SPECTRUM

The Creative Approach to Bioscience

FERRITIN
Turbi Latex

REF: 562 001 (100 T)
R1 Diluent 2 X 20 ml
R2 Latex 1 X 10 ml
C Calibrator 1 X 3 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Intended Use

In vitro diagnostic reagents for the quantitative determination of Ferritin in human serum by means of particle-enhanced turbidimetric immunoassay.

Background

Ferritin is a macromolecule with a molecular weight of at least 440 kD and is formed of apoferritin and an iron core of about 2500 Fe+3 ions. It has been found a direct correlation between the plasma ferritin concentration and the quantity of available iron stored in the body so that its determination is used for diagnosis and monitoring of iron deficiency and iron overload. Additional parameters (transferrin, transferrin saturation, and haematological investigations) could be required for the diagnosis of disturbances of distribution. In a comparison of the various parameters available for the determination of the body iron stores, plasma ferritin was the most efficient parameter, demonstrating a sensitivity of 80 %, and a specificity of 96 %. The serum concentrations of ferritin are found to be elevated in patients with infections, inflammation or in hepatic or chronic renal diseases. The determination of ferritin is particularly useful in the diagnosis of iron therapy, for the determination of iron reserves in high-risk groups, and in the differential diagnosis of anaemia.

Test Principle

This Ferritin test is based upon the reactions between Ferritin in the sample and latex covalently bound rabbit antihuman Ferritin antibodies. Ferritin values are determined photometrically.

Reagents

R1 Diluent
Trisbuffer 20mmol/L,pH8.2.
Sodium azide 0.95 g/L.

R2 Latex reagent
Latex particles coated with antihuman Ferritin antibodies.,pH 8.2
Sodium azide 0.95 g/L.

Calibrator
Human serum. Ferritin concentration is stated on the vial label.

All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Disposal of all waste material should be in accordance with local guidelines.

As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Do not freeze reagents.The Ferritin latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

The Ferritin diluent reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

Specimen Collection and Preparation

Specimens should be collected by venipuncture following good laboratory practices. Suitable assay specimens are human serum samples, as fresh as possible (stored up to 7 days at 2 - 8 ºC) or deep-frozen. Any additional clotting or precipitation, which occurs due to the freeze/thaw cycle, should be removed by centrifugation prior to assay.
Very lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15.000 rpm).

Reagent Preparation and Stability

Spectrum Ferritin reagents (**R1** & **R2**) are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 ^{O}C.

Ferritin Calibrator: Reconstitute with 3 ml distilled water. mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at at 2 - 8 ºC or 3 months at at -20 ºC.

Calibration and Calibration curve

Use Ferritin calibrator.
The sensitivity of the assay and target value of calibrator have been standardized against the 3rd international standard of ferritin (94/572, 2008 WHO). Recalibrate when control results are out of specified tolerence, when using different lot of reagent and when instrument is adjusted.

Calibration curve

Calibrator dilution	1	2	3	4
Calibrator (ul) Na Cl 9 g/L (ul)	--- 100	25 75	50 50	100 ---
Factor	0	0.25	0.5	1.0
Concentration (for example: the undiluted C = 628 ug/L)	0	157	314	628

Quality Control

Control sera are recommended to monitor the perfomance of manual and automated assay procedures. Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Procedure

1 - Bring the reagents and the photometer to 37ºC

2 - Assay conditions:
Wavelength 540 nm (530 -550 nm)
Temperature 37ºC
Cuvette 1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

Diluent (R1)	400 µl
Latex (R2)	100 µl
Calibrator or Sample	45 µl

5.Mix and read absorbance immediately (A_1) and after 5 min (A2) of the sample addition.

Calculation

Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the ferritin concentration of calibrator dilution. Ferritin concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

Sensitivity

Up to 5.04 µg/L.

Linearity

Up to 600 µg/L.

specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Expected Values

The determination of reference ranges for ferritin concentrations of clinically healthy individuals is very difficult. Ferritin concentrations are age- and sex- dependent and exhibit a wide range of distribution.

Men 30 - 220 ug/L
Women 20 - 110 ug/L

These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

References

Wick M, Pinnggera W, Lehmann P. Ferritin in iron metabolism. Diagnosis of anemias. 2nd ed. Springer-Verlag. Wien 1994.

Miles LEM, et al. Measurement of serum ferritin by a 2-site immunoradiometric assay. Anal Biochem 1974; 61:209-224

Milmann N, Sondergaard M, Sorensen CM. Iron stores in female blood donors evaluated by serum ferritin. Blut 1985;51:337-345.

Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.

Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
562 001	100 test

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

ISO 13485:2016