Diagnostic Kit for Ferritin
(Fluorescence Immunochromatographic Assay)
Instructions for Use

INTENDED USE

This kit is intended for in vitro quantitative detection of ferritin (FER) content in human serum/plasma/whole blood/fresh finger terminal blood samples and is for auxiliary diagnosis for iron metabolism related diseases, such as hemochromatosis and iron deficiency anemia, as well as monitoring the recurrence and metastasis of malignant tumor. This kit only provides the test result of ferritin, and the obtained result shall be analyzed in combination with other clinical information. This kit is for healthcare professionals.

SUMMARY

Ferritin is a soluble tissue protein that can store iron in the body. Normal human serum contains only small amount of ferritin. Decreased serum ferritin is common in iron deficiency anemia, massive blood loss, long-term diarrhea, and malnutrition, while significantly increased serum ferritin is common in megaloblastic anemia and aplastic anemia. Iron deficiency anemia has no clinical symptoms in the early stages, but laboratory tests are particularly sensitive. Therefore, the determination of ferritin can be used an effective method to monitor the level of iron metabolism in humans.

PRINCIPLE OF DETECTION

This kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively detect the ferritin (FER) in the human serum/plasma/whole blood/fresh finger terminal blood samples. The reagent strip contains anti-FER antibody pre-fixed on the test line (T) of the membrane and goat anti-chicken IgY antibody in the control line (C). The labeling pad contains pre-coated fluorescently labeled anti-FER antibody and chicken IgY antibody. When the sample is tested, the FER antigen in the sample binds to the fluorescently labeled anti-FER antibody to form an immune complex. Under the immunochromatographic effect, the complex and sample flow towards the absorbent paper inside the nitrocellulose membrane. The complex binds with the coated anti FER antibody while it passes through test line (T), to form "anti-FER antibody-FER antigen-fluorescence-labeled anti FER antibody" complex and agglutinates. When passing through the control line (C), the fluorescently labeled chicken IgY antibody binds to the coated goat anti-chicken IgY antibody to form a "goat anti-chicken IgY antibody-fluorescently labeled chicken IgY antibody" complex and agglutinates. The FER concentration in the sample is positively correlated with the fluorescence intensity, and the concentration of FER in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	53322101	53322105	53322120	53322125
Specification / Components	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test Device(s)	1	5	20	25
Sample Diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1 Test line (T line): T line area of nitrocellulose membrane is coated with anti-FER antibody.
2 Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-chicken IgY antibody.
3 Labeling pad: It is coated with fluorescent-microsphere-labeled anti FER antibody and chicken IgY antibody.
4. Main component of sample diluent is 20mM, pH7.4 PBS solution.

Warning: The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.
H412: Harmful to aquatic life with long lasting effects.
P280: Wear protective gloves/protective clothing/face protection.
P333+P313: If skin irritation or a rash occurs: Get medical advice/attention. P
362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2℃~30℃. The shell life of the kit is 24 months.
2. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedures.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2℃~8℃ for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2℃~8℃ for 7 days. If frozen below -15℃, samples can be stores for 6 months.
6. Fresh terminal blood of fingertips should be used immediately after collection.
7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.
8. Before test, sample should be in room temperature and mixed thoroughly

REAGENT PREPARATION

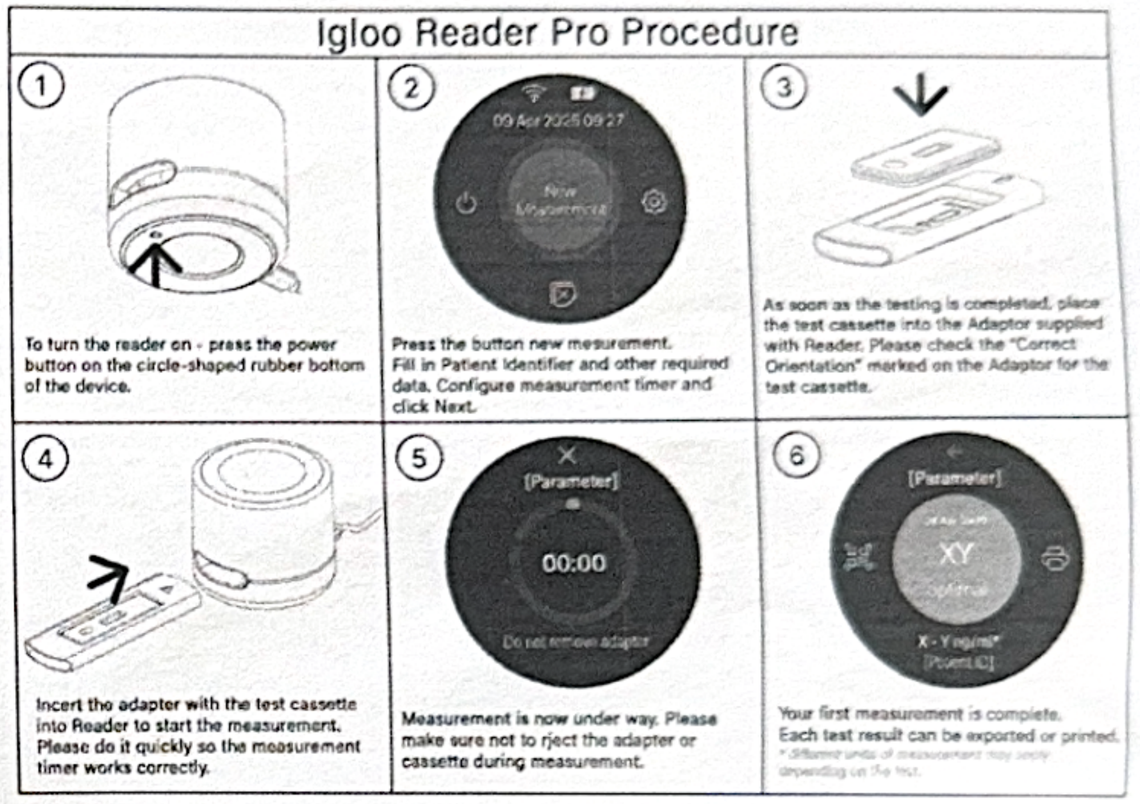
1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;
(2) Take out sample diluents, add 10μL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;
(3) Add 80μL of above mixed solution into the sample hole of test device;
(4) Rection time is 15 minutes.



REFERENCE INTERVAL

1. Male: Study of FER reference interval is conducted through referring to C28-A2 document published by US Clinical and Laboratory Standards Institute (CLSI)- How to Define and Determine Reference Intervals in the Clinical Laboratory - Second Edition and WST 402-2012 Define and Determine the Reference Intervals in Clinical Laboratory. The obtained reference interval of FER is: 23.9-336.2ng/mL.
2. Female: Study of FER reference interval is conducted through referring to C28-A2 document published by US Clinical and Laboratory Standards Institute (CLSI)- How to Define and Determine Reference Intervals in the Clinical Laboratory - Second Edition and WST 402-2012 Define and Determine the Reference Intervals in Clinical Laboratory. The obtained reference interval of FER is: 11.0-306.8ng/mL.
3. Due to difference in geography, race, age etc., each laboratory is suggested to establish reference interval of FER that is suitable for local populations and has clinical significance.

INTERPRETATION OF THE RESULT

1. If the FER measured concentration of sample is higher than the reference value range, the physiological change or stress response and other states shall be excluded. Tangible abnormal should be diagnosed in combination with clinical symptoms. Above result is only for reference.
2. Test result of this method is only applicable to evaluation using the reference value established in this method and cannot be directly compared with result of other method.
3. Other factors that may cause wrong test result include technical reason, operation error and other sample factors.

*Invalid result: If the assay result is invalid, the Igloo Reader Pro will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is persists, please contact the device manufacturer.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.

9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal enterprise reference, that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

1. Reportable range of the reagent (kit): Within 10~15000 ng/mL;
2. Linear range: Within the linear range of 10~1500 ng/mL in the reagent (kit), the analytical performance should meet the following requirements: The correlation coefficient (r) of linearity should be ≥0.9900.
3. Accuracy: The relative deviation of measured results should not exceed ±10%;
4. Limit of detection: ≤5.0 ng/mL;
5. Repeatability: CV≤15%;
6. HOOK effect: When FER concentration is ≤50000.0ng/mL, there is no HOOK effect.
7. Specificity: CEA, AFP and transferrin are detected at the following concentrations without cross phenomenon.

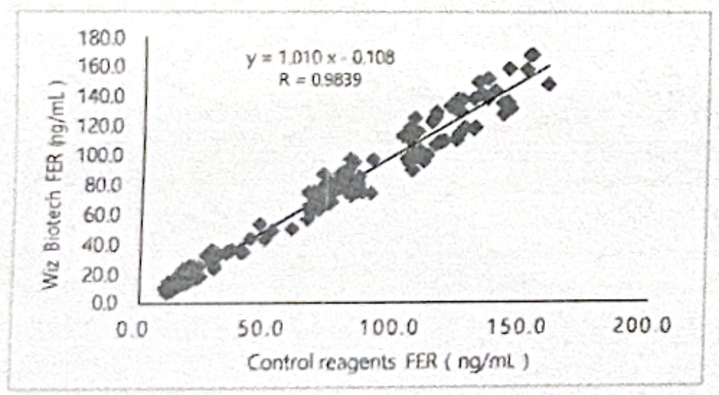
Material	Concentration	Material	Concentration
CEA	500μg/mL	AFP	500μg/mL
Transferrin	200μg/mL	-	-

8. Interfering substance: Following substances are tested at the given concentration with no interference.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2 mg/mL	Hemoglobin	10.0 mg/mL
Triglyceride	40.0 mg/mL	Rheumatoid factor	1500.0 IU/mL

9. Clinical performance

Clinical evaluation performance of the product is assessed through collecting 165 clinical samples. The results are compared by using the corresponding kit of marketed chemiluminescence method as the reference reagent. Their comparability is studied by linear regression. The correlation coefficients of the two tests are Y=1.010X-0.108 and R=0.9839, respectively.



LIMITATION

1. This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of this kit is 10~1500 ng/mL. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the maximum dilution multiple of this kit is 10 times and the reportable range is 10~15000 ng/mL.

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5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

[1] Alkhateeb AA, Connor JR. The significance of ferritin in cancer: anti-oxidation, inflammation and tumorigenesis. Biochim Biophys Acta. 2013 Dec;1836(2):245-54.
[2] Garcia-Casal MN, Peña-Rosas JP, Urrechaga E, etc. Performance and comparability of laboratory methods for measuring ferritin concentrations in human serum or plasma: A systematic review and meta-analysis. PLoS One. 2018;13(5): e 0196576. Published 2018 May 3.
[3] Garg R, Aravind S, Kaur S,etc. Role of serum ferritin as a prognostic marker in acute ischemic stroke: A preliminary observation. Ann Afr Med. 2020;19(2):95-102.
[4] Sezgin G, Monagle P, Loh TP, etc. Clinical thresholds for diagnosing iron deficiency: comparison of functional assessment of serum ferritin to population-based centiles. Sci Rep. 2020;10(1):18233. Published 2020 Oct 26.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
IVD	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2℃~30℃	REF	Catalogue number	LOT	Batch code
EC REP	Authorized Representative in the European Community		Caution		

Xiamen Wiz Biotech Co., Ltd.
Address: 3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China
Tel: +86-592-6808278 Fax: +86-592-6808279

EC REP QbD RepS BV
Groenenborgerlaan 16, 2610 Wilrijk, Belgium

CE-02.01-2022.04.11 EN
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