ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Ferritin– Instructions for use

R1: 1x25 mL • REF A-R1100004301
R2: 1x7,5 mL

CE IVD

SUMMARY AND EXPLANATION OF THE TEST

The plasma Ferritin concentration declines very early in the development of iron deficiency.
On the other hand, a large number of chronic diseases result in increased serum Ferritin concentrations. These diseases include chronic infections, chronic inflammatory disorders such as rheumatoid arthritis or renal disease, Gaucher's disease, and numerous types of malignancies, especially lymphomas, leukaemias, breast cancer and neuroblastoma. Increase in plasma Ferritin concentration also occurs in viral hepatitis or following toxic liver injury because of release of Ferritin from damaged liver cells. Plasma Ferritin concentration is also increased with increases of iron stores, as seen in patients with hemosiderosis or hemochromatosis. Besides the use of Ferritin as an iron metabolism parameter, Ferritin as also gained importance as a tumour marker for therapeutic drug monitoring and follow-up.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

Ferritin Reagent Kit
Code A-R1100004301
Reagent 1 (R1) - Buffer - 1 x 23.5 mL/vial
Reagent 2 (R2) - Latex - 1 x 4.5 mL/vial
Each vial is ready to use and contains:

Reagent 1:	**Conc.**	**U.M.**
Hepes Buffer	/	/
Sodium azide	0,95	g/L
Reagent 2:	**Conc.**	**U.M.**
Solution of suspended latex microparticles sensitized with rabbit IgG anti-uman ferritin .	/	/

Reagent Preparation:
Liquids reagents ready for use.

Storage and Stability:
If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.
Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment
Saline (9 g/L)
Calibrators and/or Control
(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.
Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).
Reagents from different lots must not be interchanged.

Safety Precautions

1. Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
2. Do not pipet by mouth.
3. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
4. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
5. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
6. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
7. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
8. All human samples must be handled and disposed of as potentially infectious materials.
9. For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Use fresh serum.
If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours.
If stored for a longer period, the sample should be frozen.

ASSAY PROCEDURE

Allow reagents to reach working temperature before using.

Quality control
It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedures
Sample/Control/Standard: Ready for use.
Reference curve: Ferritin standard kit **R-1300002901**. Use saline 9 g/L as zero point.

Method for automated instrumentation

Analyzer:	**Miura Family**	
Analyte Name :	**Ferritin** Ref.:	A-R1100004301
Method Code:	**FER**	
Type:	**Different. Sample Blk.**	
Unit:	**mg/dL**	
Filter F1:	**578 nm**	
Blank in calculation:	**Not Used**	
Step	**Reaction volume**	**U.M.**
Sample volume:	**25**	µL
Volume Reagent 1:	**200**	µL
Volume Reagent 2:	**65**	µL
Incubation Time	**60**	Sec.
Reading Time:	**300**	Sec.
Calibration	**See Reference Curve**	

EXPECTED VALUES

Men: 20 - 300 ng/mL
Woman: 15 - 200 ng/mL
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the Ferritin reagents were measured on a clinical chemistry analyzer according to the procedure R1: 150 µL and R2: 50µL.
Measuring Range: 0 - 500 ng/mL
Detection Limit: 5.0 ng/mL
Hookeffect: No Risk

Precision: [%CV]		Low	Medium	High
	Intra-Run	0.76	0.63	0.61
	Inter-Run	4.14	3.8	4.11
Accuracy: [mg/dL]	Control	Assigned	Measured	
	Aptec	85.2 (72.4-98.0)	92.1	
	Aptec	224 (190-258)	221.1	
	Siemens	87.7 (70.2-105.2)	82.5	

Specificity: Monospecific
Interferences: No interference for:
Heparin (50 mg/dL), Na Cl (1000 mg/dL), Triglyceride (2500 mg/dL), Bilirubin (30 mg/dL), Heamoglobin (250 mg/dL), EDTA (5 mg/mL)
Limitations: None
Comparison with Turbidimetry method: y = 0.9261x +015.5596 / r = 0.9868
Stability at 2°- 8°C: at least 16 months after production

BIBLIOGRAPHY

1. Lipzchitz DA, Cook JD, Finch CA. A clinical evaluation of serum ferritin as an index of iron stores. N Engl J Med. 1974; 290(22): 1213-1216
2. Worwood M. Ferritin in human tissues and serum. Clin Heamatol. 1982; 11(2): 275-307
3. Worwood M. Serum ferritin. Clin Sci(Lond)1986; 70(3): 215-220
4. Warr GW, Magor KE, Higgins DA. IgY: clues to the origins of modern antibodies. Immunology Today 1998; 16:92-8.

LOT Numero lotto / Lot numer
Consultare la metodica operativa / consult instructions for use
IVD Per uso diagnostico in-vitro / For in-vitro diagnostic use
Prodotto da / manufactured by
Data di scadenza / expiry date
Temp. Di Conservazione / storage temperature

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