FERRITIN

2 x 20/2 x 8 mL
12019043

Intended Use

The reagent is intended for *in vitro* quantitative determination of Ferritin in serum
-Latex Enhanced Immunoturbidimetry
-High Linearity of 1000 ng/mL
-Multipoint calibration

Clinical Significance

Ferritin is an iron-containing protein. It is mainly found in liver and spleen, where its function is to store and release iron in the body. It is also found in small amounts in human serum. The serum levels tend to increase due to hepatitis and malignant tumors. The measurement of ferritin is useful in diagnosis, treatment, assessment of disease progression and post-operative prognosis of abnormal iron metabolism and iron deficiency anemia.

Principle

Latex particles coated with anti-ferritin antibody are agglutinated when mixed with samples containing Ferritin. The agglutination causes an absorbance change which depends on the Ferritin concentration in the sample, this can be interpolated using a calibration curve prepared from calibrators of different concentrations.

Kit Components

Reagent/ Component	Product Code 12019043	Description
Ferritin R1	2 x 20 mL	Glycine buffer
Ferritin R2	2 x 8 mL	Suspension of latex particle bound to anti-ferrtin antibodies

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation

Ferritin R1 & R2 Reagents are ready to use.

Reagent Storage and Stability

The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C.

Open Vial Stability

Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability

Calibration is stable for 20 days.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Protein Control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Fresh Serum. Do not use lipemic or hemolysed sample.

Interferences

No interference for
Hemoglobin up to	500 mg/dL
Triglycerides up to	3000 mg/dL
Bilirubin up to	30 mg/dL
Rheumatoid Factor up to	560 IU/mL

Materials provided

Ferritin R1 & R2 Reagent

Reagents required but not provided

Agappe Ferritin Calibrator (Product Code: 11620003)
Agappe Protein Control (Bi-Level) (Product Code: 11614007)

Calibration

Agappe Ferritin Calibrator (Product Code: 11620003) is recommended for calibration of the assay.

Preparation of Calibration Curve

Prepare the following calibrator dilution using Normal saline as diluent. Multiply the concentration of the Ferritin Calibrator by the corresponding factors stated in the table below to obtain the Ferritin concentration of each dilution.

Dilution	1	2	3	4	5	6
Cali. (µL)	-	10	10	20	50	100
Normal Saline (µL)	100	150	70	60	50	-
Dil. factor	0	0.0625	0.125	0.25	0.5	1.0

Quality Control

It is recommended to use Agappe Protein Control (Bi-Level) (Product Code: 11614007) to verify the performance of the assay.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range

It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Male   :   30 - 220 ng/mL
Females   :   20 - 110 ng/mL
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

The reagent is linear up to 1000 ng/mL. If the concentration is greater than linearity (1000 ng/mL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.998$ and a regression equation of $y = 1.0139x$.

3. Precision

Control	Intra Run		Inter Run	
	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (ng/mL)	29.4	291.74	29.92	291.6
SD	1.06	2.97	1.12	3.05
CV(%)	3.55	1.02	3.75	1.05

Accuracy (ng/mL)		
Control	Expected Value	Measured Value
Control Level 1	29.4 ± 5.8	29.65
Control Level 3	293 ± 41	292.14
Agappe Control Level 1	105 ± 20.4	106

4. Sensitivity

Lower detection Limit is 10. ng/mL

Bibliography

1. Cook, J.D., Lipschitz,D.A., Laughton, M.B.B., Miles, E.M. & Finch, C.A: Serum ferritin as a measure of iron stores in normal subjects. Am.J.clin.Nutr. 27: 680, 1974.

2. Walters,G.O.,Miller, F.M & Wormwood, M.: Serum ferritin concentration on and iron stores in normal subjects. J.Clin.Pathol. 26: 770-, 1973.

──── SYMBOLS USED ON THE LABELS ────

IVD IN VITRO DIAGNOSTIC USE   **i** SEE PACKAGE INSERT FOR PROCEDURE   **LOT** LOT NUMBER   MANUFACTURER'S ADDRESS   MANUFACTURING DATE   EXPIRY DATE   TEMPERATURE LIMIT

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