【Product Name】
Total Prostate Specific Antigen (eCLIA)

【Order Information】

REF NO.	Package Size
0320501101	50T
0320501102	2×50T
0320501103	100T
0320501104	2×100T

【Intended Purpose】
Total Prostate Specific Antigen (eCLIA) is an immunoassay reagent for in vitro quantitative determination of Total Prostate Specific Antigen(tPSA) in human serum and plasma by fully automated immunassay analyzer to use as an aid in the detection of prostate cancer.
Intended testing population: Suspected prostate cancer people.

【Summary】
Prostate specific antigen (PSA) is a glycoprotein (with a molecular weight of 30kd-34kd) with a structure highly similar to that of the glandular kallikrein. PSA has the activity of serine protease. It is synthesized and secreted into semen by prostatic secreted epithelial cells. The main function of PSA is to lyse the gel proteins in semen to liquefy the semen gel and increase the sperm motility[1, 2, 3]. Low level of PSA can be detected in the serum of normal men due to permeation. Elevated serum PSA level is relevant to prostate diseases, including prostatitis, benign prostatic hyperplasia and prostate cancer[4, 5].
There are three main forms of PSA in the serum: the first is free PSA (FPSA), the second is PSA binding to α-1-antichymotrypsin (ACT) called PSA-ACT, and the third is PSA binding to α-2-macroglobulin (AMG) and manifesting as immunoreactive deficiency[4, 6, 7]. Currently, only the first two can be detected by immunoassay in commercial PSA detection, so they are together defined as total PSA (tPSA) [8]. The serum PSA detection can help monitor the response of prostate cancer patients to the treatment. After the prostate cancer eradication, if the serum PSA concentration drops below the limit of detection, it indicates the successful operation. If the serum PSA concentration drops only partially, it means that the operation is incomplete, and there are residual lesions or metastatic lesions of prostate cancer [9, 10, 11]. The serum PSA detection has reference value for monitoring the recurrence of prostate cancer and judging the prognosis of patients[9, 12, 13].
It intends to be used for dynamic monitoring of patients with malignant tumors to assist the judgment of disease progression or curative effect. It cannot be used as the basis for the early diagnosis or confirmed diagnosis of malignant tumors.
For professionals use only.

【Principle】
Sandwich principle. Total duration of assay: 9 minutes.
20 µL of sample, biotinylated monoclonal tPSA antibodies, and monoclonal tPSA antibodies labeled with ruthenium complex react to form a sandwich complex. The entire 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. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Composition】
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	Content (2×50T)	Content (50T)	Content (100T)	Content (2×100T)
Magnetic Beads (MB)	Streptavidin coated magnetic particles, 0.45 mg/mL; 0.1 M PBS; ProClin™ 300	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Biotinylated PSA antibody, 0.2 mg/L; 0.1 M PBS; ProClin™ 3000	2×3.5 mL	1×3.5 mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	Ru complex-labeled PSA antibody, 0.1 mg/L; 0.1 M PBS; ProClin™ 300	2×3.5 mL	1×3.5 mL	1×7.0 mL	2×7.0 mL
tPSA Calibrators	PSA antigen, 0.1 M HEPES buffer, ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			
tPSA Control Materials (Optional)	PSA antigen, 0.1 M HEPES buffer, ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method has been standardized against the international standard substances for NIBSC 17/100.
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 Analyzers 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

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

【Applicable Instrument】
Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【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.

Stability of the reagents	
Unopened store at 2~8°C	18 months
Store at 2~8°C after opening	8 weeks
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 Store at 2~8°C	18 months
Store at 2~8°C after opening	8 weeks

【Specimen collection, handling and storage】
It is recommended to use serum or plasma samples collected in blood collection tubes with heparin lithium, EDTA-2K and EDTA-3K anticoagulants.
Samples should be collected in accordance with the standard operation of Word Health Organization guidelines for blood collection. 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 12 hours at 18~28°C, 7 days at 2~8°C, and 90 days at -25℃~-15℃. Freezing and thawing can be performed twice.

【Testing Procedure】
Testing procedure 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. tPSA 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: 10~30ºC, 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 procedure
For quality control, use tPSA 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 can automatically calculate the analyte concentration using particular algorithm,and the result unit is ng/mL and µg/L,1 ng/mL=1 µg/L.
Specimen dilution
tPSA concentration in the sample higher than the upper limit of detection can be diluted with sample diluent.
The recommended dilution ratio is 1:50 (automatic dilution by instrument or manual dilution). If manual dilution, the result should be multiplied by the dilution ratio. If instrument automatic dilution, the instrument will automatically calculate the result.

【Reference intervals】
By analyzing the serum samples of 310 healthy males ,it was calculated that the upper limit of the reference range of 95% is 4 ng/mL.
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.

【Limitations】
The test results are only for clinical reference and cannot be used alone as the basis

The measuring range of the kit is 0.003 ng/mL~100 ng/mL. Values below the lower detection limit are reported as < 0.003 ng/mL. Values above the measuring range are reported as > 100 ng/mL (or up to 5000 ng/mL for 50 times diluted).
The measured result was unaffected by the high-dose hook effect at tPSA concentrations up to 17000 ng/mL.
When jaundice (bilirubin) ≤ 65 mg/dL, hemolysis (hemoglobin) ≤ 500 mg/dL, lipemia (triglyceride) ≤ 1500 mg/dL, biotin ≤ 20 ng/mL, and HAMA ≤ 100 ng/mL in the sample, the interference deviation of the test results is within ±15%. When the concentration of rheumatoid factor in the sample ≤ 1500 IU/mL, the relative recovery of the test results is between 85% and 115%.
When the sample contains leuprorelin acetate (100 μg/mL), cyclophosphamide (700 μg/mL), finasteride (370 ng/mL), megestrol acetate (2.4 mg/dL), methotrexate (30 μg/ mL), flutamide (10 μg/mL), doxorubicin hydrochloride (16 μg/mL), aspirin (0.5 mg/mL), and diethylstilbestrol (2 μg/mL), the interference deviation of the measured results is within ±10%.

【Analytical Performance charateristics】

Lower limits of measurement

Limit of Blank (LoB)= 0.002 ng/mL
Limit of detection (LoD)= 0.003 ng/mL
Limit of quantitation (LoQ)= 0.003 ng/mL.

Accuracy

The PSA international standard sample was tested, the relative deviation between measured value and theoretical value not more than ±10%.

Linearity

Within the range of 0.003 ng/mL~100 ng/mL, the correlation coefficient (r) of the kit should not be less than 0.9900.

Precision

The precision of tPSA are the Repeatability(%CV) ≤5%, the Within-Laboratory Precision(%CV) ≤10%, the Reproducibility(%CV) ≤10%.
Precision was determined using immunoassay reagents, samples in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute). The following results were obtained:

Sample	Mean (ng/mL)	Repeatability (%CV)	Within-Laboratory Precision (%CV)	Reproducibility (%CV)
Human serum 1	3.992	3.16%	3.18%	3.18%
Human serum 2	30.05	4.13%	4.13%	4.23%

Analytical specificity

Prepare the samples of serial concentrations in which the tPSA concentration is same but the proportions of fPSA and PSA-ACT complex are different, and the deviation between the test concentration and the theoretical concentration is within ±15%.

Measured values of control materials

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

Accuracy of calibrators

The supporting calibrators of the kit was tested, the relative deviation of its measured results should be within ±15%.

Homogeneity of calibrators and control materials

Within-bottle homogeneity:
Calibrator (Low): Standard deviation(SD) ≤ 1.0 ng/mL;
Calibrator (High) and Control Materials (Low and High): coefficient of variation (CV) ≤ 5%.
Between-bottle homogeneity:
Calibrator (Low): Standard deviation(SD) ≤ 1.0 ng/mL;
Calibrator (High) and Control Materials (Low and High): coefficient of variation (CV) ≤ 8%.

Method comparison

A comparison of the Lifotronic tPSA assay (y) with the Roche Elecsys total PSA Method (x) using clinical samples gave the following correlations:
Number of paired values: 103
Passing-Bablok regression:
y=-0.0113+0.979x
r = 0.9962
The sample concentrations were between approx 0.178 and 84.08 ng/mL.

【Precautions and Warnings】

When using this kit, the relevant operation precautions of the laboratory must be observed and it needs to be operated by a professional experimenter;
The test results of this kit can only be used as clinical reference, the patient's clinical evaluation should be based on the patient's clinical symptoms/signs, medical history, other laboratory test results and treatment response, etc.;
Due to methodological reasons or antibody specificity, the results of the same sample tested with reagents of different manufacturers may be different. Therefore, results obtained with different kits should not be directly compared, so as to prevent wrong medical interpretation; It is recommended that the Laboratory Department indicate the characteristics of the reagents in the test report issued to the clinician. If the reagent type is changed during series monitoring, continuous testing should be conducted, and the results should be compared with the original reagent results in parallel to re-determine the baseline value;
This product contains animal-derived substances, and may have potential biological risks. All samples and reaction wastes should be treated as the source of infection, and all wastes must be disposed of in accordance with 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

approved waste disposal plant.

【Bibliography】

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The Summary of Safety and Performance Report can be found here:
https://ec.europa.eu/tools/eudamed.

【Symbols Explanation】

Symbol	Title	Symbol	Title
	Manufacturer		Consult instructions for use
	Use-by date	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Contains sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		This way up
EC REP	Authorized representative in the European Community	CE 0123	CE mark including the identification number of the NB.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	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】

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726

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