TurbiMAX Ferritin

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation (R1 / R2)
AVFRT-25	25 ml	1x 22.5 ml / 1x 2.5 ml
AVFRT-50	50 ml	2x 22.5 ml / 1x 5 ml

INTENDED USE:

TurbiMAX Ferritin is an in-vitro diagnostic kit for the Quantitative Determination of Ferritin in Human Serum or Plasma.

PRODUCT FEATURES

1. Latex Enhanced Immunoturbidimetric Assay
2. Liquid Stable Two Reagents
3. 1 Calibrator provided.
4. Measurement at 546 nm (540-578 nms)
5. Test Procedure time 4 minutes at 37°C
6. Linearity : 750 ng/ml
7. Adaptable to Semi and Automated Analyzers

CLINICAL SIGNIFICANCE

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.

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.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Turbi Latex Reagent R2
3. Ferritin Calibrators : Concentration as stated on the label

REAGENT COMPOSITION

Reagent 1:

Tris Buffer (pH 7.2): 120 mM

Non reacting components and preservatives.

Reagent 2:

Latex particles coated with rabbit antibodies against human Ferritin

Non reacting components and preservatives.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

CALIBRATION

Prepare the following dilutions of the ferritin calibrator using Calibrator Diluent Buffer to obtain the concentration of each dilution, multiply the dilution Factor shown in the below table

Calibration Dilution	1	2	3	4
Calibrator Ferritin (in µl) (Concentrate)	50	100	200	400
Calibrator Diluent Buffer	350	300	200	—
Dilution Factor	1/8	1/4	1/2	1

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.2 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

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.

SYSTEM PARAMETERS:

Reaction Type (Mode)	Fixed Time- Non Linear- Multi Standard
Reaction Direction	Increasing
Wave Length	546 nm (540-578 nms)
Flow Cell Temp.	37°C
Delay Time	5 Seconds
Measuring Time	240 Seconds
Blank	Distilled Water Blank
Reagent Volume	450 µl (R1) + 50 µl (R2)
Sample Volume	50 µl
Calibrator Concentrations	(On the Vials Lot Specific)
Linearity	750 ng/ml

TEST PROCEDURE :

Reagent	Calibrator	Sample/Control
Ferritin R1	450 µl	450 µl
Calibrator	50 µl	----
Sample	—	50 µl
Ferrtin R2	50 µl	50 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

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 model such as logit/log or spline. The calibration curve is obtained with 1 calibrators at different levels.

Stability of calibration: 4 weeks

EXPECTED VALUES

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

QUALITY CONTROL & CALIBRATION

Two-level liquid controls are provided optionally by Avecon

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.

PERFORMANCE CHARACTERESTICS:

1. Linearity

Linearity : 750 ng/ml

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 6 ng/ml

3.Interferences:

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

4. Precision: The reagent has been tested for 20 days, using three levels of serum in a EP5-based study (NCCLS).

Intra-Assay

N=20	Mean (ng/ml)	SD (ng/ml)	CV%
Control serum 1	135	1.2	0.8
Control serum 2	236	1.4	0.6
Control serum 3	372	1.6	0.43

Inter-Assay

N=20	Mean (ng/ml)	SD (ng/ml)	CV%
Control serum 1	135.5	1.3	0.96
Control serum 2	237.2	1.6	0.67
Control serum 3	373.6	2.2	0.59

5. Method Comparison:

A comparison was performed between this reagent and another commercially available product. The results were as follows on a

Y = 0.9562X + 0.0008 R=0.9801 N=86 Sample range: 0.2 – 26.1 µg FEU/ml

LIMITATIONS (calibration curve): 6-750 (ng/ml), under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5. The linearity limit and measurement range depends on the sample to reagent/ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCE

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2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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