Ferritin

Immunoturbidimetric method for the determination of ferritin

SUMMARY

The plasma concentration of ferritin decreases rapidly with an iron deficiency. An increase in ferritin concentration is produced by a large number of chronic diseases. These diseases include chronic infections, chronic inflammatory disorders such as rheumatoid arthritis or renal disease, Gaucher's disease and numerous types of malignancies, especially lymphomas, leukemias, breast cancer and neuroblastoma. Also an increase in the plasma concentration of ferritin occurred in viral hepatitis or toxic liver lesions as a result of ferritin release from damaged liver cells. The plasma concentration of ferritin also increases with increasing iron deposits, as t is observed in patients with hemosiderosis or hemochromatosis. Besides the use of ferritin as iron metabolism parameters, it determination also gained importance as a tumor marker for the control and monitoring of therapeutic drugs.

PRINCIPLE

Ferritin present in the sample reacts with the latex particles coated with anti-human ferritin producing agglutination. The turbidity caused by the agglutination is proportional to the ferritin concentration in the sample and can be measured spectrophotometrically.

PROVIDED REAGENTS

A. Reagent A: 100 mmol/l HEPES buffer, pH 7.0.
B. Reagent B: latex particles coated with rabbit antibodies anti-human ferritin in 100 mmol/l HEPES buffer, pH 7.0.

NON-PROVIDED REAGENTS

Ferritin Calibrator Turbitest AA from Wiener lab.
Saline Solution (9 g/l NaCl).

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.

WARNINGS

Reagents are for “in vitro” diagnostic use.
Use the reagents according to the working procedures for clinical laboratories.
Reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable at 2-10ºC until the expiration date stated on the box. Do not freeze.

SAMPLE

Serum or plasma
a) Collection: obtain in the usual way. Immediately separate serum from clot. Centrifuge samples that contain precipitate before the assay.
b) Additives: if plasma is used, it is recommended to use EDTA as anticoagulant.
c) Known interfering substances: no interferences have been observed with bilirubin up to 20 mg/dl and hemoglobin up to 500 mg/dl. Maximum interference of 10% is observed in lipemic samples with 1000 mg/dl triglycerides.
See Young, D.S. in References for effect of drugs on the present method.
d) Stability and storage instructions: preferably use fresh serum. If the test cannot be performed during the day, sample can be stored for up to 1 week at 2-10ºC. For longer period of storage, sample should be frozen.

MATERIAL REQUIRED (non-provided)

- Volumetric material for measuring stated volumes.
- Automated analyzer.

CALIBRATION

For calibration use **Ferritin Calibrator Turbitest AA** provided separately by Wiener lab.
Calibrator concentrations are lot specific and values are indicated in the labels.
Saline solution, 0.9% NaCl shall be used for zero calibrator (blank solution).
It is recommended that each laboratory determine calibration frequency, as this would depend on the analyzer in use as well as the types and number of other assays being run.
A new calibration curve should be drawn at least once a month or when a new lot of reagent is used.

REACTION CONDITIONS

General parameters for automated analyzers:
- Type of reaction: endpoint
- Long. primary wave: 575 nm
- Temperature: 37°C
- Sample volume: 30 ul
- Volume of Reagent A: 180 ul
- Volume of Reagent B: 60 ul
- Incubation Reagent A: 250 sec
- Incubation Reagent B: 30 sec
- Calibration: 5 points

QUALITY CONTROL METHOD

Control Inmunológico nivel 1 or **Control Inmunológico nivel 2 Turbitest AA** from Wiener lab.
Controls should be processed in the same manner as samples.

REFERENCE VALUES

Men: 30 - 300 ng/ml
Women < 50 year: 15 - 160 ng/ml
Women > 50 year: 20 - 300 ng/ml
Children and adolescents: 15 - 120 ng/ml

In the literature (Tietz, N.W.) the following reference value range is mentioned:
Newborns: 25 - 200 ng/ml
1 month: 200 - 600 ng/ml
2-5 months: 50 - 200 ng/ml
6 months to 15 year: 7 - 140 ng/ml
Adults:
Men: 20 - 250 ng/ml
Women: 10 - 120 ng/ml

It is recommended that each laboratory establish its own reference range for the population. For diagnosis, ferritin results should always be tested in conjunction with the patient's medical history, clinical examination and other findings.

UNIT CONVERSION

Ferritin (pmol/l) = 2.247 x ferritin (ng/ml)

PROCEDURE LIMITATIONS

See Known interfering substances under SAMPLE.
Do not pipet by mouth.
To preserve the integrity of the reagents should be avoided all kinds of contaminations, using for measuring only micropipettes perfectly clean and dry.
Samples containing ferritin levels above the test range should be diluted using 9 g /l NaCl (e.g. 1+1) and should be tested again. Correct the results according to the dilution factor (e.g. 2).

PERFORMANCE

a) Precision: precision was evaluated according to the protocol CLSI EP5-A. In this study two samples with different levels were tested, performing 2 daily runs by duplicates during 20 days.

Mean	CV_{wr}	CV_{total}
126.73 ng/ml	2.28%	2.11%
376.46 ng/ml	1.73%	1.99%

b) Detection limit: 5 ng/ml.
c) Linearity: up to 500 ng/ml.
d) Prozone effect: not observed until 4000 ng/ml ferritin.

PARAMETERS FOR AUTOANALYZERS

For programming instructions, see the operator manual of the analyzer in use.
For calibration use **Ferritin Calibrator Turbitest AA** from Wiener lab.

WIENER LAB. PROVIDES

- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
  (Cat. Nº 1999747)
- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
  (Cat. Nº 1009291)
- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
  (Cat. Nº 1009390)
- 1 x 30 ml Reagent A
  1 x 10 ml Reagent B
  (Cat. Nº 1009675)

REFERENCES

- Tietz Textbook of Clinical Chemistry - Burtis, C.; Ashwood, E. (5º Edition) WB Saunders, 2001.
- Young, D.S. - "Effects of Drugs on Clinical Laboratory Tests", AACC Press, 5th ed., 2000.
- Lee M.H., Means R.T. Jr. - “Extremely elevated serum ferritin levels in a university hospital: associated diseases and clinical significance” - Am. J. Med. 98:566-71; 1995.
- Baynes R.D., Cook J.D. – “Current issues in iron deficiency”- Curr. Opin. Hematol.3:145-9; 1996.

Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.

CE — This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

EC REP — Authorized representative in the European Community

IVD — "In vitro" diagnostic medical device

Σ — Contains sufficient for <n> tests

Use by

Temperature limitation (store at)

Do not freeze

Biological risks

Volume after reconstitution

Cont. — Contents

LOT — Batch code

Manufactured by:

Harmful

Corrosive / Caustic

Irritant

Consult instructions for use

Calibr. — Calibrator

CONTROL — Control

CONTROL + — Positive Control

CONTROL − — Negative Control

REF — Catalog number

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