Instruction For Use

【Product Name】

Laminin (LN) eCLIA

【Order Information】

REF NO.	Package Size
692025	50T
692026	2×50T
692017	100T
692018	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of Laminin in human serum.

Laminin (LN) is a large non-collagen glycoprotein in the human body, consisting of an α chain and two β chains. LN is positively correlated with the degree of fibrosis and portal hypertension. The higher the level of LN, the more significant of the esophageal varices in patients with cirrhosis.

When fibrosis occurs in the hepatic sinus, LN deposition and intrahepatic blood flow resistance increase, which is the pathological basis of portal hypertension and leads to esophageal varices rupture and bleeding.Therefore, the level of serum LN is of great value in the diagnosis of portal hypertension[1,2].

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes

- 1st incubation: 50 μL of sample, biotinylated monoclonal LN-specific antibody and monoclonal LN-specific 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.
- Result are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

【Main Component】

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.

Component	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated; microparticles; 0.1M PBS; preservative	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
(RB)	Anti-LN-Ab~biotin; 0.1M PBS; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
(RA)	Anti-LN-Ab~Ru(bpy)$^{2+}_3$; 0.1M PBS; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
Calibrators	Horse serum; preservative	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	Horse serum; preservative	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traced to manufacturer's selected measurement procedures..

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
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

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

- 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 2℃-8℃.

Do not freeze.

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

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Stored on the analyzers at 2℃~15℃	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 2℃~8℃	18 months
Store at 2℃~8℃ 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 is recommended. Blood samples should be collected following standard venipuncture procedures. 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.

It is recommended to complete the test in time after sample collection. Samples can stable for 8 hours at 18~28℃, 24 hours at 2~8℃ 30 days at -25℃~-15℃, Freeze 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 LN test according to the operational manual.

Put the LN reagent pack into the correct analyzer slot to automatically suspend magnetic beads at least 30 minutes before testing.

Recommended ambient temperature:10~30°C; Relative humidity: ≤ 80%..

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 user 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 28 days;

(3) quality control misses the target.

(4)The Buffer of different lots are used.

Quality control

For quality control, use LN control materials.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Please make sure that the correct values are used.

Calculation

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

Specimen dilution

The detection range is wide enough, no dilution is required.

【Biological reference interval】

According to serum test results of 300 healthy human (male 152, female 148) in Guangdong Province, P. R. China, the percentile 2.5 to 97.5 gives reference range of 50 ng/mL.

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 diagnosis or rule-out of diseases alone.

The measuring range of the kit is 5 ~ 850 ng/mL. For samples with LN content below the lower detection limit, the results are reported as < 5 ng/mL; If the LN content is above the upper detection limit, the results are reported as > 850 ng/mL.

When the sample containing bilirubin ≤ 200 mg/dL, triglyceride ≤ 2000 mg/dL, biotin ≤ 10 ng/mL, hemoglobin ≤ 50 mg/dL, HAMA (human anti-murine antibodies) ≤ 200 ng/mL, or the rheumatoid factor concentration ≤800 IU/mL, interference deviation to the test result lies within ±10%.

Even the concentration of LN reached 10000 ng/mL, hook effect is unobservable.

【Analytical Performance】

Lower limit of measurement

Lower detection limit is 5 ng/mL.

Accuracy

Measuring the different concentration LN antigen additives samples,the percentage of recovery should be between 90%-110%.

The relative bias of measuring trueness control materials within ± 10%

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 5 ~ 850 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Between-lot precision

The coefficient of variation (CV) ≤ 10%.

Analytical specificity

Test the following analog-additive blank samples, the cross reaction rate as below.

Analog	Concentration (ng/mL)	Cross reactivity
CI	500	1%
CII	1000	0.5%
CIII	2000	0.1%
CIV	2000	0.1%

Homogeneity of calibrators and control materials

Within-bottle homogeneity: coefficient of variation CV≤ 10%;
Between-bottle homogeneity: coefficient of variation CV≤ 10%.

Method comparison

A comparison of the Lifotronic LN assay (y) with the commercial LN reagent kit (x) using clinical samples gave the following correlations:
Number of serum samples measured: 118
Linear regression:
y=1.003x-0.881
r = 0.9945
The sample concentrations were between 2.31 and 749.7 ng/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to comply with regulations in the laboratory.

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

Test results of the kit are for clinical reference only, and clinical evaluation of patients should be combined with their symptoms and signs, medical history, other laboratory examination results and treatment responses.

Due to factors such as methodology or antibody specificity, testing identical samples with reagents from different manufacturers may get different results, and the results from different kits should not compare directly, lest cause the wrong medical explanation; It's suggested that laboratorians should point out the characteristics of used reagent in the test report to the clinician. In serial monitoring, if the reagent type is changed, a continuous parallel test should be performed and comparison of the results to the former to determine new baseline value.

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.

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.

【Symbols Explanation】

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

【Literature References】

1. Aumailley, M., M. Pesch, L. Tunggal, F. Gaill, and R. Fässler. Altered synthesis of laminin 1 and absence of basement membrane component deposition in β1 integrin-deficient embryoid bodies. J. Cell Sci. 2000, 113:259–268.
2. Colognato, H., and P.D. Yurchenco. Form and function: the laminin family of heterotrimers. Developmental Dynamics, 2000, 218(2):213–234.

【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
Email: 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

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