

Aldosterone ELISA



DRG

DRG ELISA

Aldosterone

Intended use:

The DRG Aldosterone ELISA is an enzyme immunoassay for the quantitative *in vitro* diagnostic measurement of Aldosterone in serum and plasma.

Summary and explanation of the test:

The steroid hormone Aldosterone is a potent mineral corticoid that is produced by the outer-section (zona glomerulosa) of the **adrenal cortex** in the **adrenal gland**. The synthesis and release are controlled by the renin-angiotensin system, plasma potassium concentration, the pituitary peptide ACTH, and by the blood pressure via pressure sensitive baroreceptors in the vessel walls of nearly all large arteries of the body. Aldosterone promotes the reabsorption of sodium and water from the distal tubules of the kidney into the blood, secretion of potassium into the urine, and increase of blood pressure by elevated circulating blood volume. Chronic overproduction and secretion of Aldosterone leads to hypertension.

Assay characteristics:

- Assay Principle: Competitive ELISA
- Dynamic Range: 5.7 - 1000 pg/mL of Aldosterone
- Total Assay Time: 2 hours
- Sample Volume: 50 µl of Serum or Plasma (EDTA, Citrate, Heparin)
- Mean Intra Assay Precision: 7.6
- Mean Inter Assay Precision: 9.5

Clinical relevance

Measurement of Aldosterone levels in serum in conjunction with plasma renin levels can be used to differentiate between primary and secondary aldosteronism.

Condition	Serum Aldosterone	Plasma Renin
Primary Aldosteronism	High	Low
Secondary Aldosteronism	High	High

The measurement of aldosterone in concert with selective suppression and stimulation tests can be used to further differentiate primary aldosteronism into two basic types:

- Primary aldosteronism caused by an adenoma of one or both adrenals
- Primary aldosteronism caused by adrenal hyperplasia.

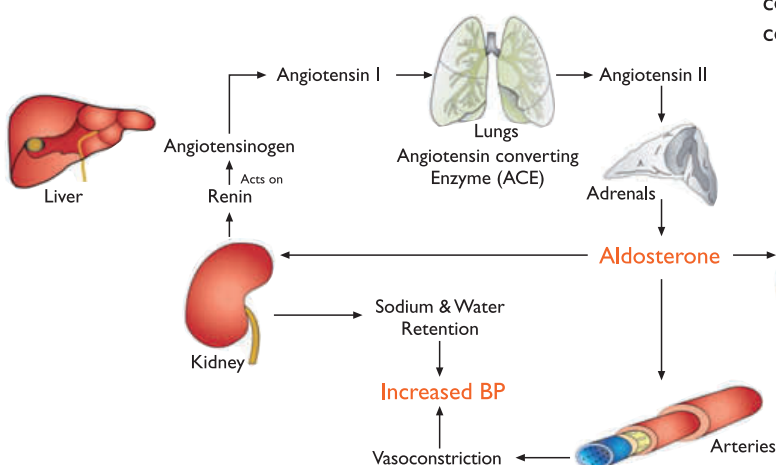
This differentiation is vital in the treatment and management of the disease. The adrenal adenomas respond well to surgery whereas hyperplastic disease of the adrenals is generally better managed medically. In summary, the precise and accurate measurement of serum aldosterone by enzyme immunoassay can be an important adjunct to a diagnostic laboratory battery for the differential diagnosis of hypertensive disease.

Principle of the test

The DRG Aldosterone ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding.

The microtiter wells are coated with a polyclonal antibody directed towards an antigenic site of the Aldosterone molecule. Endogenous Aldosterone of a patient samples competes with an Aldosterone -horsearadish peroxidase conjugate for binding to the coated antibody. After incubation, the unbound conjugate is washed off.

After addition of the substrate solution, the intensity of colour developed is inversely proportional to the concentration of Aldosterone in the patient sample.



Linearity

	Sample 1	Sample 2	Sample 3
Concentration (pg/mL)	600.5	546.2	672.0
Average Recovery	98.4	95.5	96.4
Range of Recovery (%)	from 95.5 to 103.0	87.8 103.6	86.0 102.5

Recovery

	Sample 1	Sample 2	Sample 3
Concentration (pg/mL)	82.7	96.1	167.9
Average Recovery	112.5	111.0	106.8
Range of Recovery (%)	from 108.2 to 114.6	108.9 114.5	92.4 114.8

Reproducibility

Intra Assay

The within assay variability is shown below:

Sample	n	Mean (pg/mL)	CV (%)
1	20	85.1	9.7
2	20	210.3	7.4
3	20	532.2	5.6

Inter Assay

The between assay variability is shown below:

Sample	n	Mean (pg/mL)	CV (%)
1	40	101.0	9.9
2	40	315.1	8.6
3	40	656.8	9.4

Dynamic Range

The dynamic range of the DRG Aldosterone ELISA is between 5.7-1000 pg/mL.

Expected normal values

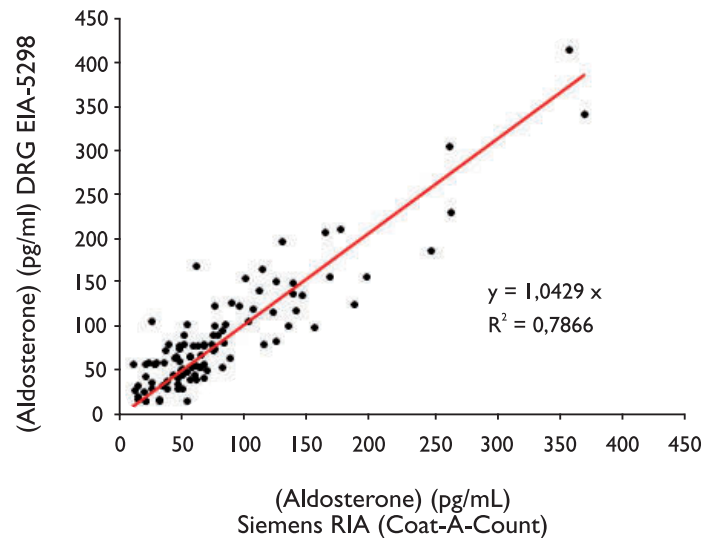
In a study conducted with apparently normal healthy adults, using the DRG Aldosterone ELISA the following values are observed:

Healthy Adults	Valid N	Mean (pg/mL)	Median (pg/mL)	5 th Percentile (pg/mL)	95 th Percentile (pg/mL)
Supine position	60	62.8	50.9	12.0	157.5
Upright position	60	68.8	52.5	13.3	231.4

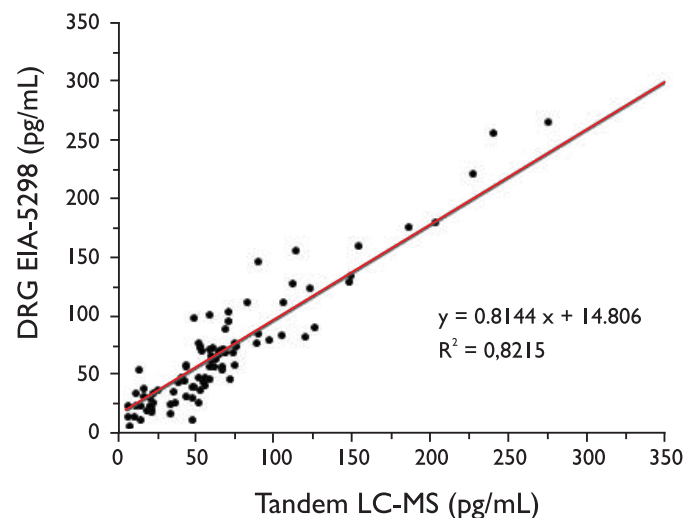
Conversion Factor: pg/mL x 2.775 → pmol/L

Method Comparison Aldosterone

DRG Aldosterone EIA-5298 showed good correlation to Siemens RIA (COAT-A-COUNT) with correlation coefficient of 0.904 (n=107)



DRG Aldosterone EIA-5298 showed good correlation to Tandem LC-MS with correlation coefficient of 0.906 (n=90)



Specificity

Aldosterone	100 %
3 beta, 5 alpha Tetrahydroaldosterone	17.2 %
3 beta, 5 beta Tetrahydroaldosterone	0.12 %
Prednisone	0.017 %
Cortisol, 11-Deoxycortisol, 11-Deoxycorticosterone	< 0.003 %
Progesterone, Prednisone, 17-OH Progesterone	< 0.003 %
Testosterone, Androstendione	< 0.003 %

Sensitivity

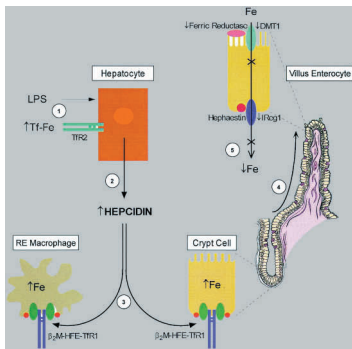
The analytical sensitivity of the DRG active Aldosterone ELISA is 5.7 pg/mL.

DRG ELISAS

Tumormarker	Gyn. Endocrinology	Prenatal Supervision	Saliva Diagnostics
CYFRA 21-1 CA 72-4 CA 15-3 CA 125 CA 19-9 CEA TPS TPA PSA free PSA NSE Chromogranin	Estradiol Progesterone 17a-OH Progesterone DHEA-S Testosterone DHEA Estrone Androstendione DHT SHBG DHEA LH, FSH, PRL	PAPP-A Free β HCG AFP Free Estriol HCG HPL PLGF	Cortisol Estradiol Testosterone DHEA Progesterone 17a-OH Progesterone Estrone
			Bone Metabolism 25-OH Vitamin D Total
			Hypertension Renin Aldosterone

New

New



ELISAS that perform

DRG develops and manufactures diagnostic ELISA test kits for use in clinical and research laboratories. The experience of our production and management team guarantees to provide high quality products, competitive prices and excellent customer service.

DRG works to DIN EN ISO 9001:2000, ISO 13485:2003 and ISO 13485:2003 under CMDCAS standard, certified by TÜV Rheinland Product Safety GmbH, an indication of our commitment to customer service, quality control and improved health care.

DRG Diagnostics

DRG Instruments GmbH, founded in 1973 by Dr. Geacintov, subsidiary of DRG Intl. Inc., USA, is a diagnostics manufacturer of ELISAS. The DRG Group operates through a network of DRG subsidiaries in Germany, Poland, Russia and the Czech Republic and through distributors worldwide.



DRG Subsidiaries

Czech Republic
DRG spol. s.r.o.,
Brno

China
DRG Intl. China,
Beijing

Poland
DRG MedTek South Poland,
Gliwice
DRG MedTek Sp. zo.o.,
Warszawa

Russia
DRG TechSystems,
Moscow
DRG Biomed 0.0.0.,
St. Petersburg



DRG Instruments GmbH, Germany
Frauenbergstraße 18
D-35039 Marburg
Tel. +49 (0) 64 21/17 00 0,
Fax +49 (0) 64 21/17 00 50
Internet: www.drg-diagnostics.de
E-mail: drg@drg-diagnostics.de

Distributed by



DRG International Inc. USA
841 Mountain Avenue
Springfield, N.J. 07081 U.S.A.
Tel: +1 (9 08) 2 33-20 79
Fax: +1 (9 08) 2 33-07 58
Internet: www.drg-international.com
E-Mail: corp@drg-international.com