FER

Ferritin Test Kit
(Nephelometry Immunoassay Method)

Instructions for Use

Version: A/5

REF HP-FER-25

Manufacturer

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Product Name

General Name： Ferritin Test Kit（Nephelometry Immunoassay Method）

Specification

Package Specification
25 Tests/ Kit.

Intended Use

It is used to detect the content of Ferritin (FER) in human serum. it is mainly used for the auxiliary diagnosis of iron metabolism related diseases.

Test Principle

The sheep anti-human ferritin antibody is coated on the latex particles. The ferritin in the sample specifically binds to the corresponding antibody-sensitized latex in the reagent to form an antigen-antibody complex, which causes a change in scattering intensity and scattering under the irradiation of incident light. The rate of change of light intensity is positively correlated with the content of ferritin in the sample, and the rate of change of scattered light intensity is determined by calculating the standard curve to calculate the content of ferritin in the sample.

Component

The FER test kit consists of two reagents R1 and R2, as shown on Figure 1.

Figure 1

Reagent 1   Reagent 2

Name	Content		Quantity
Reagent 1 (R1）	PBS buffer		0.1mol/L
	PEG		Appropriate
	NaN_3		1‰
	Surfactant		Appropriate
Reagent 2 (R2)	FER Antibody		>0.2g/L
	PBS buffer		0.1mol/L
	NaN_3		1‰
	Stabilizer		Appropriate
	Surfactant		Appropriate
IC Card (optional)		/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum, avoid hemolysis. Fasting blood collection and separation of serum as soon as possible. The sample store at 2-8°C for 3 days, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

Procedures

HP-083/4-I&HP-083/4-II POCT Immunoassay System

Note:
- Please read user manual of HP-083/4-I and HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of FER test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.
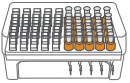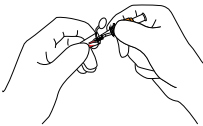
Step 1 Sample Preparation

1a Allow the test kit back to room temperaturefor 30 minutes before use.

1b Use the R2 with quantitative capillary to collect sample.

1c Insert the R2 into R1.

Note:
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing

2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1

2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.

2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

Note:
- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

Step 1 Sample Preparation

2a Allow the test kit back to room temperature for 30 minutes before use.

2b Use the R2 with quantitative capillary to collect sample.

3c Insert the R2 into R1.

Note:
- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing

4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.

2. New lots of reagent.

3. New operator training.

4. The results can not match the clinical symptoms.

5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

20-250ng/mL
Recommended that each laboratory establish its own reference range.

Interpretation

The test result ≤ 20ng/mL, may indicate iron deficiency anemia.

The test result. ≥250ng/mL, It may indicate hemochromatosis or liver injury.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

Hemoglobin ≤ 5g / L, bilirubin ≤ 300μmol / L, triglyceride ≤ 10mmol / L, no effect on the determination.

Performance Characteristics

1. linear range: 10ng / mL ~ 1000ng / mL, r ≥ 0.990

The linear deviation in the range of [10 ~ 50] ng / ml should not exceed ±5 ng / mL,

The linear deviation in the range of (50 to 1000] ng/mL should not exceed ±10%.

2. Blank limit: no more than 5ng/mL

3. Precision

Test the control material by Ferritin Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	30.1	1.10	3.7	1.24	4.1
Control 2	112.7	5.84	5.2	4.20	3.7
Control 3	390.0	13.04	3.3	19.77	5.1

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	31.2	1.11	3.6	1.18	3.8
Control 2	108.1	5.11	4.7	5.37	5.0
Control 3	395.2	14.43	3.7	11.00	2.8

c.

HP-AFS/1Automatic Immunoassay System					
Sample	Mean ng/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	29.3	1.25	4.3	0.95	3.2
Control 2	113.2	5.32	4.7	5.57	4.9
Control 3	402.0	13.53	3.4	14.79	3.7

4. Methodology comparison
Compared to FER LIA (x) by test the same serum sample, the relative data as below:

| HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 0.97X+0.08	0.94

The concentration of sample is about 10ng/mL -1000 ng/ mL.

Precautions

⚠ **Attention：**
Only for in vitro diagnostic.
Only for professional use.
All samples and reactive wastes are treated as sources of infection.
Do not use the kits beyond shelf life.
Do not mix different batches of reagents.
The experiment environment temperature is 18~25℃, humidity is 40~60% is recommended.

⚠ **Warning :**

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
⌛	Use-By date	❄⊘	Do not freeze
LOT	Batch code	☣	Biological risks
🏭	Manufacturer	⊘	Do Not Reuse
🌡	Temperature Limit		
▽Σ	Contains sufficient for <n> tests		
⊘	Do not use if package is damaged		
📖	Consult Instructions for use		
☀	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1. WANG Tianju, QING Zhizhi. The role of myeloperoxidase in cardiovascular diseases[J]. Journal of Practical Preventive Medicine, 2009, 16(2): 623-625.

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CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折