Instruction For Use

【Product Name】

Renin (eCLIA)

【Order Information】

REF NO.	Package Size
0320511901	100T
0320511902	50T
0320511903	2×100T
0320511904	2×50T

【Intended Use】

Immunoassay for the in vitro quantitative determination of Renin in human plasma. Determination of Renin is used for auxiliary diagnosis of renal hypertension and endocrine hypertension.

【Summary】

Renin is a proteolytic enzyme with a molecular weight of 42000 daltons, mainly synthesized by the paracaglomerular cells of the kidney, stored as renin or renin granules and released due to physiological stimuli such as blood volume, decreased blood pressure, and sodium loss[1]. Renin is mainly used clinically in the auxiliary diagnosis of renal hypertension and endocrine hypertension. Renin forms angiotensin I (a decapeptide substance) by hydrolytic lysis of the renin substrate angiotensinogen. Angiotensinogen is a glycoprotein that is synthesized in the liver. In turn, the angiotensin-converting enzyme (ACE) converts angiotensin I to angiotensinII (octapeptide substance). It can promote aldosterone release and inhibit renin secretion through a negative feedback mechanism. The renin angiotensin aldosterone system (RAAS) plays a crucial role in water homeostasis and in the regulation of electrolyte balance and arterial blood pressure. Thus, the determination of plasma renin and aldosterone is an indicator of the renin angiotensin aldosterone system.

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

80 µL of sample, a biotinylated monoclonal antibody, and a monoclonal antibody labeled with ruthenium complex 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.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials. 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)
Magnetic Beads (MB)	Streptavidin-coated microparticles 0.45mg/mL; ProClin300	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Anti-Ab~biotin; 2-(N-morpholine) ethyl sulfonate buffer; ProClin300	2×3.5 mL	1×3.5 mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	Anti--Ab~Ru ;2- N-morpholine) ethyl sulfonate buffer ; ProClin300	2×3.5 mL	1×3.5 mL	1×7.0 mL	2×7.0 mL
Calibrators	Renin antigen, lyophilized	High: 1×2.0 mL Low: 1×2.0 mL			
Control Materials (Optional)	Renin antigen, lyophilized	High: 1×2.0 mL Low: 1×2.0 mL			

Traceability: This method has been standardized against the international standard substances for NIBSC 68/356.

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

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】

Stored 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.

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened store 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 lyophilized. And there 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 reconstituted	7 days
Store at -15°C or lower than -15°C after reconstituted.	1 month (freeze-thawed only once)

Store calibrators and control materials upright in order to prevent the calibrator 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 plasma samples with EDTA-3K, EDTA-2K, and EDTA-sodium 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.

In sample treatment, the inactive predecessor of renin, was converted to renin by cold activation, yielding an inflated result. A cold activation reaction occurs when a patient's sample is frozen at 4°C or less than 4°C for a certain time or when the sample is frozen but in a liquid state (if not frozen). Renin protocold activation to renin is more likely to occur in serum samples. The blood concentration of reninogen is about 10 times higher than that of renin.

The only valid source of the sample was the human EDTA plasma. Renin values detected using serum, hepatolipid blood or citrate plasma samples are all relatively low and therefore not recommended.

Standardized operational patient sample preparation and processing procedures is strongly recommended. Blood samples must be collected at room temperature by venipuncture in a silicate glass tube containing EDTA anticoagulant, vacuum collection or equivalent container. The occurrence of hemolysis indicates an improper operation during sample collection or processing. Fasting sampling is recommended, but it is not necessary. Record the date and pose (supine or upright) of the blood samples. Do not prefreeze EDTA blood collection tubes or store tubes, blood samples should be processed at room temperature. EDTA plasma tubes were placed in a centrifuge without refrigeration, and EDTA plasma was immediately centrifuged from the cells, and the samples were aliquoted and rapidly frozen to -20°C or below.

Samples can be stable 4 weeks at -15°C or lower than -15°C. Do not store at 2 ~ 8°C. samples can be freeze-thawed 3 times.

The refrigerated / frozen samples must be restored to room temperature before testing.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, one should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up Renin test according to the operational manual.

Put the Renin rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 minutes before testing.

Recommended ambient temperature:10~30°C; Relative humidity: ≤ 80%.

Handing of lyophilized calibrators and control materials:

Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 20 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators or control materials to the additional bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -15°C or lower than -15°C.

Calibration

Calibration tests should be performed using matching calibration products.

Before calibration, the reagent information and main calibration curve information of the kit (Radio Frequency Identification, inductive electronic chip card or near-receiving card) are required to be imported into the system.

matching calibrators to obtain the standard curve tested by the current system (the analyzer can automatically determine the validity of the standard curve according to the adjustment results).
Recalibration is recommended when:
(1) the lots of reagents are changed;
(2) the same lot of reagents were used on the analyzer beyond 28 days;
(3) quality control misses the target;
(4) the lots of buffer are changed.

Quality control

For quality control, use Renin 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 pg/mL or μIU/mL.
Conversion relationship: pg/mL×1.67= μIU/mL.

【Biological reference interval】

By testing healthy human plasma samples, the reference interval of 5% to 95% is calculated:
Supine position: 1.817 ~ 24.52 pg/mL;
Upright position: 2.814 ~ 28.57 pg/mL.
Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges. Each laboratory should investigate the transfer-ability of the expected values to its own patient population and if necessary determine its own reference ranges.

【Interpretation of results】

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. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
The measuring range of the kit is 0.1~500 pg/mL. For samples with Renin content below the lower detection limit, the results are reported as < 0.1 pg/mL; If the Renin content is above the upper detection limit, the results are reported as > 500 pg/mL.
When the samples had jaundice (bilirubin)≤20 mg/dL, Hemolysis (Hemoglobin) ≤500 mg/dL, Lipoblood (triglyceride)≤3000 mg/dL, total protein ≤6 g/dL, biotin≤30 ng/mL, and HAMA ≤100 ng/mL, the relative deviation of the measurement results was within ± 10%; when the rheumatoid factor was 400 IU/mL, the relative recovery of the measurement results was between 90% and 110%.
When interfering samples containing commonly used drugs were tested: vitamin H (200 ng/mL), furanilic acid (5.99 mg/dL), nifedipine (40 μg/dL), and captopril (42.4 μg/dL), the relative deviation of the results was within ± 10%.
When the prorenin concentration was 10 ng/mL, the relative deviation of the measured results was within ± 10%.
No high dose hook effect at Renin concentration reached 3000 pg/mL.

【Analytical Performance】

Lower limit of measurement

Limit of Blank (LoB) = 0.1 pg/mL.
Limit of detection (LoD)= 0.5 pg/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 0.5~500 pg/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than or equal to 8%.

Between-lot precision

The coefficient of variation (CV) is less than or equal to 10%.

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 ±10%.

Homogeneity of calibrators and control materials

Between-bottle homogeneity: The coefficient of variation (CV) is less than or equal to 10%.

【Precaution and Warning】

This kit is for in vitro diagnostic use only.
When using this kit, it is necessary to observe the relevant matters in the laboratory.
The test results of this kit are for clinical reference only, and the clinical evaluation of patients should be combined with their symptoms/signs, medical history, other laboratory examination results and treatment reactions.
Due to reasons such as methodologies or antibody specificity, the use of reagents to test the same samples of different manufacturers may get different test results, the results with different kits should not compare directly, lest cause the wrong medicine explanation;It is suggested that the laboratory should indicate the characteristics of the reagent in the test report to the clinician.In the series monitoring, if the reagent type is changed, the continuity detection should be performed and parallel comparison with the results of the original reagent to determine the baseline value.
This product contains animal source material and may have potential biological risk.All samples and reaction wastes should be treated as the source of infection, and all waste must be disposed of 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		

【Literature References】

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3. Montori VM, Schwartz GL, Chapman AB, et al. Validity of the aldosterone-renin ratio used to screen for primary aldosteronism. Mayo clin Proc 2001;76:877-82.
4. Funder JW, Carey RM, Mantero F, et al. The Management of Primary Aldosteronism: Case Detection, Diagnosis, and Treatment. An Endocrine Society Clinical Pratice Guideline. J Cin Endocrinol Metab 2016;101（5）: 1889-1916.
5. Brenner & Rector's The kidney, 7thed. Saunders, 2004.

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【Version and Revision】

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