Instruction For Use

【Product Name】

PCT STAT (eCLIA)

【Order Information】

REF NO.	Package Size
0320510401	50 T
0320510402	2×50 T
0320510403	100 T
0320510404	2×100 T

【Intended Use】

Immunoassay for the in vitro quantitative determination of Procalcitonin (PCT) in human serum and plasma.

PCT is a 116 amino acid glycoprotein with a molecular weight of 12.7 kDa, which is the precursor of calcitonin and consists of N-procT, immature calcitonin and osteocalcin. PCT in human body is expressed by neuroendocrine cells (including thyroid, lung and pancreatic tissue cells) and digested into calcitonin (CT), carboxy-terminal peptide and amino-terminal peptide[1-2]. PCT is mainly produced under the induction stimulation of bacterial toxins and inflammatory cytokines, and is mainly used in the auxiliary diagnosis of bacterial infectious diseases. The level is very low in viral infections or autoimmune diseases[3]. The level of serum PCT also reflects the severity of the disease, and is also a good indicator to judge the prognosis and evaluate the curative effect [4-5].

【Test Principle】

Sandwich principle. Total duration of assay: 9 minutes.

30 µL of sample, biotinylated PCT antibodies and PCT antibodies labeled with ruthenium complex react to form a 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 system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. After the electrode is energized, chemiluminescence is generated, and the resulting optical signal is measured by photomultiplier tube, processed by instrument, and the concentration of PCT in the sample is calculated by calibration curve.

【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 (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles, 0.45mg/mL; ProClin™300	2×1.8mL	1×1.8mL	1×3.5mL	2×3.5mL
(RB)	Biotinylated monoclonal PCT antibodies, 1.5mg/L; 0.1 M PBS; ProClin™300	2×3.0mL	1×3.0mL	1×6.0mL	2×6.0mL
(RA)	PCT antibodies labeled with ruthenium, 0.5mg/L; 0.1 M PBS; ProClin™300	2×4.0mL	1×4.0mL	1×8.0mL	2×8.0mL
Calibrators	PCT antigen; horse serum; ProClin™300; lyophilized	High: 1×4.0 mL Low: 1×4.0 mL			
Control Materials (Optional)	PCT antigen; horse serum; ProClin™300; lyophilized	High: 1×4.0 mL Low: 1×4.0 mL		High: 2×4.0 mL Low: 2×4.0 mL	

The calibration value assignment of calibrators can be traced back to the BRAHMS PCT LIA.

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 0320510111, 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-8°C.

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°C	18 months
Store at 2~8°C after opening	8 weeks
Stored on the analyzers at 2~15°C	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°C	18 months
Store at 2ºC~8ºC after resolution	3 days
Store at -25ºC~-15ºC after resolution	3 months (freeze-thawed only once)

Store calibrators and control materials upright in order to prevent the calibrator solution 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-K3, EDTA-K2, Heparin lithium, Heparin sodium blood collection tubes.

Blood samples should be collected in accordance with the standard operation of venipuncture. After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.

Samples can be stored for 8 hours at 18~28ºC, 3 days at 2~8ºC, and 3 months at -15ºC or below. Freezing and thawing can be performed 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. PCT STAT 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: 10~30ºC; relative humidity: ≤80%.

Handing of lyophilized calibrators and control materials

Carefully dissolve the contents of lyophilized calibrator by adding exactly 4.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators to empty tubes after the tubes were marked. Aliquots intended for storage at -25°C~-15°C should be frozen immediately.

Carefully dissolve the contents of lyophilized control material by adding exactly 4.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted control materials to empty tubes after the tubes were marked. Aliquots intended for storage at -25°C~-15°C should be frozen immediately.

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 4 weeks;

(3) Quality control findings outside the defined limits.

(4) The Buffer of different lots are used.

Quality control

For quality control, use PCT STAT 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, μg/L.
Conversion factors: ng/mL×1.0= μg/L

【Biological reference interval】

The upper limit of 95% reference interval was calculated to be 0.049 ng/mL by testing 251 healthy people in Guangdong hospitals..
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.

【Interpretation of results】

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 blank limit of the kit is 0.01 ng/mL, and the detection range is 0.01～100 ng/mL. If the PCT concentration in the sample is lower than the lower limit of detection, the result is reported as <0.01 ng/mL; if the PCT concentration in the sample is higher than the upper limit of detection, the result is reported as >100 ng/mL(5-fold dilution samples are reported as > 500 ng/mL).
When jaundice (bilirubin) is ≤ 30 mg/dL, hemolysis (hemoglobin) is ≤ 700 mg/dL, lipemia (triglyceride) is ≤ 2000 mg/dL, biotin is ≤ 30 ng/mL, total protein is ≤ 80 g/L, HAMA is ≤ 289.44 ng/mL, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample is ≤ 2000 IU/mL, the relative recovery of the test results is between 90% and 110%.
When the PCT concentration reaches 1500 ng/mL, The results were not affected by hook effect.

【Analytical Performance】

Limit of Detection

Limit of Detection ≤ 0.02 ng/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 0.02 ~ 100 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than or equal to 6.0%.

Between-lot precision

The coefficient of variation (CV) is less than or equal to 10.0%.

Homogeneity of calibrators and control materials

Within-bottle homogeneity: The coefficient of variation (CV) is less than or equal to 6.0%.
Between-bottle homogeneity: The coefficient of variation (CV) is less than or equal to 10.0%.

Accuracy of calibrators

The relative deviation shall not exceed ±10%.

Measured values of quality control

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 PCT STAT assay (y) with the Roche Elecsys PCT Method (x) using clinical samples gave the following correlations:
Number of serum samples measured: 107
Linear regression:
y = 0.9967x + 0.0339
r=0.9996
The sample concentrations were between approx 0.021 and 97.48 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.

【Literature References】

1. Gendrel D, Bohuon C. Procalcitonin as a marker of bacterial infection. Pediatr Infect Dis J 2000;19:679-688.
2. Becker KL, Nylén ES, White JC, Müller B, Snider RH. Procalcitonin and the Calcitonin Gene Family of Peptides in Inflammation, Infection, and Sepsis: A Journey from Calcitonin Back to Its Precursors. J Clin Endocrinol Metab 2004;89(4):1512-1525.
3. Clec'h C, Ferriere F, Karoubi P, Fosse JP, Cupa M, Hoang P, Cohen Y. Diagnostic and prognostic value of procalcitonin in patients with septic shock. Crit Care Med 2004;32(5): 1166-1169.
4. Gaïni S, Koldkjær OG, Møller HJ, Pedersen C, Pedersen SS. A comparison of high-mobility group-box 1 protein, lipopolysaccharide -binding protein and procalcitonin in severe community-aquired infections and bacteraemia: a prospective study. Crit Care 2007;11(4): 77-87.
5. Castelli GP, Pognani C, Cita M, Stuani A, Sgarbi L, Paladini R. Procalcitonin, C-reactive protein, white blood cells and SOFA score in ICU: diagnosis and monitoring of sepsis. Minerva Anestesiol 2006;72:69-80.

【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		

【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】

Umedwings Netherlands B.V.
Treubstraat 1, 2288EG, Rijswijk, The Netherlands
Tel: +31(0) 642758955
E-mail: ar@umedwings.eu

【Version and Revision】

Version: 2.0
Issue Date: 2025-03-04