Instruction For Use

【Product Name】

Cholylglycine (CG) eCLIA

【Order Information】

REF NO.	Package Size
692023	50T
692024	2×50T
692015	100T
692016	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of cholylglycine in human serum. The results can be used in assisting diagnosis of hepatobiliary diseases.

Cholylglycine(CG) is synthesized from cholesterol in the liver to cholic acid, and then with a combination of glycine, forming a kind of conjugated bile acid, is the main components of the bile acid and impotantmetabolite of cholesterol[1,2]. Trace concentrations of cholyglycine acid are useful to reflect the damage degree in liver cells, and useful in the diagnosis and prognosis of Liver diseases.

【Test Principle】

The determination of Cholylglycine was adopted by competition method.Total duration of assay: 18 minutes.

- 1st incubation: 20 μL of sample and biotinylated monoclonal CG-specific antibody to form an antibody-hapten complex
- 2nd incubation: After addition of CG labeled with a ruthenium complex and streptavidin-coated microparticles, the still-free binding sites of the the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin. 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-CG-Ab~biotin; 0.05M Tris; preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
(RA)	CG~Ru(bpy)$^{2+}_3$; 0.05M Tris; 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 standard test tubes or vacuum tubes with separation glue. 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 in suggestion.

It is recommended to complete the test in time after sample collection. Samples can stable for 4 hours at 18~28℃, 12 hours at 2~8℃, 1 month 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. CG 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 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) 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 CG 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 μg/mL or mg/L : 1 μg/mL=1 mg/L.

【Biological reference interval】

According to serum test results of 240 healthy human (male 120, female 120) , the percentile 2.5 to 97.5 gives reference range is 2.8 μg/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 0.02 ~ 40 μg/mL. For samples with CG content below the lower detection limit, the results are reported as < 0.02 μg/mL; If the CG content is above the upper detection limit, the results are reported as > 40 μg/mL.

When the sample containing bilirubin ≤ 60 mg/dL, triglyceride ≤ 100 mg/dL, total protein ≤ 10 g/dL, biotin ≤ 15 ng/mL, hemoglobin ≤ 20 mg/dL, HAMA (human anti-murine antibodies) ≤ 100 ng/mL, or the rheumatoid factor concentration ≤800 IU/mL, interference deviation to the test result lies within ±10%.

【Analytical Performance】

Lower limit of measurement

The lower detection limit is 0.02 μg/mL.

Accuracy

Measuring the different concentration CG 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 0.02 ~ 40 μg/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is no more than 8%.

Between-lot precision

The coefficient of variation (CV) is no more than 10%.

Analytical specificity

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

Analog	Concentration (μg/mL)	Cross reactivity
TESTO	170	1%
PROG	400	1%

Homogeneity of calibrators and control material

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

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

【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. Shen D , Zheng J , Cui X , et al. Analysis of cholyglycine acid as a biomarker for the early diagnosis of liver disease by fluorescence polarization immunoassay[J]. Sensors and Actuators, 2018, B256(MAR.):846-852.
2. Yunus, Tanggo, Shigetoshi, et al. Clinical usefulness of serum cholylglycine determination in various liver diseases[J]. Journal of Gastroenterology, 1982.

【Manufacturer】

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【Version and Revision】

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