FERRITIN
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL502F	1 x 30 ml	FERRITIN - 1	2-8°C
	1 x 10 ml	FERRITIN - 2	
GL512F	5 x 30 ml	FERRITIN - 1	2-8°C
	5 x 10 ml	FERRITIN - 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Ferritin in serum on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

Ferritin is a macromolecule with a molecular weight of at least 440kD and is formed of apoferritin and an iron core of about $2500Fe^{+3}$ 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 haematological investigations) could be required 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, inflammations or in hepatic or chronic renal diseases. The determination of Ferritin is particularly useful in the diagnosis or iron therapy, for the determination of iron reserves in high-risk groups, and in the differential diagnosis of anaemia.

PRINCIPLE OF THE TEST:

This assay is based upon the reactions between Ferritin in the sample and latex-covalently bound antibodies against human Ferritin. Ferritin values are determined turbidimetrically, at 500 to 600 nm, using fixed-time measurement with sample blank correction.

Ferritin Antigen + Anti- Ferritin Antibodies ⟶ Antigen/Antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear, colourless liquid.
Reagent 2: White turbid appearance.
Any significant changes could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration Tests*
Reagent 1	Phosphate Buffer pH6.5 with Protein Stabilisers	0.05 M
	PRESERVATIVE	---
Reagent 2	Anti-ferritin antibodies	---
	PRESERVATIVE	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.

If stored and handled properly:
- Unopened components are stable until expiry date stated on the label.
- Once open, components are stable for 1 month at 2-8°C.

TYPE OF SPECIMEN:

Use serum as specimen.
Lipemic or turbid specimen must be clarified before the assay.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum should be separated from cells within 2 hours after collection.
Stability: 7 days at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Ferritin Calibrator	GL9601	Photometer	N/A
Ferritin Controls set (6x 1 ml)	GL9022	General Laboratory Equipment	N/A

Assay procedure:
Wavelength: λ: 500 - 600 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1 ml	1 ml	1 ml
Sample	----	----	100 µl
Calibrator	----	100 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	350 µl	350 µl	350 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after further 10 minutes.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Laboratory QC Programme.

CALCULATION:

- Calculate the ΔAbs for each calibrator (ΔAbs = OD2-OD1) and construct a calibration curve.
- Calculate the ΔAbs for each sample. Determine the corresponding concentration from the calibration curve.

(Conversion Factor: ng/ml = µg/l)

EXPECTED VALUES:

Infant	Cord	100 to 250 µg/l (100 to 250 ng/ml)
	Up to 2 months, rise to:	600 µg/l (600 ng/ml)
	Followed by a fall down to:	1µg/l (Hb-neosynthesis) (1ng/ml)
Children and Teenage	(2months to 18Years of age)	15 – 120 µg/l (15 – 120 ng/ml)
Men		30 – 300 µg/l (30 – 300 ng/ml)
Women	Pre-menopausal	10 – 160 µg/l (10 – 160 ng/ml)
	Post-menopausal	30 – 300 µg/l (30 – 300 ng/ml)

Each laboratory should establish its own reference range. Ferritin results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear up to 500ng/ml (500 µg/l).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Prozone:
The system did not show prozone phenomenon at least up to 10000µg/l (10000µg/ml).

Interfering substances:
Haemolysis: Less than 10% interference up to 15 g/l Haemoglobin
Bilirubin: Less than 10% interference up to 427µmol/l Bilirubin.

Sensitivity:
The Lowest Detectable Level was estimated at 5.2µg/l (52 µg/ml).

Precision:

Within Run N = 10	Mean *(µg/l)*	*% CV*	*Between Run N = 10*	Mean *(µg/l)*	*% CV*
Level 1	35.5	7.5	Level 1	35.5	8.5
Level 2	287.2	1.6	Level 2	287.2	3.2

Method Comparison:
Using 46 samples, a comparison, between this Ferritin test (y) and another commercially available test (x), gave the following results:

y = 1.01x - 0.34	r = 0.995	Sample range from 1 to 600µg/l

BIBLIOGRAPHY:

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SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
BUF	Buffer	Ab	Antibody
CAL	Calibrator	CE	CE Mark - Device comply with the Directives 98/79/EC
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

GLENBIO LTD
10 Kilbegs Road, Antrim, Co. Antrim, BT41 4NN
Tel/Fax: +44(0)2879659842
Email: info@glenbio.com
Web: www.glenbio.com

EC REP GLENBIO IRELAND LTD
17b Fota Business Park, Carrigtwohill, Co. Cork,
T45 PK77, Ireland

CE

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