todylaboratories®

Clinical Chemistry

CE IVD REF C23CC1119

Ferritin Turbidimetric Instructions For Use

For in-vitro diagnostic use only.
Store at 2-8°C.

KIT CONTENTS

R1: Assay Buffer	1 x 20 ml
R2: Latex Reagent	1 x 5 ml
R4: Ferritin Calibrator	1 x 1 ml

INTENDED USE

In vitro quantitative determination of Ferritin in human serum.

SUMMARY

The plasma Ferritin concentration declines very early in the development of iron deficiency.
A large number of chronic diseases result in increased serum Ferritin concentrations. 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, leukaemia's, breast cancer and neuroblastoma. Increase in plasma Ferritin concentration also occurs in viral hepatitis or following toxic liver injury as a result of release of Ferritin from damaged liver cells. Plasma Ferritin concentration is also increased with increases of iron stores, as seen in patients with haemosiderosis or haemochromatosis. Besides the use of Ferritin as an iron metabolism parameter, Ferritin as also gained importance as a tumour marker for therapeutic drug monitoring and follow-up.

TEST PRINCIPLE

The latex particles coated with anti human ferritin are agglutinated when they react with samples that contain ferritin. The latex particles agglutination is proportional to the concentration of the ferritin in the sample and can be measured by turbidimetry

REAGENT CONCENTRATION

R1 Assay Buffer	Assay buffer (Glycine) pH 8.5	20 mmol/l
R2 Latex Reagent	Antibody Reagent: Latex coated with Anti-Human Ferritin Antibody	0.57 mmol/l
R4 Ferritin Calibrator	Human Ferritin Calibrator	Lot Specific

SAMPLE

Fresh Serum. Samples containing fibrin must be centrifuged before testing.
Do not use haemolysed samples.

STABILITY

1 weeks at +4°C to + 8°C
3 month at -20°C

CALIBRATION CURVE

Prepare dilutions of the Calibrator using NaCl 9 g/L as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the ferritin concentration of each point on the curve.

Dilution	1	2	3	4
Ferritin-CAL (µL)	-	33.3	66.6	100
NaCl 9 g/L (µL)	100	66.6	33.3	0
Factor	0.0	1/3	2/3	1.0

MANUAL PROCEDURE

Wavelength	Temperature	Cuvette	Measurement
540 nm (530 – 550nm)	37ºC	1 cm light path	Against water

Allow Reagents to come to room temperature before use.

Pipette into test tubes as follows:		
	Blank	**Calibrator/Sample**
R1 ASSAY BUFFER	800 µl	800 µl
Calibrator/Sample	-	90 µl
Distilled water	90 µl	-
R2: Latex Reagent	200 µl	200 µl
Mix well and read the absorbance at 37oC. Record the absorbance immediately (A1). Read the absorbance again after 5 minutes exactly (A2).		

CALCULATION

Calculate the absorbance difference (A_2-A_1) for each point of the calibration curve and plot the values obtained against the ferritin concentration for each calibrator dilution. The ferritin concentration in the sample can then be read from the intercept point (A_2-A_1) on the calibration curve.

NOTES

In vitro diagnostic use only.
Sodium azide has been reported to form lead or copper azide in laboratory plumbing. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti- hepatitis C antibodies.

MEASURING/REPORTABLE RANGE

5.0 - 600 µg/L
At higher concentrations, dilute the sample with 0.9% NaCl (e.g 1 + 1). Multiply the result by the appropriate factor (e.g. 2).

REFERENCE VALUE

Men: 20 - 250 µg/l
Women: 20 – 200 µg/l
Children: 7-140 µg/l
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the Ferritin results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

ANALYTICAL PERFORMANCE

Analytical sensitivity (lower detection limit): 2.06 mA / µg/L
Detection limit: 3 µg/L
The lower detection limit represents the lowest measurable ferritin concentration that can be distinguished from zero.
Linearity: Up to 300 µg/L
Prozone effect: Up tp 4000 µg/L

PRECISION

	Mean µg/L	CV %
Intra Assay (n-100)	33.4	5.1
	289.8	1.2
Inter Assay (n-100)	33.4	6.3
	289.8	2.6

INTERFERENCES

Bilirubin (20 mg/dL), haemoglobin (10 g/L) and rheumatoid factors (600 IU/mL) do not interfere. Lipaemia interferes. Other substances may interfere.

ACCURACY

Results obtained with this reagents did not show systematic differences when compared with commercial reagents of similar characteristics. Studies of comparison are available on request.

QUALITY CONTROL

For quality control, use suitable control material. We recommend Protein Control Set.
The control intervals and j 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.

HEALTH & SAFETY

This kit is designed for use by suitably qualified laboratory personnel only. Exercise the normal precautions required for the handling of laboratory reagents. Do not ingest the material. Dispose of material according to local guidelines.

BIBLIOGRAPHY

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SYMBOL INDEX

IVD For In Vitro Diagnostics Use Only
LOT Lot Number
REF Catalogue Number
Storage Temperature
Expiry Date (Year/Month)
Warning, Read Enclosed Documents
Instructions For Use
Manufactured By

Revision No.12 SEPT/16; St. 26.10.20

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