Ferritin (FER) Diagnostic Reagent Kit (Latex-Enhanced Immunoturbidimetry)
Product Instruction

Product name

Generic Name: Ferritin Diagnostic Reagent Kit (Latex-Enhanced Immunoturbidimetry)
Abbreviation: FER

Package Specifications

R1	R2
60ml×1	30ml×1
40ml×1	20ml×1
60ml×2	30ml×2

Calibrator (liquid):
Specification 1 (1mL×5; 5 levels);
Quality Control (Liquid):
Specification 1 (1mL×2; 2 levels);

Intended use

This kit is used for quantitative in vitro determination of the content of ferritin (Fer) in human serum or other body fluid samples. It is mainly used for the auxiliary diagnosis of iron metabolism-related diseases, such as hemochromatosis and iron-deficiency anemia.

Clinical significance

Ferritin is an iron-containing protein with a molecular weight of approximately 450,000. It is found mainly in the human liver and spleen, where its function is to eliminate and store iron in the body, and is also found in small amounts in human serum. This amount varies according to the movement of iron in the body, and hepatitis and malignant tumors, may be seen to increase due to cell destruction or tumor cell production, independent of iron reserves. Consequently, the measurement of ferritin is considered to be useful in the diagnosis, treatment, assessment of disease progression, and postoperative prognosis for abnormality in iron metabolism such as iron deficiency anemia and hyperferremia as well as hepatitis and malignant tumors.

Principle

When an antigen-antibody reaction occurs between ferritin in a sample and anti-ferritin antibody which has been bound to latex particles agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of ferritin in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Main ingredient

Composition	Main ingredients
R1	PBS buffer solution pH7.4 100mmol/L, PEG 10-20g/L
R2	Ferritin Antibody Latex Granules, Buffer 100mmol/L, sodium chloride 20g/L.
Calibration	PBS buffer solution 50mM, Sucrose 5%, BSA 8%, FER 0.05%.
Quality control	PBS buffer solution 50mM, Sucrose 5%, BSA 8%, FER 0.01%.

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8℃ (do not freeze). After being opened for the first time, the kit can be stored at 2-8℃ in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Fresh serum.
-20℃, stable for 7 days.

Assay procedure

1. Reagent preparation

This reagent is liquid and can be used directly.

Main wavelength	570 nm	Sample(S)	5 μl
Subwavelength	800 nm	Reagent 1	100 μl
Reation temperature	37℃	Reagent 2	50 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	5 μl
R1	100 μl
Mix well, incubate at 37° C for 5 minutes, then add	
R2	50 μl
Mix well, incubate at 37℃for 1 minute, absorbance A1; incubate at 37℃for 5 minutes, absorbance A2 △A= A2-A1	

Calculations

Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in ng/ml on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval
10-300 ng/ml.
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration
The assay requires the use of a FER calibrator. Recalibration is recommended at anytime if one of the following events occurs:
- The Lot number of reagents changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

Performance characteristics
1. Measuring range
10 ng/ml - 800 ng/ml
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.
2. Sensitivity
When a control serum (200 ng/ml) is used as a sample, the range of absorbance change is more than 0.015ABS.
3. Precision

Within-Run	
n= 20	Level 1
Mean (ng/ml)	150±50
CV (%)	CV≤5%

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters for analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	800
Wave Length Prim	570
ABS. Limit	32000
Sample Volume（uL）	5
R1 Volume（uL）	100
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	5
Sample DIL. VOL.	/
R1 Volume（uL）	100
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	570
Measure Wave 2	800
METHOD	END
SLOPE	-
Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	

FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	5AB
Formula	spline
STD(1) Conc.#	*
Unit	n g/m L

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