Ferritin Assay Kit (FER)

Method: Latex Immunoturbidimetric

Cat . No.	Size	Instrument
GB690M	R1: 1×40ml R2: 1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GS691M	R1: 1×40ml R2: 1×20ml	For Hitachi 7170/7180& Olympus AU640/400/600
GT691M	R1: 1×40ml R2: 1×20ml	For Toshiba

INTENDED USE
For the *in vitro* quantitative determination of Ferritin in serum and plasma.

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.

ASSAY 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.

REAGENT COMPOSITION

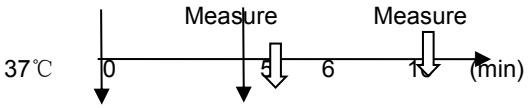
Contents	
R1	Tris/HCl buffer, NaCl
R2	Tris/HCl buffer、Anti (human) -Ferritin coated by latex particals、Nacl

SAMPLE COLLECTION AND PREPARATION
Use serum and plasma (EDTA) .
The sample can be stable for 7 days at 2-8℃,4 weeks at -20℃(frozen for one time only)

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: 2 Point End 18-34
Wave length (sub/main): 800/570nm

Sample 7 µl
R1: 140µl R2: 70 µl



CALIBRATION
Recommend using Gcell calibrator GC-FER.

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of Ferritin in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL
For quality control, use Gcell GQ-FER as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Man：20-300 ng/ml
Woman：10-120 ng/ml
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
In the range of 6~ 450 ng/ml, the linear correlation coefficient r ≥ 0.990. In the range of 6 ~ 50 ng/ml (containing 50ng/ml), linearity deviation shall not exceed ± 5 ng/ml. Between 50 ~ 450 ng/ml, the linear deviation should not exceed ± 10%.

PRECISION
The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(ng/ml)	97.5	402.6
SD	1.52	3.08
CV(%)	1.56	0.77

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	98.5	99.4	101.4

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi 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: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE version 2014

$\bar{x}$	99.8
(Xmax-Xmin)/$\bar{x}$	(101.4-98.5)/99.8*100=2.91%

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Bilirubin: up to 85 mg/dl
Hemoglobin: up to 300mg/dl
Intralipid: up to 250mg/L

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

References

INDEX OF SYMBOLS

	Manufacture
	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 Kuang Yi 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: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn