FERRITN

REF: 557 001  100 test
R1 Buffer : 20 ml
R2 Latex : 7.5 ml

Intended Use

In vitro diagnostic reagents for the quantitative determination of Ferritin in human serum by immunturbidimetric procedure.

Background

Ferritin is a macromolecule with a molecular weight of at least 440 kD and is formed of apo-ferritin 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.

Test Principle

The Ferritin test is based upon the reactions between Ferritin in the sample and latexcovalently 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 37ºC. 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 microparticles covalently bound anti-ferritin antibodies suspended in a neutral aqueous solution, with 0,09 % sodium azide as preservative.

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.

Material Required
Automatic analyzer.

Saline solution.

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 ºC). Do not freeze.

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

The Ferritin latex reagent should have a lightly yellow, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

Specimen Collection and Preparation

Serum 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 º C) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay.

Heavily lipemic sera may lead to a non-specific reaction due to chylomicrons. 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).

System Parameter

Wavelength: 600 nm
Optical path: 1 cm
Assay type: Turbidimetric
Temperature: 37 ºC
Incubation time: 4 min.

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/Buffer reagent: 200 µl
Volume R2/Latex reagent: 75 µl
Volume sample: 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.

Note: 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 and Quality Control

Standardization: use Spectrum Calibrator or other suitable calibrator material. The method was standardized against WHO 80/578 International Standard

For quality control use Spectrum 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.

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.

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 15 - 120 µg/l
(6 weeks to 18 years of age)

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.

References


Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207

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