Ferritin Assay Kit (FER)

Method: Latex Immunoturbidimetric Method

Cat.NO.	Package Size	Analyzer
EGS691M	R1:1×40ml R2: 1×20ml	For Hitachi917& OlympusAU640/400/600
EGB690M	R1:1×40ml R2: 1×20ml	For Hitachi 717 &ShimadzuCL7200/8000
EGH691M	R1:1×40ml R2: 1×20ml	For Hitachi902
EGD691M	R1:12×4.3ml R2: 6×4.3ml	For Siemens Dupont/Siemens Behring Series
EGFER460 BS	R1: 1×20mL R2: 1×10mL	For Mindray BS120/180/190/200/220/2 30/240/430/460/830
EGGFER	R1: 1×20mL R2: 1×10mL	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of Ferritin in serum or plasma.

CLINICAL SIGNIFICANCE

Ferritin is produced in the reticuloendothelial tissue system, including a protein shell, ferritin (MW 445000), the core of which contains varying amounts of iron to form iron hydroxide-phosphate complexes. Different complexes contain two subunits: acidic H (heavy) and weakly basic L (light). Alkaline heteroferritin is related to the long-term iron storage of iron and exists in the liver, spleen, and bone marrow; acidic heteroferritin is mainly related to placenta and myocardial diseases. The ferritin detection index is a good index to check the content of iron storage in the human body. It can indicate the lack of iron ions in the human body and the condition of iron treatment.

ASSAY PRINCIPLE

The ferritin in the sample reacts with the ferritin antibody coated on the latex particles to form turbidity, and the increase in turbidity is proportional to the ferritin content in the sample. The increase in turbidity is compared with the working curve to calculate the ferritin content in the sample.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Amino acetic acid buffer NaCl	170mmol/L; 100 mmol/L
Reagent 2 (R2)	
Amino acetic acid buffer Anti (human) -Ferritin coated by latex particals	170mmol/L; 0.07% (W/V)

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.

2.The production date and expiry date are shown on the label.

3.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.

4.Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 570nm.

It is recommended to use this kit on biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Serum.

EDTA anticoagulant plasma.

The sample can be stable for 7 days at 2-8℃,4 weeks at -20℃(frozen for one time only)

ASSAY PROCEDURE

Test Condition(Hitachi 917)

Main wavelength	570 nm	Sample (S)	7 μl
Secondary wavelength	800 nm	Reagent 1(R1)	140 μl
Reaction temperature	37℃	Reagent 2(R2)	70 μl
Cuvette diameter	1cm	Reaction type	End-point method

Operate procedure

Add into cuvette;	
Sample(S)	7 μl
Reagent 1(R1)	140 μl
Mix well and incubate for 5 minutes at 37℃	
Reagent 2(R2)	70μl
Mix well and incubate for 300s, measure the final absorbance.	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn

biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell Fer calibrator.

Calibrator traces to the international reference materials NIBSC94/572.

1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.

2. Requirements for calibration and its frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell Fer control**.** The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:

1 Check the parameter setting and light source.

2 Check the cleanliness of the cuvette and sampling needle.

3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.

4 Check the reaction temperature.

5 Check the validity of the kit.

CALCULATION RESULT

According to the specific calibration mode of the project, the instrument will automatically generate calibration curve and calculate the content of the measured object from the change value of absorbance in the sample.

REFERENCE RANGE

Male:20-300 ng/mL

Female:10-120 ng/mL

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCES

The effect of bilirubin ≤ 85 mg/dL, hemoglobin ≤ 300 mg/dL, Intralipid ≤ 333mg/dL, is less than 10%.

ACCURACY

The kit is tested with NIBSC94/572 international reference material. The deviation of the results should ≤10%.

SENSITIVITY

When the sample concentration is 200 ng/mL, the change of absorbance should ≥ 0.01000.

LINEARITY

In the range of [6,500]ng/mL ,the correlation coefficient r ≥ 0.990.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning and afternoon, for total 20 days. The results are as follows:

A)Repeatability(N=20)

	Mean(ng/mL)	CV（%）
Level1	107.1	2.26
Level 2	381.4	0.9

B)Intermediate precision(N=80)

	Mean(ng/mL)	CV（%）
Level1	111.51	3.88
Level 2	385.08	4.08

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.

2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.

3. Do not mix or exchange reagents with different batches in the process of detection.

4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.

5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations. medical waste disposal regulations.

REFERENCES

1. Wick M,Pinggera W, Lehmann P. Iron metabolism Diagnosis and Therapy of Anemias . New

York:Springer-Verlag, 1996, 3rd edition.Vienna.

2. Han Zhijun,Huang Zhifeng, etc.Automatic analysis of commonly used items in clinical chemistry. Liaoning: liaoning science and technology press，2005,1151.

INDEX OF SYMBOLS

	Manufacturer
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn