

FERRITIN

Latex Enhanced Turbidimetric Method

Intended use:

This product is used to determine the level of ferritin in serum and plasma. Ferritin is a spherical, hollow iron storage protein that stores about 450,000 iron atoms. Ferritin is mainly distributed in liver and spleen, and participates in detoxification and storage. The content of ferritin in serum is very small, but the dynamic change of its value reflects the storage of iron in the body. The determination of serum FER concentration is very useful for the diagnosis, treatment and prognosis of iron metabolism abnormalities such as anemia and iron excess, liver diseases, etc.

Testing Principle

Iron antigen + latex coated ferritin antibody → The turbidity of insoluble complexes was measured at 570 nm, and the ferritin content of samples could be calculated by calibration.

Reagent concentration:

R1:	
PBS Buffer solution	0.1 mol/L
PEG	Appropriate Amount
NaN ₃	1 %
Surface Active Agent	Appropriate Amount
R2:	
FER Antibody	> 0.2 g/L
PBS Buffer solution	0.1 mol/L
NaN ₃	%1
Stabilizer	Appropriate Amount
Surface Active Agent	Appropriate Amount

Preparation and stability:

All reagents are ready to use.

The kit was stable for 18 months at 2 - 8°C. Pay attention to refrigeration during transportation and refrigeration should not be allowed in summer transportation. The reagent was opened and stored at 2-8°C for 4 weeks. (If R2 mix weekly.)

Specimen:

It is suitable for fresh serum or plasma samples. If the samples collected on the same day can not be determined in time, please keep them at - 20°C and thaw them quickly at 37°C before use.

Ferritin in serum is stable for 7 days at 2-8 °C

Limitations - interference:

1. When the concentration of the sample $\geq 1000\text{ng} / \text{mL}$, more than the detection limit, it should be diluted by saline for many times.
2. Only when using this kit, the matching calibration product is used in the applicable inspection system.

Expected values:

Normal reference range:

Male	20-250 ng/ml;
Female	20-200 ng/ml
Children	7-140 ng/ml

According to the distribution range of 95% of normal people.

It is suggested that each laboratory verify this reference range or establish its own reference range.

Measuring/reportable range:

Reagent appearance: R1 colorless clear transparent without foreign body; R2 milky white and without foreign body
Blank: Absorbance Value ≤ 1.6

Linearity range: In 20—1000ng / mL linear correlation coefficients $r \geq 0.99$

Analytical sensitivity (lower detection limit)

Reagent analysis Sensitivity: 100ng/ml concentration, absorbance change value ≥ 0.01

Test Methods

1. Double reagents can be used directly after opening without preparation.
2. Test conditions
Basic parameters of automatic biochemical instruments

Wavelength:	570 nm
Assay mode:	Two-point endpoint method or fixed-time method: 5 min / 5 min
Sample:	8 uL
Reagent 1 ; Reagent 2	150 uL : 50 uL
Five-point calibration, using a non-linear computing model, such as Spline	
Reaction Direction :	Increase
Unit :	ng/mL

3. The automatic biochemical analyzer has its own program parameter input method. The basic parameters mentioned above need to be combined with the program parameter input method of the automatic biochemical analyzer. The reagent can be automatically measured only after the parameters of the computer are input.

4. Calibration instructions: 5 points liquid, balance to room temperature for direct use after taking out.

5. Result calculation : The corresponding A is calibrated by the calibrator concentration. The FER concentration in the sample is read out from the calibration curve through the ΔA of the sample

Interpretation of Test Results

1. The linearity of this kit depends on the ratio of samples and reagents, reducing the amount of specimens can increase linearity, but decrease the reagent sensitivity. Excessive sample size will affect the standard curve.
2. The first metering should be performed 40 seconds after the addition of R2, and the second metering is performed 300 seconds after the addition of R2.
3. When used for diagnostic and therapeutic purposes, the results of this test should always be combined with history, symptoms and other clinical outcomes for patients explained.

Quality Control:

Control Serum:
BIOANALYTIC FERRITIN CONTROL SET 2 x 0.5 ml #B10865

Calibration:
S1: BIOANALYTIC FERRITIN CAL SET 4 x 0.5 ml #B11953

FERRITIN

Latex Enhanced Turbidimetric Method

Order information (Cat No.):

CC405	AB405	B21150	B25151	B30151	B33151	B36151
CC406	AB406	B21151	B27150	B31150	B34150	B37150
OL405	CR405-406	B22150	B27151	B31151	B34151	B37151
OL406	BFER300	B24150	B28150	B32150	B35150	B80150
KL405	BFER150	B24151	B28151	B32151	B35151	B80151
KL406	BFER75	B25150	B30150	B33150	B36150	B80152

Manufacturer





Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti

Adres : İkitelli O.S.B Mutsan San. Sit. M4 Blok No: 19 Başakşehir/İSTANBUL

Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50

Web :www.diaclinica.com

SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions



ISO 9001:2015
ISO 13485:2016

