Instruction For Use

【Product Name】

Ferritin (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
694013	50T
694014	2×50T
694015	100T
694016	2×100T

【Intended Use】

Immunoassay for the in vitro quantitative determination of Ferritin in human serum and plasma. It's mainly used for iron-metabolism-related diseases, such as hemochromatosis and iron-deficiency anemia.

A large protein with a molecular weight of at least 440KD, consisting of a protein shell consisting of 24 subunits and a ferric ion. High levels of ferritin are present in liver cells, spleen cells, bone marrow cells and red blood cells. In these tissues, ferritin ACTS as the main repository for excess iron in the body, preventing the toxic effects of excess iron and facilitating the maintenance of a dynamic reserve of red blood cell production.Ferritin is also present in plasma, and its plasma concentration is usually a good indicator of the body's iron reserves[1].Serum ferritin value changes with different physiological periods and pathological conditions, from which we can see its relationship with iron reserve[2].

【Test Principle】

Sandwich principle.Total duration of assay: 18 minutes.

- 1st incubation: 5 μL of sample, biotinylated monoclonal Ferritin antibody and monoclonal Ferritin antibody labeled with a ruthenium complex react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex binds to the solid phase via interaction of biotin and streptavidin.
- Measurement: The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with Buffer. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via calibration and a master curve provided via the reagent barcode.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials (Optional), different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles, preservative	1×1.75 mL	2×1.75 mL	1×3.5 mL	2×3.5 mL
(RB)	Anti-Ferritin-Ab ~biotin, PBS, preservative	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
(RA)	Anti-Ferritin-Ab ~$Ru(bpy)_3^{2+}$, PBS, preservative	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
Calibrators	bovine serum, preservative	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	bovine serum, preservative	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traced back to 3rd WHO reference material 94/572.

See the control material value sheet for the target values and ranges of control materials.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- [illegible] Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105

【Storage and Shelf Life】

Store at 2ºC-8ºC.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the reagents	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks
Stored on the analyzers at 2ºC~15ºC	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and control materials	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

Human serum and plasma added with heparin lithium, heparin sodium and EDTA-K_2, EDTA-K_3, anti-coagulants are recommended. Blood samples should be collected by standard operation of venous puncture; after complete coagulation, the tangible component should be removed by centrifugation. The sample should avoid bubbling during testing. Lipid layer floating on the upper of the sample should be removed. Samples with severe hemolysis are not recommended. Samples would better to be tested in 48 hours after collection, otherwise, should be stored at 2~8ºC for no more than 7 days or at -25~-15°C for 12 months. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, one should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up Ferritin test according to the operational manual.

Put the Ferritin rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification (RFID) reagent card (refer to instrument operational manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) the reagents of different lot are used

(2) the same lot of reagents were used on the analyzer beyond 4 weeks

(3) quality control misses the target

Quality control

For quality control, use Ferritin control materials.

In addition, other suitable control material can be used.

In order to ensure the reliability of test results, it's recommended to test the control materials every 24 hours. After each calibration, reagent lot change, maintenance or failure repairment, quality control is recommended. The quality control results should fall within the scope of local regulations. If beyond, the analyzer status, reagents, calibration and other factors should be checked.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is ng/mL .

Specimen dilution

Samples with Ferritin concentrations above the measuring range can be diluted with ferritin-negative sample. The recommended dilution ratio is 1:50. After manual dilution, multiply the result by the dilution factor.

【Biological Reference Interval】

According to serum test results of 240 healthy human (including 120 males and 120 females), the percentile 5 to 95 gives reference intervals as the following sheet.

Gender/Sex	Reference Interval	Sample Quantity
Male	28~390 ng/mL	120

Female	12~143 ng/mL	120

Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges.

【Result Interpretation】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

Test results are used only for clinical reference and cannot be used as the basis for confirmation or rule-out of diseases alone.

When the sample containing bilirubin ≤65 mg/dL, hemoglobin ≤0.5 g/dL, triglyceride ≤3300 mg/dL, biotin ≤50 ng/mL, or total protein ≤10 g/dL, rheumatoid factor ≤2500 IU/mL, HAMA ≤500 ng/mL, interference deviation to the test result lies within ±10%. There is no high-dose hook effect at Ferritin concentration 100000 ng/mL.

【Measuring Range】

The measuring range of the kit is 0.2~2000 ng/mL. For samples with ferritin content below the lower detection limit, the results are reported in <0.2 ng/mL; If the ferritin content is above the upper detection limit, then the sample should be diluted and re-tested. The results are reported after multiplying with the dilution factor.

【Analytical Performance】

Lower limits of measurement

Limit of Detection= 0.2 ng/mL .

Accuracy

The relative bias of measuring the 3rd WHO reference material 94/572 should not exceed ±10%. Or testing standard traceability of accuracy control products, the relative deviation of it's test results should not exceed ±10%.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.2~2000 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 6%.

Between-lot variation

The coefficient of variation (CV) ≤ 10%.

Method Comparison

A comparison of the Lifotronic Ferritin assay (y) with the Roche Ferritin reagent kit (x) using clinical samples gave the following correlations:

Number of serum samples measured: 125

Linear regression:

y = 0.99269x-1.4125

r = 0.999

The sample concentrations were between 0.945 and 1933 ng/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

Exercise the normal precautions required for handling all laboratory reagents.

All reagents and samples including specimen, reagents, calibrators and control materials should avoid foaming before and during test.

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations.

Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/ spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.

【Symbol Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use by date	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limitation		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

【Reference】

1. Wick M., Pinggera W., Lehmann P., Diagnostic Strategies: Ferritin in Iron Metabolism. IN: Iron Metabolism: Diagnosis and Therapy of Anemias 1996, 3rd Edition. Springer, Vienna.
2. Lipschitz, D. A., Cook, J. D., Finch, C. A., A Clinical Evaluation of Serum Ferritin as an Index of Iron Stores. New England Journal of Medicine 1974, 290(22): 1213-1216.

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.
Lifotronic Tower, No. 8, Qiuzhi East Road, Guancheng Community, Guanhu Street, Longhua, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
E-mail: inter-service@lifotronic.com

【European Representative】

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel. +49-40-2513175 Fax. +49-40-255726

【Version and Revision】

Version: 2.0
Issue Date: 2025-03-04