【Product Name】
Free Prostate Specific Antigen (eCLIA)

【Order Information】

REF NO.	Package Size
0320501001	50T
0320501002	2×50T
0320501003	100T
0320501004	2×100T

【Intended Purpose】
Free Prostate Specific Antigen (eCLIA) is an immunoassay reagent for in vitro quantitative determination of Free Prostate Specific Antigen (fPSA) in human serum and plasma by fully automated immunoassay analyzer, The ratio of fPSA to tPSA (%fPSA) can be used for the differential diagnosis of prostate cancer and benign prostatic conditions.
Intended testing population: Suspected prostate cancer and benign prostatic conditions people.

【Summary】
Prostate Specific Antigen (PSA) is a member of human prostate kallikrein gene family, it is a serine protease that contains chymotrypsin-like activity[1,2]. PSA with a molecular weight of about 30 KD, is synthesized and secreted into semen by prostatic epithelial cells. It is one of the main components of seminal plasma[1,3,4]. 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[5,6,7]. Currently, only the first two can be detected by immunoassay in commercial PSA detection, so they are together defined as total PSA (tPSA)[8]. PSA is not specific to the prostate and lacks sufficient sensitivity and specificity. Although PSA has tissue specificity, its secretion will also increase in non-malignant conditions such as benign prostatic hyperplasia (BPH). Many studies have found that fPSA% is lower in prostate cancer patients than in those with other benign lesions or the normal control. The lower the relative concentration of fPSA, the higher the risk of prostate cancer in men[4,8,9].
fPSA/tPSA ratio can be used in the differential diagnosis of prostate cancer and benign prostatic conditions and in 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 anti-fPSA antibody, and anti-PSA antibody 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. 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 reagent components of lot numbers should not be used interchangeably.

Components	Ingredients	Content (50T)	Content (2×50T)	Content (100T)	Content (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles 0.45 mg/mL; 0.1M PBS; 0.05% ProClin™ 300	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Biotinylated anti-fPSA antibody 0.2 mg/L, 0.1 M PBS; 0.05% ProClin™ 300	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	Anti-PSA antibody labeled with ruthenium complex 0.1 mg/L; 0.1 M PBS; 0.05% ProClin™ 300	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
fPSA Calibrators	PSA antigen, 0.1 M HEPES; 0.05% ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			
fPSA Control Materials (Optional)	PSA antigen, 0.1 M HEPES; 0.05% ProClin™ 300	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method has been standardized against the second-generation international standard substances for free prostate specific antigen (NIBSC 17/102).
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 Cup/Assay Tip, 12×2×105

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~8ºC.
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 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks
on the analyzers at 2ºC~15ºC	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 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks

【Specimen collection, handling and storage】
It is recommended to use human serum samples or plasma samples collected with heparin lithium, EDTA-K2 and EDTA-K3 blood collection tubes.
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 18ºC~28ºC, 7 days at 2ºC~8ºC, and 3 months at -25ºC~-15ºC. Samples can be freeze-thawed only 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. fPSA 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 fPSA 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 calculates the analyte concentration using particular algorithm, and the result unit is ng/mL or µg/L.
Specimen dilution
Not necessary due to the broad measuring range.

【Reference interval】
By analyzing the serum samples of 313 healthy test subjects from men, it was calculated that the upper limit of the reference interval of 95th percentile is 1.016 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.

【Interpretation of results】
Serum PSA concentration is in the gray zone of 4 ng/mL to 10 ng/mL, if the digital rectal examination (DRE) is positive, further prostate biopsy should be done to confirm the diagnosis. If DRE is negative, the free PSA percentage (%fPSA) test should be performed. If %fPSA<10%, a biopsy of the prostate should be considered to confirm the diagnosis[10].

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 measuring range of the kit is 0.01-50 ng/mL. Values below the lower detection limit are reported as < 0.01 ng/mL. Values above the measuring range are reported as > 50 ng/mL.

The measured result was unaffected by the high-dose hook effect at fPSA concentrations up to 15000 ng/mL.

When the sample containing triglyceride ≤ 1500 mg/dL, bilirubin ≤ 65 mg/dL, hemoglobin ≤ 500 mg/dL, biotin ≤ 20 ng/mL, HAMA ≤ 100 ng/mL, the interference deviation of the measured results lies within ±15%. When the rheumatoid factor concentration reached 1500 IU/mL, the relative recovery of the test result is between 85% and 115%.

When the sample containing 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 lies within ± 10%.

【Analytical Performance charateristics】

Lower limits of measurement

Limit of Blank = 0.005 ng/mL
Limit of Detection= 0.01 ng/mL
Limit of Quantitation = 0.01 ng/mL.

Accuracy

The fPSA international standard sample was tested, and the ratio of measured value to theoretical value should be within the range of 0.85-1.15. Or the recovery sample added with an appropriate concentration was tested, and the recovery should be within the range of 85%~115%.

Linearity

Within the range of 0.01~50 ng/mL, the correlation coefficient (r) of the kit should be greater than or equal to 0.9900.

Precision

The precision of fPSA are the Repeatability(%CV) ≤ 5%, the Within-Laboratory Precision(%CV) ≤10%, the Reproducibility(%CV) ≤10%.

Precision was determined using immunoassay reagent, 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	2.308	1.82%	1.82%	4.05%
Human serum 2	32.30	1.59%	1.66%	5.03%

Analytical specificity

Use the international standard of fPSA and the international standard of PSA to prepare the samples of serial concentrations, 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 fPSA assay (y) with the Roche Elecsys free PSA method (x) using clinical samples gave the following correlations:

Number of serum samples measured: 104
Passing-Bablok:
y=1.008x+0.0108
r = 0.9984
The sample concentrations were between 0.056 and 45.49 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

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.

【Bibliography】

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10. WST 460-2015 Clinical application of prostate specific antigen detection for prostate cancer

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】

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