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FERRITIN

REF: K-9560M

MONOREAGENT PROCEDURE

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

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 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 hematological 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

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

Each Ferritin kit contains:

A.- Buffer – 37.5 mL of phosphate buffer, pH: 6.7, containing protein stabilizers and 0,09 % sodium azide as preservative.

B.- Latex reagent – 15 mL of a suspension of latex microparticules covalently bound anti-ferritin antibodies suspended in a neutral aqueous solution, with 0,09 % sodium azide as preservative

C.- Calibrator – 1 x 6 mL. Human - based reference fluid. Preservative: sodium azide, 0.09%. 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

Reagent Preparation

Working Reagent is prepared with 1 part of Latex Reagent and 2.5 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

Calibration Curve and Controls

Analytical Range up to 500 ng/mL.

Use Biolatex Ferritin Calibrator Set

For quality control use Biolatex Control or another 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.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at +2 - +8ºC. Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at +2 - +8ºC after use. 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 discarted.

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

WR is stable for up to 5 days at 4ºC. **It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.**

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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

Spectrophotometric analyser. Controls.

Specimens

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...+8ºC) 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).

Procedure

Wavelength		600 nm	
Temperature		37ºC	
Cuvette		1cm light path	
Measurement against distilled water blank.			
Bring the reagents at 37ºC and pipette:			
	Calibrator	Sample	Blank
Calibrator	40 µl	---	---
Sample	---	40 µl	---
Distilled Water	---	---	40 µl
Work. Reagent	500 µl	500 µl	500 µl
Mix and measure absorbance immediately (A1) incubate 5 min (37ºC), after incubation read absorbance (A2).			

Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If is an one point calibration:

$$\frac{(A2-A1)_{sample} - (A2-A1)_{blank}}{(A2-A1)_{calibrator} - (A2-A1)_{blank}} x CalibratorConcentration$$

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 a 250 ng/mL. 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	15 - 120 ng/mL. (6 weeks to 18 years of age).
Men	30 - 300 ng/mL
Women (Pre-menopausal)	10 - 160 ng/mL
Women (Post-menopausal)	30 - 300 ng/mL

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

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, the data must be calculated by each instrument.

Literature

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Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

Fecha de Caducidad Expirate Date Date de Péremption Data di Scadenza Data Expiração Verwendbar bis	Temperatura de almacén Storage Temperature Temperature de Conservation Temperatura de Conservazione Temperatura de Conservação Lagertemperatur	LOT Número de Lote Lot Number Número de Lot Numero di Lotto Número de Lote Chargen-Nr	IVD Para Diagnóstico In Vitro For In Vitro Diagnostic Usage In Vitro Per Uso Diagnostico In Vitro Utilizar em Diagnostico In Vitro In Vitro Diagnosticum	REF Número de catálogo Catalog Number Numéro de catalogue Numero di catalogo Número de catálogo Katalognummer	CE Conformidad Europea European Conformity Conformité aux normes européennes Conformità europea Comformidade com as normas europeias CE-Konformitätskennzeichnung	Fabricado por Manufactured by Fabriqué par Fabbricato da Fabricado por Hergestellt	REAG Reactivo Reagent Réactif Reagenti Reagente Reagenz	CAL Calibrador Calibrator Calibrateur Calibradore Calibrador Kalibrator	Buffer Tampón Buffer Tampon Tampone Buffer Puffer	LYOPH Liofilizado Lyophilised Lyophilisé Liofilo Liofilizado Lyophilisiert	Conc. Concentración Concentration Concentration Concentrazione Concentraçao Konzentration	Control H / Control L Control Alto / Control Bajo Control High / Control Low Contrôle élevé / Contrôle Bas Controllo Alto / Controllo Basso Controlo Alto / Controlo Baixo Kontrolle Hoch / Kontrolle Niegrid