HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 22 tháng 7 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

Uông Tuấn Phương

COD 31934 1 x 15 mL	COD 31935 1 x 45 mL
Only for *in vitro* use in the clinical laboratory	

FERRITIN

BioSystems

CE

FERRITIN
LATEX

INTENDED USE

Reagent for the measurement of ferritin concentration in human serum for the assessment of iron imbalance.

CLINICAL BENEFIT

Ferritin is present at particularly high concentrations in liver, bone marrow and spleen.

The plasma ferritin is in equilibrium with body stores and variations in the quantity of iron in the storage compartment are reflected in plasma ferritin concentration.

Serum ferritin concentration declines very early in the development of iron deficiency and it serves as a very sensitive indicator of iron deficiency. On the other hand, a large number of chronic infections, chronic inflamatory disorders (rheumatoid arthritis, renal disease) and malignancies (lymphomas, leukemias, breast cancer, neuroblastoma) result in increased serum ferritin concentration. Plasma ferritin is also increased in patients with hemosiderosis or hemochromatosis 1,2,3. Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of ferritin imbalance. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Serum ferritin causes agglutination of latex particles coated with anti-human ferritin antibodies. The agglutination of the latex particles is proportional to the ferritin concentration and can be measured by turbidimetry[4].

CONTENTS

	COD 31934	COD 31935
A. Reagent	1 x 10 mL	1 x 30 mL
B. Reagent	1 x 5 mL	1 x 15 mL

COMPOSITION

A. Reagent. Glycine buffer 170 mmol/L, sodium chloride 100 mmol/L, sodium azide 0.95 g/L, pH 8.2.

B. Reagent. Suspension of latex particles coated with anti-human ferritin antibodies, sodium azide 0.95 g/L (Note 1).

STORAGE AND STABILITY

Store at 2-8 ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

Indications of deterioration:

– Reagents: absorbance of the blank over 1.700 at 540 nm.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

S. Ferritin Standard. For 1 x 3 mL (BioSystems cod. 31127). Human serum. Ferritin concentration is given on the label. The concentration value is traceable to the Biological Reference Material WHO 94/572 (National Institute for Biological Standards and Control, NIBSC).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

Reconstitute with 3.00 mL of distilled water. Stable for 1 month at 2-8ºC.

Calibration curve: Prepare dilutions of the Ferritin Standard using 9 g/L saline as diluent. Multiply the concentration of the Ferritin Standard by the corresponding factor indicated below to obtain the ferritin concentration of the dilutions (Note 2).

DILUTION	1	2	3	4	5
Ferritin Standard (µL)	30	60	120	180	240
Saline (µL)	210	180	120	60	–
Factor	0.125	0.25	0.5	0.75	1.0

REAGENT PREPARATION

Working Reagent: Pour the contents of a Reagent B vial (Note 1), into a Reagent A bottle. Mix thoroughly. Stable for 30 days at 2-8ºC. Smaller Working Reagent volumes can be prepared by mixing: 1 mL of Reagent B + 2 mL of Reagent A. Shake the Reagent B vial before pipetting.

SAMPLES

Serum collected by standard procedures. Hemolyzed or lipemic samples are not suitable for testing.

Ferritin in serum is stable for 7 days at 2-8ºC.

PROCEDURE

1. Bring the Working Reagent and the instrument to 37ºC.
2. Zero the instrument with distilled water (Note 3)
3. Pipette into a cuvette:

Working Reagent	1.0 mL
Standard (S) or Sample	30 µL

4. Mix and insert cuvette into the instrument. Start stopwatch.
5. Record the absorbance at 540 nm after 10 seconds (A_1) and after 5 minutes (A_2).

CALCULATIONS

Calibration curve: Calculate the absorbance difference ($A_{Standard} - A_{Blank}$) of each point of the calibration curve and plot the values found against the ferritin concentration. Ferritin concentration in the sample is calculated by interpolation of its absorbance ($A_{Sample} - A_{Blank}$) on the calibration curve (see Note 2).

QUALITY CONTROL

It is recommended to use Protein Control Serum levels I (cod. 31211) and II (cod. 31212) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum[1,5]

Children: 7-140 µg/L
Men: 20 - 250 µg/L
Women: 20 - 200 µg/L

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

– Detection limit: 5.4 µg/L.
– Measurement interval (approximate depending on the standard concentration): 5.4-500 µg/L.
– Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
53 µg/L	3.0%	3.9 %
121 µg/L	1.6 %	2.6 %

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

– Interferences: bilirubin (up to 62 mg/dL), hemolysis (hemoglobin up to 1000 mg/dL), lipemia (triglycerides up to 500 mg/dL) and rheumatoid factors (up to 520 IU/mL) do not interfere. Other drugs and substances may interfere[6].
– Zone effect: > 30,000 µg/L.

NOTES

1. Shake the Reagent B vial gently before using.
2. The calibration curve is linear up to 300 µg/L in some instruments. In these cases, calibration may be performed with a single point (aprox.125 µg/L).
3. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

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