Pariksha Biotech
A game changer in IVD

Ferritin Estimation Kit

High-Q Ferritin

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

HIGH Q®
Command on Quality

Intended Use:

For the Quantitative Determination of Ferritin in Human Serum or Plasma

Summary:

Serum ferritin is particularly useful for distinguishing between iron deficiency and anemia due to chronic disorders, because in these cases ferritin levels are increased. Serum ferritin levels below 10 µg/L almost always suggest iron deficiency. Serum ferritin is also increased in other anemias such as aplastic anemia, sideroblastic anemia and chronic hemolytic anemia. In idiopathic hemochromatosis and in multi-transfusion patients may be exceptionally high.

Method and Principle:

When the sample is mixed with the appropriate buffer (R1) and latex particles coated with anti- Ferritin antibodies (R2), Ferritin reacts with the specific antibodies leading to agglutination of latex particles. This agglutination is detected as turbidity change and it is proportional to Ferritin concentration in the sample.

Interferences and Sensitivity:

Hook effect:

No hook effect is observed up to 50000 ng/ml.

Sensitivity:

The lowest detectable level of Ferritin is estimated at 4 ng/ml. The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.The reagent is designed especially for use with discrete analyzers.

Calibration:

Pariksha provides Ferritin 5 Level Calibrator Set (Lot Specific) for calibration. Calibrate the assay every 30 Days. Re calibration should also be repeated after major maintenance is performed on the analyzer or after a critical part is replaced or when a significant shift in control values occurs.

Quality Control:

Two-level liquid controls are provided optionally.Target values for Ferritin should be verified with the corresponding working protocol. Results outside the specified values even after re calibration could be due to reagent deterioration, instrument malfunction or error during test procedure.

Attention:

A) Applications on routine analyzers may be totally different from what developed as manual determination; in addition the procedures are specific for each analyzer.

B) Very deep attention must be given to interfering substances: Certain drugs and other substances are able to influence levels of Ferritin

C) The clinical diagnosis cannot be done correctly using the result of only one test, but have to be done integrating critically the results of different laboratory tests and clinical data.

D) A lot of factors, as ambient temperature, the working reagent temperature, wash accuracy and the type of spectrophotometer, may affect the tests performances.

E) The calibration curve has to be always repeated at each change of the lot of the Reagent and/or calibrator.

Reagent Composition:

Reagent 1:

Tris Buffer (pH 7.2): 150 mM
Non reacting components and preservatives.

Reagent 2:

Latex particles coated with Goat antibodies against human Ferritin
Non reacting components and preservatives.

Sample:

Use serum or Plasma with EDTA as specimen. Sample is stable for 2 days when stored at 2 – 8°C and for 6 months when stored at –20°C.

Assay Procedure:

System Parameters:

Calibration Method	Multi Point Linear/ Non Linear/Spline
Reaction Type (Mode)	Fixed Time/Two Point
Reaction Direction	Increasing
Wave Length	630 nm (600-630 nms)
Flow Cell Temp.	37°C
Delay Time	5 Seconds
Measuring Time	240 Seconds
Blank	Distilled Water Blank
Reagent Volume	400 µl (R1) + 100 µl (R2)
Sample Volume)	50 µl
Calibrator Concentrations	(On the Vials Lot Specific)
Linearity	1000 ng/mL

Procedure:

Reagent	Calibrator	Sample/Control
Ferritin R1	400 µl	400 µl
Calibrator(1,2,3,4,5)	50 µl	----
Sample	—	50 µl
Ferritin R2	100 µl	100 µl

1) Read absorbance A1 after 5 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 240 Seconds (Measuring)
3) Calculate the absorbance differences ΔA=A2–A1 for each point of the calibration curve, controls and all unknown samples.
4) The concentration of Ferritin in the unknown sample can be calculated from ΔA=A2–A1

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5) Using a 3rd order polynomial mathematical model where abscissa (X) is the ΔA=A2–A1 and ordinate (Y) is the concentration of Ferritin or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the Ferritin concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculation:

The concentration of Ferritin in unknown samples is derived from a calibration curve using an appropriate mathematical models such as Multi Point Linear/Non Linear/ Spline. The calibration curve is obtained with 5 calibrators at different levels.

Stability of calibration: 4 weeks

Reference Intervals:
Serum/Plasma:

Infants:	**25 – 200 ng/mL**
6 months-15 years:	**7 – 142 ng/mL**
Adult men:	**20 – 300 ng/mL**
Adult women:	**10 – 120 ng/mL**

Each laboratory should determine its own expected values as dictated by good laboratory practice

Performance Characteristics:
Linearity:
The assay is linear within measuring range 6 – 1000 ng/ml. When values exceed this range samples should be diluted accordingly.

Interference

Lipemic:	≤ 13% up to 400mg/dL intralipid
Hemoglobin:	≤ 7% up to 500mg/dL
Non Conj. Bilirubin:	≤ 6% up to 20 mg/dL
Conj. Bilirubin:	≤ 3% up to 20mg/dL
Ascorbic Acid:	≤ 6% up to 3mg/dL

Precautions:

1) This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
2) Samples should be considered as potentially infectious. Handle according to universal precautions and good laboratory practices.
3) Dispose all waste according to national laws.

Bibliography:

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3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Bernard A., Lauwerys R. Turbidimetric latex immunoassay for serum ferritin. Journal of Immunological methods 1984; 71:141-147

Ordering Information:

Ref./Cat. No.	Pack Size	Presentation
P-FER-20	20 ml	Two Liquid Reagents and 5 Level Calibrator Set
P-FER-40	40 ml	

Product Features

- **Latex Enhanced Turbidimetric Immuno Assay (LETIA)**
- **Liquid Stable Two Reagents**
- **5 level Calibrators provided**
- **2 Level Controls provided (Optional)**
- **Measuring wavelength 630 nms (600-630)**
- **4 Minutes test procedure (5 Sec + 240 Sec)**
- **Linearity: 1000 ng/mL**
- **Adaptable to Semi and Fully auto analyzers**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C–8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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