

# FERRITIN Assay (Latex Enhanced Turbidimetric Method) Instructions

## 【Product Name】

Name: Ferritin (Latex\_Enhanced Turbidimetric Method)

## 【Packaging Specification】

Reagent specifications: 3:1

## 【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.

## 【Main Components】

Reagent	Components	Content
R1	PBS Buffer Solution	0.1mol/L
	PEG	Appropriate Amount
	NaN <sub>3</sub>	1%
	Surface Active Agent	Appropriate Amount
R2	FER Antibody	>0.2g/L
	PBS Buffer Solution	0.1mol/L
	NaN <sub>3</sub>	1%
	Stabilizer	Appropriate Amount
	Surface Active Agent	Appropriate Amount
Calibrator	C1- 100ng/ml, C2- 200ng/ml, C3- 500ng/ml, C4- 1000ng/ml	

## 【Storage Conditions and Effectiveness Period】

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.

## 【Applicable Instrument】

This reagent is suitable for automatic biochemical analyzer.

## 【Sample Requirements】

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.

## 【Test Method】

1. Double reagents can be used directly after opening without preparation.

2. Test conditions

Basic parameters of automatic biochemical instruments

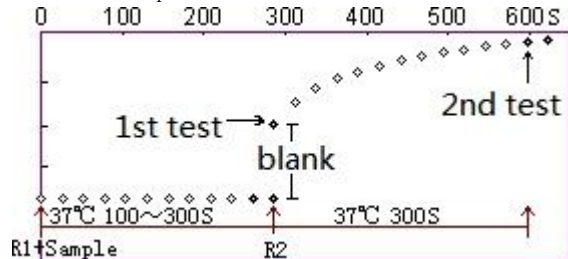
Two-point endpoint method or fixed-time method:

Sample	Reagent (R1/R2)	Temperature	Reaction Time (T1/T2)	Wavelength
8ul	150ul/50ul	37°C	300s/300s	570/800nm

Unit	Reaction Direction	Standard Curve Simulating Equation
ng/mL	Increase	Five-point calibration, using a non-linear computing model, such as Spline

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.

3. Reaction parameters + Reaction curve



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

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

## 【Reference Range】

Normal reference range: Male 20-250ng/ml;  
Female 20-200ng/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.

## 【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.

## 【Limitations】

1. When the concentration of the sample  $\geq 1000$ ng / mL, more than the detection limit, it should be diluted

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by saline for many times.

2. Only when using this kit, the matching calibration product is used in the applicable inspection system.

### 【Product Performance】

Reagent appearance: R1 colorless clear transparent without foreign body; R2 milky white and without foreign body

Blank: Absorbance Value  $\leq 1.6$

Reagent analysis Sensitivity: 100ng/ml concentration, absorbance change value  $\geq 0.01$

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

### 【Precautions】

1. This kit is a kind of Latex Enhanced Immunotransmittance Turbidimetric Reagent. Sub-wavelength is not recommended in it.
2. This product can only be used for In Vitro diagnostic
3. Do not mix different batches of reagents, recalibrate before using new kit with different lots.



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