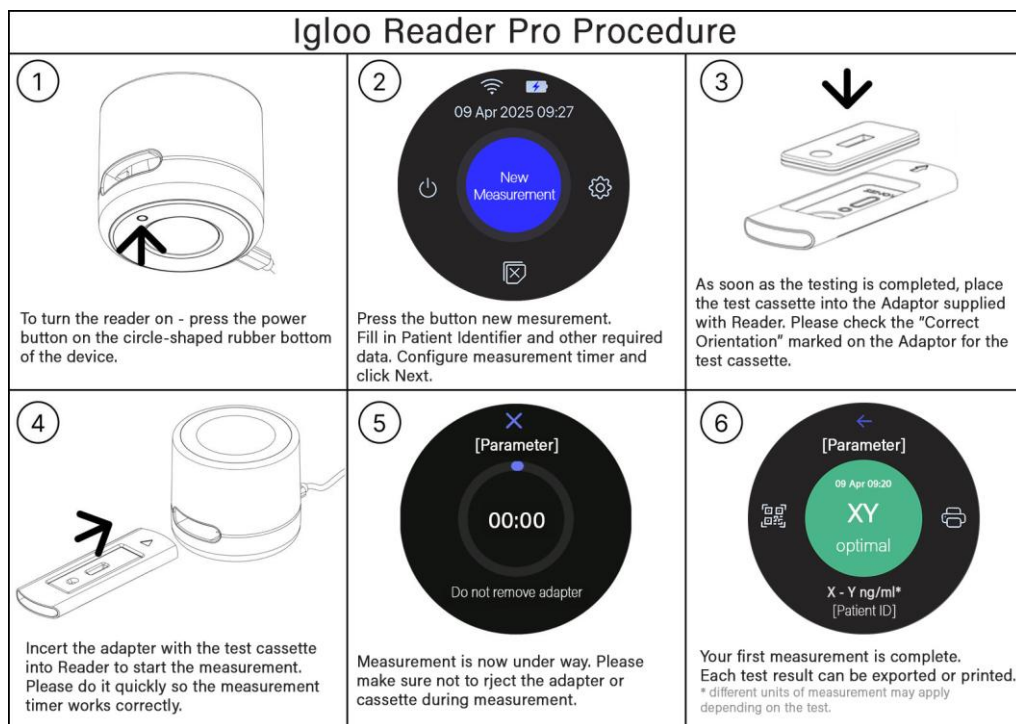
Male : 16-220 ng/mL

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. Limit of Blank: 5ng/mL.
2. Linearity range: 10-1000ng/mL, $r \geq 0.990$.
3. Accuracy: the relative deviation is within the range of $\pm 15\%$.
4. Within-Run Precision: $\leq 15\%$.
5. Between-Run Precision: $\leq 15\%$.

[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 contamination.

[REFERENCES]

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2. Yao ZI, xia JR. The significance of serum ferritin detection in the assessment of liver injury [J]. Chinese Journal of Tropical Medicine. 2004, 4(3).
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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 at 4-30°C
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion