Instruction For Use

【Product Name】

ALD (eCLIA)

【Order Information】

REF NO.	Package Size
0320511801	100T
0320511802	50T
0320511803	2×100T
0320511804	2×50T

【Intended Use】

Immunoassay for the in vitro quantitative determination of aldosterone (ALD) in human serum and plasma by fully automated immunassay analyzer. Determination of ALD is used for auxiliary evaluation of adrenal cortical function.

【Summary】

Aldosterone is a potent mineralocorticoid, synthesized only by the glomerular band of the adrenal cortex. In the kidney, aldosterone actively enhances sodium reabsorption, passively increases water absorption in the lumen of the distal lumen, and actively secrete potassium and hydrogen ions into this luminal structure[1]. Its secretion is affected by a variety of factors, mainly regulated by the renin-angiotensin-aldosterone secretion axis, such as angiotensin II, serum potassium concentration, and adrenocorticotropic hormone (ACTH) concentration regulation in vivo[2]. Aldosterone is mainly used clinically to assist in the evaluation of adrenocortical function. Blood aldosterone concentration is an important indicator for the screening and diagnosis of primary aldoonism (primary aldehyde), congenital adrenal cortical hyperplasia, Liddle syndrome and other diseases. Blood increased aldosterone is also a risk factor for cardiovascular and cerebrovascular events, chronic kidney disease, and metabolic syndrome[3-5]. Abnormal increase in ALD can occur in a variety of diseases, mainly in primary aldosterone (primary hyperaldosteroni-sm, PA)[6], primary aldosterone (primary aldehyde) is one of the common causes of secondary hypertension. Some diseases, such as anterior pituitary hypofunction, congenital ovarian hypoplasia, adrenal cortex dysfunction, can cause secondary aldosterone reduction.

【Test Principle】

Competition principle. Total duration of assay: 18 minutes.

80 μL of sample are incubated with monoclonal antibody derivate labeled with a ruthenium complex. The binding sites of the labeled antibody become occupied by the sample analyte (dependingon its concentration). After addition of streptavidin-coated microparticles and a biotinylatedantigen, 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 (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)
Magnetic Beads (MB)	Streptavidin-coated microparticles 0.75 mg/mL; ProClin300	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Ag~biotin 0.8 mg/L ethyl sulfonate buffer; ProClin300	2×2.5 mL	1×2.5 mL	1×5.0 mL	2×5.0 mL
Reagent A (RA)	Anti--Ab~Ru 0.2 mg/L ethyl sulfonate buffer; ProClin300	2×2.5 mL	1×2.5 mL	1×5.0 mL	2×5.0 mL
Calibrators	ALD antigen, PBS buffer; ProClin300	High: 1×1.5 mL Low: 1×1.5 mL			
Control Materials (Optional)	ALD antigen, PBS buffer; ProClin300	High: 1×1.5 mL Low: 1×1.5 mL			

Traceability: This method has been standardized against the 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 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】

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
Stored 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 opening	8 weeks

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】

Human serum and EDTA-K, EDTA-Na plasma are recommended. 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 would better to be tested in 6 hours after collection, otherwise, should be stable for 12 hours at 2-8 ℃ or 30 days at -15℃ or lower than -15℃. Freezing and thawing cycle is permitted third.

【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 ALD test according to the operational manual.

Put the ALD 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%.

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. The analyzer adjusts the main calibration curve through the test results of the matchin g calibrators to obtain the standard curve tested by the current system (the analyzer ca n automatically determine the validity of the standard curve according to the adjustme nt 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 ALD 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.

Sample dilution

Samples with ALD concentration above the detection range can be diluted with sample dilution. It is recommended to dilute by 1:5 (either automatically by the instrument or by hand). If diluted by hand, the result should be multiplied by the dilution multiple. If the instrument is automatically diluted, the instrument will automatically calculate the result.

【Biological reference interval】

By testing healthy human serum and plasma samples, the reference interval of 5% to 95% is calculated:

Position	Serum (pg/mL)	Plasma (pg/mL)
Upright	31.84 ~ 395.2	31.25 ~ 351.4
Supine	30.11 ~ 227.8	28.84 ~ 240.4

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 transferability 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 5~2000 pg/mL. For samples with ALD content below the lower detection limit, the results are reported as < 5 pg/mL; If the ALD content is above the upper detection limit, the results are reported as > 2000 pg/mL.
When the sample contained jaundice (bilirubin) ≤ 30 mg/dL, lipoblood (triglyceride) ≤ 3000 mg/dL, hemolysis (hemoglobin) ≤ 0.6 g/dL, biotin ≤ 30 ng/mL, and HAMA ≤ 100 ng/mL the interference deviation of the measurement results was within ± 10%.
Samples containing 500 ng/mL progesterone, 500 ng/mL testosterone, and 500 ng/mL hydrocortisone were tested with a cross-reaction rate of ≤ 0.02%.

【Analytical Performance】

Lower limit of measurement

Limit of Blank (LoB) = 5 pg/mL.
Limit of detection (LoD)= 15 pg/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 15~2000 pg/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than or equal to 8.0%.

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 8.0%.

Method comparison

A comparison of the Lifotronic ALD assay (y) with the Mindary ALD Method (x) using clinical samples gave the following correlations:
Number of serum samples measured: 122
Linear regression:
Y=0.9737X+8.4287
r=0.9984
The sample concentrations were between 16.32 and 1822 pg/mL.
Number of plasma samples measured: 102
Linear regression:
Y=1.0027X+0.4252
r=0.9972
The sample concentrations were between 14.36 and 1612 pg/mL.

【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		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		

【Literature References】

1. Root, Allen W. Disorders of aldosterone synthesis, secretion and cellular function. [J]. Current Opinion in Pediatrics. 2014;26(4):480-486.
2. Freel E, Connell J. Mechanisms of hypertension: the expanding role of aldosterone. [J]. J Am Soc Nephrol. 2004;15(8):1993-2001.
3. Paolo M, Silvia M, Chiara B, et al. Long-term cardio- and cerebrovascular events in patients with primary aldosteronism.[J]. Journal of Clinical Endocrinology & Metabolism. 2013;98(12):4826-4833.
4. Chen W, Li F, He C, et al. Elevated prevalence of abnormal glucose metabolism in patients with primary aldosteronism: a meta-analysis[J]. Irish Journal of Medical Science. 2014;183(2):283-291.
5. Rossi GP, Bernini G, Desideri G, et al. Renal damage in primary aldosteronism: results of the PAPY Study. [J]. Hypertension. 2006;48(2):232-238.
6. Funder JW, Carey RM, Mantero F, et al. The management of primary aldosteronism: Case detection,diagnosis, and treatment: An endocrine society clinical practice guideline. [J]. Journal of Clinical Endocrinology& Metabolism. 2016;101(5):1889-1916.

【Manufacturer】

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【Version and Revision】

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