

FERRITIN

REF: L-9560T
B-9460T

Product for In Vitro Diagnostic use. The product should be used for the quantitative determination of ferritin in human serum by the immunoturbidimetric procedure.

Diagnostic Relevance

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 Fe³⁺ 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's 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.

Principle

The Ferritin test is based upon the reactions between Ferritin in the sample and latex-covalently bound antibodies against human Ferritin. Ferritin values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 500 µg/L. The measuring temperature is 37°C. The assay can be performed on different instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

Buffer - phosphate buffer (pH 6.5), containing protein stabilizers and < 0.1 % sodium azide as preservative.

Latex reagent -suspension of latex microparticules covalently bound anti-ferritin

antibodies suspended in a neutral aqueous solution, with 0,09 % sodium azide as preservative.

Precautions

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.

Materials required

Automatic analyzer. Saline solution. Calibrator. Controls.

Storage and Stability

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at +2...+8°C. Do not freeze. The Ferritin buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded. 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.

Specimens

Fresh or deep frozen serum. Ferritin remains stable for 7 days at +2 to +8°C. If the test should be performed later, it is recommended to freeze the serum. 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).

Procedure

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use.

Volume R1/working reagent:	Volume R2/start reagent:	Volume sample:
200 µl	75 µl	25 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 4 min after read 2nd reading.		
Wavelength: 600 nm		Incubation Time at 37° C: 4 min

* Volume, time and wavelength are recommended. Adjust them depending of analyser features.

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

Calibration. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material. The method was standardized against the WHO 80/578 international standard.

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Calculation

The turbidimetric analysers automatically calculate the Ferritin concentration of each sample. Conversion: ng/ml = µg/l.

Reference 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.

Children:	
Cord blood contains	100 to 250 µg/l
In the first two months of life there is a rise of up to:	600 µg/l
Followed by a fall of down to	1 µg/l (Hb-neosynthesis)
Children and adolescents (6 weeks to 18 years of age)	15 - 120 µg/l.
Men	30 - 300 µg/l
Women (Pre-menopausal)	10 - 160 µg/l
Women (Post-menopausal)	30 - 300 µg/l

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

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers or in manual procedures.

Specific Performance Characteristics*

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, this data must be calculated by each instrument.

(*) Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

- 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
- Milman N, Sondergaard M, Sorensen CM. Iron stores in female blood donors evaluated by serum ferritin. Blut 1985;51:337-345.
- Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 - 224



Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symboles figurant sur les étiquettes. Spiegazione dei simboli utilizzati sull'etichetta. Significado dos símbolos indicados nas etiquetas. Erläuterung der Symbole auf den Etiketten.												
Fecha de Caducidad Expiry Date Date de Périemption Data di Scadenza Data Expiração Verwendbar bis	Temperatura de almacen Storage Temperature Temperatura de Conservation Temperatura de Conservazione Temperatura de Conservação Lagertemperatur	Número de Lote Lot Number Número de Lot Número di Lotto Número de Lote Chargen-Nr	Para Diagnóstico In Vitro For In Vitro Diagnostic Usage In Vitro Per Uso Diagnostico In Vitro Utilizar em Diagnostico In Vitro In Vitro Diagnosticum	Número de catálogo Catalog Number Número de catalogue Número di catalogo Número de catálogo Katalognummer	Conformidad Europea European Conformity Conformité aux normes européennes Conformità europea Conformidade com as normas europeias CE-Konformitätskennzeichnung	Fabricado por Manufactured by Fabriqué par Fabricado da Fabricado por Hergestellt	Reactivo Reagent Réactif Reagenti Reagenz	Calibrador Calibrator Calibrateur Calibratore Calibrador Kalibrator	Tampón Buffer Tampón Tampone Buffer Puffer	Liofilizado Lyophilised Lyophilisé Liofilo Liofilizado Lyophilisiert	Concentración Concentration Concentration Concentrazione Concentração Konzentration	Control Alto / Control Bajo Control High / Control Low Contrôle élevé / Contrôle Bas Controllo Alto / Controllo Basso Controlo Alto / Controllo Baixo Kontrolle Hoch / Kontrolle Niedrig