PATHOZYME DIAGNOSTICS

FERRITIN

(TURBIDIMETRY METHOD)

CAT NO.: FER

Reagent kit for quantitative estimation of Ferritin Serum.

DIAGNOSTIC SIGNIFICANCE:

Ferritin is the major iron storage compound in the body and is considered one of the most reliable indicators of iron status of patients. A clinical evaluation of serum ferritin is an index of iron stores. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk. Plasma ferritin is also increased in patients with hemosiderosis or hemochromatosis

PRINCIPLE:

The latex particles coated with anti human ferritin are Agglutinated when they react with samples that contain ferritin. The latex particles agglutination is proportional to the concentration of the Ferritin in the sample and can be measured by turbidimetry.

SPECIMEN COLLECTION:

Fresh serum. Stable for 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

KIT PRESENTATION:

Pack Size	1 X 20 ml	1 X 50 ml
R1 - Ferritin (Buffer Reagent)	1 X 16 ml	1 X 40 ml
R2 - Ferritin (Latex Reagent)	1 X 04 ml	1 X 10 ml
FERRITIN Calibrator	1 Vial	1 Vial

WORKING REAGENT PREPARATION:

R1 – Ferritin (Buffer Reagent) & R2 – Ferritin (Latex Reagent) are Ready To Use.

REAGENT STORAGE AND STABILITY:

All reagents are stable at 2-8^{0}C until the expiry date stated on the label.

CALIBRATION CURVE: Prepare dilutions of the Calibrator using NaCl 9 g/L as Buffer. 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
Ferritin Calibrator (µL)	--	25	50	75	100
NaCl 9 g/L (µL)	100	75	50	25	--
Factor	0.0	0.25	0.5	0.75	1.0

ASSAY PARAMETERS:

Reaction	**: Fix Time**	**Sample Volume**	**: 50 µl**
Wavelength	**: 630 nm**	**R1 + R2 Volume**	**: 800 µl + 200 µl**
Flow Cell Temp.	**: 37^{0}C**	**Calibrator Conc.**	**: As On Vial**
Initial Delay	**: 5 Sec**	**Reaction Slope**	**: Increasing**
Interval Time	**: 480 Sec**	**Zero Setting**	**: Dist. Water**
Read Time	**: 480 Sec**	**Linearity**	**: 1000**
No. of Reading	**: 01**	**Unit**	**: µg/L**

PROCEDURE:

Pipette into TT	Calibrator	Test
R1 - Ferritin (Buffer Reagent)	800 µl	800 µl
Ferritin Calibrator	50 µl	--
Sample (Test)	--	50 µl
R2 - Ferritin (Latex Reagent)	200 µl	200 µl

Mix & aspirate immediately and read difference in absorbance between 5 seconds (AT_1) and 480 seconds (AT_2) for Calibrator and Test at 630 nm.

CALCULATION:

$$\text{Ferritin (µg/L)} = \frac{\Delta\text{Abs of Test X Calibrator Conc.}}{\Delta\text{Abs of Calibrator}}$$

Where $\Delta Abs = (AT_1) - (AT_2)$

NORMAL VALUES:

Children : 7 – 140 µg/L
Men : 20 – 250 µg/L
Women : 20 – 200 µg/L
Each laboratory should establish its own reference range

LINEARITY:

This method is linear up to **1000 µg/L**. For values above 1000 µg/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

Detection limit: Values less than 3 µg/L give non reproducible results.
Analytical sensitivity: 2.07 mA /µg Ferritin/L.
Prozone effect: Up to 4000 µg/L.

INTERFERENCES:

Bilirubin (20 mg/dL), Hemoglobin (40 g/L) and Lipemia (10 g/L) and Rheumatoid Factor (600 IU/ml) do not interfere. Other substances may interfere.

NOTE:

1. Calibrator dilutions in plastic tubes should be avoided. Ferritin antigen may coat to the walls of plastic tubes.
2. Heterophilic antibodies in human serum can react with reagent antibodies, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES:

1. Newman DJ, Henneberry H, Price CP. *Ann Clin Biochem* 29: 122-42 (1992)
2. Young DS. *Effects of drugs on clinical laboratory tests*. 3th ed. AACC Press (1997).
3. Tietz Textbook of clinical chemistry, 3rd Ed. Burtis CA, Ashwood ER. WB Saunders Co., (1999).

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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