EUROIMMUN

Medizinische Labordiagnostika AG

Aldosterone ELISA



- Reliable aldosterone determination to support the diagnosis of hyperaldosteronism
- 100% specificity for aldosterone no cross reactivity with structurally similar reactants
- Automated test processing on open ELISA platform with shaking function possible

	Technical data				
Coa	ting	Polyclonal anti-aldosterone antibodies			
Cali	bration	Quantitative, in picograms per millilitre (pg/ml), 6 calibrators			
San	nple material	Serum or plasma, 50 µl undiluted			
Rea	gents	Ready for use, with the exception of the wash buffer $(10 \times)$			
Tes	t procedure	60 min/20 min, shaking, room temperature (sample incubation/substrate incubation)			
Mea	asurement	450 nm wavelength			
Tes	t kit format	96 break-off wells, incl. all reagents			
Order no.		EQ 6143-9601			

Clinical significance

Autoimmune diagnostics

The hormone aldosterone is produced from cholesterol in the zona glomerulosa of the adrenal cortex. It is a mineralocorticoid and binds to mineralocorticoid receptors in the kidneys, heart, blood vessels, liver and in other tissues. Aldosterone is regulated via the renin-angiotensin-aldosterone system (RAAS). It acts mainly in the kidneys, increasing the resorption of sodium from the distal tubules and the excretion of potassium. An increase in the potassium level increases the blood volume and blood pressure.

Hyperaldosteronism can be either primary or secondary, with a very similar clinical picture. Up to 10% of all hypertonia cases are caused by primary hyperaldosteronism. The secondary form is less frequent. Primary hyperaldosteronism (Conn's syndrome) is caused by overproduction of aldosterone in the adrenal cortex. In two thirds of cases the aetiology is idiopathic bilateral adrenal hyperplasia and in one third it is an underlying tumour in the zona glomerulosa. In primary hyperaldosteronism, the renin level is also low. It may be completely suppressed in manifest disease. In secondary hyperaldosteronism, the aldosterone and renin levels are increased. The aldosterone level is low in chronic adrenal cortex insufficiency and anterior hypopituitarism. The normal value of aldosterone in the blood depends on the position of the patient during sample collection (upright or supine) in addition to the sodium uptake because the blood pressure is different in the two positions. The Endocrine Society guidelines recommend that blood samples for the determination of aldosterone and renin are taken after patients have been out of bed for at least two hours and after they have been seated for 5 to 15 minutes.

The reference ranges for serum aldosterone at normal sodium supply for adults are between 40 and 310 pg/ml (standing) and 10 and 160 pg/ml (horizontal). The normal values for babies and children (1 to 15 years old) range from 320 to 1,278 pg/ml and 73 to 425 pg/ml, respectively. The blood aldosterone level decreases with age. In suspected cases of hyperaldosteronism, the ratio of aldosterone to renin in plasma should be determined. This is useful for the differentiation between primary and secondary hyperaldosteronism. The use of cortisone-based medication, beta blockers or acid pump inhibitors may lead to low aldosterone levels.

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Antigen detection Molecular genetic diagnostics

Automation

Infection diagnostics Allergy diagnostics

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Detection limit

The limit of blank (LoB) of the test system is 0.0025 pg/ml. The limit of detection (LoD) is 9.1 pg/ml.

Linearity

The linearity of the Aldosterone ELISA was determined by assaying at least 4 serial dilutions of patient samples (serum). The Aldosterone ELISA is linear at least in the investigated concentration range: 31.6 pg/ml to 1,152 pg/ml.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay variation coefficients (CV) using 4 serum samples. The intra-assay CVs are based on 24 measurements and the inter-assay CVs on 20 measurements repeated on 10 days.

Intra-a	ssay precision,	n=24	Inter-assay precision, n = 20		
Sample	Mean value (pg/ml)	CV (%)	Sample	Mean value (pg/ml)	CV (%)
1	81.2	9.4	5	80.8	12.8
2	284.5	9.1	6	209.0	10.7
3	403.0	5.5	7	454.5	11.4
4	529.5	6.9	8	677.3	11.7

Reference range

For the determination of normal values, 183 serum samples from healthy donors were analysed using the EUROIMMUN Aldosterone ELISA.

Every laboratory should use its own normal values established under specific ambient conditions.

Sample material	n	95% confidence interval
Serum (normal sodium, upright)	183	0–199 pg/ml

Method comparison

Autoimmune diagnostics

The EUROIMMUN ELISA (y) was compared with the reference method LC-MS/MS Aldosterone (x), the correlation was as follows (n = 31): y = 1.09x + 50.79; R² = 0.92.



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Reference, LC-MS/MS, aldosterone (pg/ml)

Automation

Allergy diagnostics