Instruction for Use

【Product name】

Collagen Type IV（CIV）eCLIA

【Order Information】

REF NO.	Package Size
692021	50T
692022	2×50T
692013	100T
692014	2×100T

【Intended use】

Immunoassay for the in vitro quantitative determination of Collagen Type IV in human serum .

Collagen Type IV (CIV) is made up of a α2 chain and two α1 chains. CIV is synthesized by secretion of epithelial cells and Secretion to cells. Collagen Type IV is metabolized and synthesized mainly in the liver. The content of CIV is l % in the normal liver tissue. CIV is mainly distributed in vascular and the basement membrane of bile duct, the CIV in serum come from the degradation of basement membrane, The content of CIV collagen type will change if the metabolism of CIV changes in liver tissue[1-3].

【Test Principle】

The determination of Collagen Type IV was adopted by sandwich method. Total duration of assay: 18 minutes.

- 1st incubation: 50 μL sample, biotinylated monoclonal CIV-specific antibody and monoclonal CIV-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.
- Results are determined via 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-CIV-Ab~biotin; 0.1M PBS; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
(RA)	Anti-CIV-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 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 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 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 in accordance with the standard venipuncture procedures. After the samples were completely coagulated, centrifugation was carried out to remove the residual cellular substances.Samples should be free of bubbles during detection;If there is a lipid layer covering the sample after centrifugation, it should be removed by means of means.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

Before testing, the system operation manual of the measuring instrument should be carefully read, so as to obtain relevant information such as system operating procedures, sample management, safety precautions and maintenance, and materials required for testing should be prepared. CIV testing procedures should be set up in accordance with the system operating procedures.

Before using the reagent, put it into the analyzer 30 minutes in advance to automatically stir the magnetic bead particles and keep them in suspension.

Recommended environment temperature for testing: 10~30℃, relative humidity: ≤80.0%..

Calibration

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

Before calibration, the reagent information should be imported into the analyzer via radio frequency identification reagent card (refer to instrument user manual).

Recalibration is recommended as follows :

(1) When using a new lot of reagent;

(2) When the same lot of reagents has been used on the analyzer for more than 4 weeks;

(3) If the quality control result exceeds the defined limit;

(4) When changing the buffers of different lot numbers.

Quality control

For quality control, use CIV control materials.

In addition, other suitable control material can be used.

Controls 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 concentration of the analyte, and the result unit is ng/mL.

Sample dilution

Wide detection range, no dilution required.

【Biological reference intervals】

According to serum test results of 293 healthy human (male 147 female 146) , the

percentile 2.5 to 97.5 gives reference range of 50 ng/mL.
Each laboratory should investigate the transferability of the reference interval to its own patient population and if necessary determine its own reference ranges.

【Result Interpretation】

In interpreting the results, the patient's overall clinical situation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

The test results are only for clinical reference and cannot be used as the basis for diagnosis or exclusion alone.
When the sample containing bilirubin ≤ 100mg/dL, triglyceride ≤ 2000mg/dL,, biotin ≤ 10 ng/mL, hemoglobin ≤ 50mg/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 CIV reached 20000 ng/mL, hook effect is unobservable.

【Measuring range】

The measuring range of the kit is 5.0~2000 ng/mL. Results below the lower detection limitare reported as <5.0 ng/mL. Results above the measuring range are reported as >2000 ng/mL.

【Analytical performance】

Lower limit of measurement

Lower detection limit=5.0 ng/mL.

Accuracy

Measuring the different concentration CIV antigen additives samples,the percentage of recovery should be between 90%-110%.
The standardized traceability accuracy control was determined with the ratio of measured value to labeled value between 0.900 ~ 1.100

Linearity

The correlation coefficient (r) was not less than 0.9900 in the interval of 5.0~2000 ng/mL.

Within-run precision (repeatibility)

CV≤ 7.5%.

Between-lot precision

CV≤ 10%.

Analytical specificity

The cross reaction rate of laminin (LN) with a concentration of 8000 ng/mL was ≤0.5%.

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 CIV assay (y) with the commercial CIV reagent kit (x) using clinical samples gave the following correlations:
Number of serum samples measured: 116
Linear regression:
y=0.995x-0.634
r = 0.999
The sample concentrations were between 4.16 and 1931.9 ng/mL.

【Precautions and Warnings】

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.
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		

【Reference】

1. Ambiru S, Miyazaki M, Nakagawa K, et al. Increased serum type collagen 7-S levels in patients with hepatic metastasis. Am J Gastroenterology, 1995, 90(5):783.
2. Hewitt RE, Powe DG, Morrell K,et al. Laminin and Collagen subunit distribution in normal and neoplastic tissues of colorectum and breast.Br J Cancer, 1997, 75(2):221.
3. Santos VN, Leite-Mor MM, Kondo M, et. al. Serum laminin, type IV collagen and hyaluronan as fibrosis markers in non-alcoholic fatty liver disease. Braz J Med Biol Res. 2005 May; 38(5):747-53.

【Manufacturer】

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