

Ferritin (FER)



Order Information

Cat. No.
OAR1076

Kit Configuration
Reagent 1: 2 x 20 mL
Reagent 2: 1 x 10 mL
Calibrator: 1 x 3 mL

Summary

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.

Method

Latex Immuno-Turbidimetric method

Principle

FER-Turbilatex is a quantitative turbidimetric test for the measurement of Ferritin (FER) in human serum or plasma. Latex particles coated with specific anti-human FER are agglutinated when mixed with samples containing FER. The agglutination causes an absorbance change, dependent upon the FER contents of the patient sample that can be quantified by comparison from a calibrator of known FER concentration.

Reagent Storage instruction and stability

The reagent is stable until the expiration date on the label when stored tightly closed at 2°-8°C.

If found Particles and Turbidity is observed means reagent deterioration.

Do not freeze; frozen Latex or Diluent could change the functionality of the test

All the components of the kit are stable until the expiration date on the label when stored tightly.

Reagent 1: Buffer

Solution Reagent 2:

Latex Solution

Calibrator: Ferritin Calibrator – (Value on Label)

Composition

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with anti-human FER and Preservative.

Calibrator: Ferritin – (Value on Label)

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 are ready to use.

Ferritin Calibrator: Reconstitute with 3.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use. Calibrator Stable for 1 month at 2°-8°C or 3 months at -20°C. (Freeze only Once!)

Calibration Curve (For Fully Automated Analyzers)

Prepare dilutions of the Calibrator using NaCl 9 g/L as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the ferritin concentration of each point of the curve.

Dilution	1	2	3	4	5	6
Ferritin-CAL (µL)	--	25	50	100	200	400
NaCl 9 g/L (µL)	0	375	350	300	200	--
Factor	0	0.0625	0.125	0.250	0.50	1.00

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days at 2° – 8°C

30 days at -20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength: 540 nm (530-600)

Temperature: 37°C

Cuvette light path: 10

mm

	Sample/ Calibrator
Reagent 1	800 µL
Sample /Calibrator /Water-Blank	100 µL
Reagent 2	200 µL
Mix well and read the absorbance immediately (A1), then incubate for 5 minutes at 37°C and read the absorbance (A2).	

Calculations

$$\text{Ferritin } (\mu\text{g/L}) = \frac{(\text{A2-A1}) \text{ Sample}}{(\text{A2-A1}) \text{ Calibrator}} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics and Measuring Range

The test has been developed determine FER activities within a measuring range from 3 - 600 µg/L. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 3 µg/L.

Linearity

The higher limit of detection is 600 µg/L.

Precision

Intra-assay n = 20	Mean (µg/L)	SD (µg/L)	CV (%)
Sample 1	42.59	0.99	2.33
Sample 2	151.68	1.04	0.68

Inter-assay n = 20	Mean (µg/L)	SD (µg/L)	C V (%)
Sample 1	77.87	0.88	1.13
Sample 2	186.38	1.87	1.01

Method Comparison

A comparison of Nucleus Diagnosys Ferritin (FER) (y) with a commercially available test (x) using 15 samples gave following results:

$$y = 1.020x - 1.759; r2 = 0.997.$$

Reference Range

Infants to Children (upto 16 years): 7-150 µg/L
Adults (Women): 15-150 µg/L,
Adults (Men): 20-220 µg/L

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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