Instruction For Use

【Product Name】

Gastrin-17 (eCLIA)

【Package】

REF NO.	Package Size
0320500103	50T
0320500104	2×50T
0320500101	100T
0320500102	2×100T

【Intended Use】

The kit is expected to be used for the in vitro quantitative detection of gastrin-17 in human serum or plasma.

Gastrin is a polypeptide hormone secreted by G cells in gastric antrum and duodenal mucosa. It was first discovered and named by British scholar Edkins in 1906 [1]. Clinically, it is mainly used for the auxiliary diagnosis of clinical atrophic gastritis. The gastrin gene is located on the long arm of chromosome 17, with a total length of 4.1 kb. Progastrin containing 101 amino acid residues is generated in the endoplasmic reticulum[2,3]. The N-terminal signal peptide of progastrin is clipped to 21 amino acids to form a progastrin containing 80 amino acids. Progastrin is rapidly cleaved and modified by peptidase and carboxypeptidase to form glycine-extended gastrin (mainly glycine-extended gastrin 34). Glycine-extended gastrin 34 can either cut the C-terminal polypeptide into glycine-extended gastrin 17, or amidate the C-terminal glycine to form amidated gastrin 34, amidated lysine-lysine of gastrin 34. The acid junction is sheared to form amidated gastrin 17.

【Test Principle】

Sandwich principle.Total duration of assay:18 minutes

60 μL of sample, Gastrin-17 labeled with antibody Ruthenium (Ru) complex and the other one labeled with biotin to form an antigen-antibody sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. 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 a calibration and a master curve provided via the reagent barcode.

【Main Component】

The reagent pack consist of MB, RA ,RB, calibrators and control materials(optional), and different components and reagents of lot numbers should not be used interchangeably.

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
(MB)	Magnetic particles coated with streptavidin; ProClin 300	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
(RB)	Biotin-labeled Gastrin-17 mouse monoclonal antibody; 25mM EPPS buffer; Perservative	2×2.5 mL	1×2.5 mL	1×5.0 mL	2×5.0 mL
(RA)	Ru complex labeled Gastrin-17 mouse monoclonal antibody; 25mM EPPS buffer; Perservative	2×2.5 mL	1×2.5 mL	1×5.0 mL	2×5.0 mL
Calibrators	Gastrin-17 antigen; Tris (hydroxymethyl) aminomethane buffer;Perservative; lyophilized	High: 1×2.0 mL Medium: 1×2.0 mL Low: 1×2.0 mL			
Control materials (Optional)	Gastrin-17 antigen; Tris (hydroxymethyl) aminomethane buffer; Perservative; lyophilized	High: 1×2.0 mL Low: 1×2.0 mL			

Traceability:This method can be traceable 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, 5×1 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 store at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Store 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 resolution	8 days
Store at -25℃~-15℃ after resolution	2 months (frezze only once)

Store calibrators and control materials upright in order to prevent the calibrators and control materials from adhering to the cap of the vial.

【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】

It is recommended to use human serum samples or plasma samples collected with EDTA-K2, Sodiumcitrate blood collection tubes.

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 in suggestion.

Samples can be stored for 8 hours at 18~28℃, 12 hours at 2~8 ℃, and 30 days at -15℃ or below. allowing two freeze-thaw.

【Testing 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. Gastrin-17 testing procedures should be called and 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%.

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 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 findings outside the defined limits.

(4) The Buffer of different lots are used.

Pre-treatment of lyophilized calibrator and control material:

The calibrator or control material should be accurately added 2.0 mL deionized water into and then sealed at room temperature（18～28℃） for 15 minutes to fully mix the components.The air bubbles shouldn't be permitted during the mixture process. The calibrated or control materials should be marked and keep dispensed after mixing. Please remember to transfer them at -15℃ or below quickly If you don't use them immediately.

Quality control procedure

For quality control, use Gastrin-17 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 can automatically calculate the analyte concentration, with the result in pmol/L.

【Reference Interval】

By analyzing the serum samples of 240 healthy population from hospitals, the reference range of Gastrin-17 drawed by the percentile 5 to 95 is 1.625 ~ 7.549 pmol/L.
Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

【Result Interpretation】

When interpreting the test results, it is necessary to refer to the patient's overall clinical situation, including: symptoms, medical history as well as other corresponding data and information.

【Limitations】

The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.
The detection range of the kit is 0.6 ~ 500 pmol/L. If the Gastrin-17 concentration in the sample is lower than the lower limit of detection, the result is reported as less than this value (for example, <0.6 pmol/L); if the Gastrin-17 concentration in the sample is higher than the upper limit of detection, the result is reported as greater than this value (for example, >500 pmol/L).
When the Gastrin-17 concentration reaches 10000 pmol/L, there is no high-dose hook effect.
When the sample containing triglyceride ≤ 2000 mg/dL, bilirubin ≤20mg/dL,biotin ≤20 ng/mL, hemoglobin ≤ 200 mg/dL,and HAMA ≤ 30 ng/mL, the interference deviation of concentration to the test results lies within ±15%.When the RF concentration in the sample is <1000 IU/mL, the relative recovery of the test results is between 85%-115%.
When the analogs were detected at 100 ng/mL thyroglobulin, 1000 pg/mL gastrin 34, and 1000 pg/mL gastrin 14, the measured value of Gastrin-17 was lower than 1.0 pmol/L.

【Analytical Performance】

Lower limit of measurement

Limit of detection: ≤0.6 pmol/L.

Linearity

Within the range of 0.6~500pmol/L, the correlation coefficient (r) of the kit should not be less than 0.9900.

Within-run imprecision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Between-lot imprecision

The coefficient of variation (CV) ≤ 10%.

Accuracy

The recovery rate of Gastrin-17 additive samples is between 85% and 115%.

Homogeneity of calibratiors and control materials

Within-bottle homogeneity: Coefficient of variation (CV) ≤10%;
Between-bottle homogeneity: Coefficient of variation (CV) ≤ 10%.

Measured value of quality control product

The measured results of supporting assigned quality control of the kit should be within the quality control range.

Method Comparison

A comparison of the Lifotronic Gastrin-17 assay (y) with the commercial Gastrin-17 Method (x) using clinical samples gave the following correlations:
Number of serum samples measured: 249
Linear regression:
Y=1.0208X+0.8942
r=0.9948
The sample concentrations were between approx 1.001 and 487.6 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.

【Symbols 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		Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		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. Edkins JS. The chemical mechanism of gastric secretion.[J].J Physiol. 1906;34(1-2):133-144.
2. Boel E, Vuust J, Norris F, Norris K, Wind A, Rehfeld JF, Marcher KA. Molecular cloning of human gastrin cDNA: evidence for evolution of gastrin by gene duplication. [J]. Proc Natl Acad Sci USA.1983;80(10):2866-2869.
3. Wiborg O, Berglund L, Boel E, Norris F. Norris K, Rehfeld JF, Marcher KA, Vuust J.[J]. Structure of a human gastrin gene. Proc Natl Acad Sci USA, 1984;81:1067-1069.

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