SPECTRUM

The Creative Approach to Bioscience

FERRITIN
Turbi Latex

REF:562 000 (**50 T**)
R1 Diluent 1 X 20 ml
R2 Latex 1 X 5 ml
C Calibrator 1 X 3 ml

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

REF: 562 002 (**200 T**)
R1 Diluent 4 X 20 ml
R2 Latex 2 X 10 ml
C Calibrator 1 X 3 ml

REF:562 001-1(**100 T**)
R1 Diluent 2 X 20 ml
R2 Latex 1 X 10 ml
Without calibrator

REF: 562 002-1 (**200 T**)
R1 Diluent 4 X 20 ml
R2 Latex 2 X 10 ml
Without calibrator

SYMBOLS IN PRODUCT LABELLING

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

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.

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 are 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.

Deterioration

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 discarded.

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** and **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.Open vial is stable for 3 months 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 2 - 8 ºC or 3 months 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 a different lot of reagent and when instrument is adjusted.

Calibration curve

Calibrator dilution	1	2	3	4
Calibrator (µl)	---	25	50	100
Na Cl 9 g/L (µl)	100	75	50	---
Factor	0	0.25	0.5	1.0
Concentration	0	157	314	628

(for example: the undiluted C = 628 µg/L)

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).After 5 minutes of the sample addition, read (A2).

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.

Performance characteristics

Detection limit

5,04 µg/L

Prozone effect

No prozone effect was detected at least up to 9000 µg/L

Precision

According to the EP5-A2 standards (CLSI), the reagent has been tested for 20 days, measuring each level per duplicate twice a day (n=80):

	Intra-assay (n= 80)		
Mean (µg/L)	33.4	114.5	289.8
SD	1.7	1.4	2.4
CV %	5.1	1.2	0.8

Total (n= 80)		
33.4	114.5	289.8
1.7	1.4	2.4
5.1	1.2	0.8

Method comparison

The reagent was compared to another commercially available Ferritin reagent by testing 144 samples (male and female), with concentrations between 6,97 and 730 ug/L. The coefficient of correlation (r) was 0,988, and the equation y = 0,96x + 1,15

Sensitivity

When run as recommended, the minimum detection limit of the assay is 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 µg/L
Women	20 - 110 µg/L
New born	25 - 200 µg/L
Infants 1 month	200 - 600 µg/L
Infants (2-5 months)	50 - 200 µg/L
Children (6 months -15 years)	7-140 µg/L

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

Waste Disposal

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

References

1- Wick M, Pinnggera W, Lehmann P. Ferritin in iron metabolism. Diagnosis of anemias. 2nd ed. Springer-Verlag. Wien 1994.
2- Miles LEM, et al. Measurement of serum ferritin by a 2-site immunoradiometric assay. Anal Biochem 1974; 61:209-224
3- Milmann N, Sondergaard M, Sorensen CM. Iron stores in female blood donors evaluated by serum ferritin. Blut 1985;51:337-345.
4- Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.
5- Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
562 000	50 test
562 001	100 test
562 002	200 test
562 001-1	100 test (without calibrator)
562 002-1	200 test (without calibrator)

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