

FERRITIN

(Latex-Turbidimetry Method)

Intended Use

Ferritin assay kit is intended for the In-vitro quantitative determination of Ferritin in human serum sample.

Clinical Significance

The 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.

Principle

The Iron antigen + Latex coated ferritin antibody – The turbidity of insoluble complexes was measured at 578 nm and the ferritin content of samples could be calculated by calibration.

Reagent provided

1. Buffer Reagent R1
2. Latex Reagent R2
3. Calibrator:

Working Reagent Preparation

Ferritin reagent are ready to use liquid reagent.

Reagent storage and stability

The reagent kit should be stored at 2-8°C and is stable till the expiry date indicated on the label.

Specimen collection and preservation

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. The assay should be carried out as far as possible on the same day. Serum and plasma samples are stable for 1 week at 4°C and 1 month at -10°C. The samples should be brought to room temperature prior to use. Avoid use of haemolysed and grossly contaminated samples.

Assay guidelines for Analyzers

Reaction type	Fixed Timewith Multi-Point Calibration
Curve	Non Linear (Spline, Logic Log4 Para)
Reaction Slope	Increasing
Wavelength	578 nm
Flow cell Temperature	37°C
Incubation (R1+ Sample)	5 min. 37°C
Delay time	10 seconds
Reading time	300 Seconds
Blank with	Reagent blank
Sample volume	15 µl (0.015 ml)
Reagent 1 volume	300 µl (0.300 ml)
Reagent 2 volume	100 µl (0.100 ml)
Calibrator conc.	As on vial
Lower limit	20
Higher limit	250
Linearity	1000ng/mL

Assay guidelines for Manual procedure

Pre warm the required amount of working reagent at 37°C before use. Perform the assay as given below:

Reagents	Blank	Calibrator	Test
Reagent 1	300 µl (0.300 ml)	300 µl (0.300 ml)	300 µl (0.300 ml)
Calibrator	-	15 µl (0.015ml)	-
Serum/Plasma	-	-	15 µl (0.015ml)
Mix and Incubate at 37°C for 5 minutes Than Add Reagent 2			
Reagent 2	100 µl (0.100 ml)	100 µl (0.100 ml)	100 µl (0.100 ml)

1. Mix well and read the absorbance after 10 sec. A1 and after 5 minutes A2 of the sample additional at 578 nm.

Calculation

$$\text{Ferritin ng/mL} = \frac{\text{Sample } \Delta\text{Abs/min.}}{\text{Cal } \Delta\text{Abs/min.}} \times \text{Calibrator of Conc.}$$

Note: Since temperature conversion factors are given only as an approximate conversion, it is suggested that values be reported at the temperature of measurement.

Normal Range

Men : 20 – 250 ng/mL
Female : 20 – 200 ng/mL

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitations

A Sample with a Ferritin level exceeding (20 - 1000 ng/mL) The linearity limit should be diluted 1:5 with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, and cleanliness of glassware and accuracy of pipetting.

References

1. Cook, J.D. Lipschitz ,D.A. Laghton, M.B.B. Miles ,E.M & Finch, C.A. Serum Ferritin as a measure of iron stores in normal subjects.
2. Walters, G.O. Miller , F.M.& Wormwood ,M: Serum ferritin concentration on and iron stores in normal subjects.J.ClinPathol. 26:770,1973.

Symbols

IVD	In Vitro Diagnostics.	 Caution.	 Keep away from sun light.	 Date of Manufacture.
LOT	Batch No.	 Read Instructions.	 Fragile.	 Product Expiry Date.
CONT	Content.	 Storage Temperature.	 Keep Dry.	 Manufactured By.
REF	Catalogue No.			



KEE DIAGNOSTICS PVT LTD

CIN: U24231DL2004PTC128343 .

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A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.

NEW DELHI-110028.

W. www.keediagnosics.com.

E. info@keediagnosics.com. T. 011 43136000.



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