new ALDOSTERONE ELISA kit

DBC's NEW ALDOSTERONE ELISA KIT INCLUDES A READY-TO-USE CONJUGATE AND BLOCKING AGENTS

REF CAN-ALD-500



a significant proportion of hypertensive individuals suffer from resistant hypertension due to factors such as non-compliance, poor nutritional practice (high salt, alcohol, licorice) or secondary hypertension (20% of

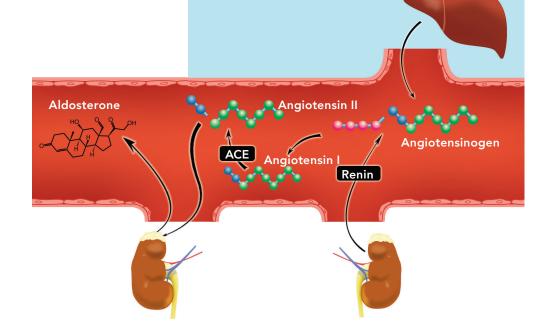
all resistant hypertension cases). Diagnosing the cause of hypertension is of paramount importance to select the correct therapy.

Heart failure, stroke, renal conditions and dementia are some of the common consequences of uncontrolled hyper-tension; the occurrence of these conditions however, can be reduced when the underlying source of resistant hypertension is identified and a follow up therapy is applied.

THE RENIN-ANGIOTENSIN-ALDOSTERONE

AXIS plays a key role in resistant hypertension.

During normal homeostasis, renin is released under conditions of dehydration or low blood pressure (see figure below). Renin enzymatic activity then promotes the cleavage of Angiotensinogen and generation of Angiotensin I, which in turn is transformed into Angiotensin II and activates aldosterone release (which causes salt and water retention, and excretion of potassium, magnesium, and other ions).



When this metabolism is altered, three patterns of aldosterone and renin activity levels can be produced:

- 1. Primary hyperaldosteronism causes salt and water retention, feeding back to suppress renin activity.
- 2. Renal or renovascular causes of hypertension lead to elevated renin activity with secondary hyperaldosteronism.
- 3. Impairment of the renal tubular epithelial sodium channel (such as Liddle's syndrome) causes salt and water retention and suppresses both renin activity and aldosterone.

ALDOSTERONE MEASUREMENT is therefore an outstanding tool to determine the physiological causes of resistant hypertension, permitting the physician to choose the most appropriate therapy.¹⁻³

The following algorithm was used in a study of resistant hypertension in three hypertension clinics in Africa, in a study funded by Grand Challenges Canada. This approach increased systolic blood pressure control from 25% in usual care to 75% in individualized care based on aldosterone/renin profiling.⁴

| | Primary Aldosteronism | Liddle's Variants, Adducin Polymorphisms | Renal or Renovascular |
|-------------|-----------------------|---|--------------------------|
| Aldosterone | High | Low | High |
| Renin | Low | Low | High |

| Primary treatment | Aldosterone antagonists: | Amiloride |
|-------------------|------------------------------|-------------------------------|
| | Spironolactone | Angiotensin receptor blockers |
| | Eplerenone | Aliskiren |
| | (Amiloride for men where | (rarely revascularization) |
| | eplerenone is not available) | |
| | (rarely surgery) | |
| | | |

The precise and accurate measurement of aldosterone by enzyme immunoassay can be an important tool for the diagnosis of the underlying cause of hypertension, leading to appropriate therapy.

This approach not only improves blood pressure control, thus reducing the risk of stroke, heart failure and renal failure, but also reduces adverse effects of medication and may reduce the cost of medication by identifying specific therapy.

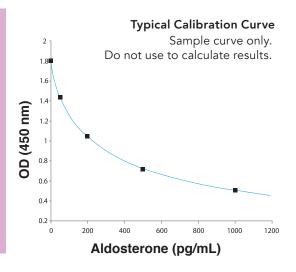
DBC has launched a new Aldosterone kit (CAN-ALD-500) that includes a ready-to-use conjugate and blocking agents that prevent interferences by sample endogenous substances.

ASSAY PRINCIPLE

The new DBC Aldosterone ELISA kit (CAN-ALD-500) is a competitive immunoassay that uses innovative chemistry and a specific anti-aldosterone antibody that binds quantitatively to all isomers of aldosterone.

PROCEDURE

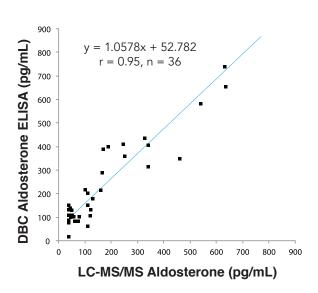
50 μL calibrators/samples
100 μL of Ready-to-Use Conjugate
1 h room temperature/shaking
Wash 3x
150 μL TMB
20 min room temperature/shaking
50 μL of stop solution
Read in a plate reader at 450 nm



PERFORMANCE

| Parameter | DBC | Competitor 1 | Competitor 2 | LC-MS/MS | |
|-----------------------|----------|--------------|----------------|----------|--|
| Total assay time | 1h 20min | 1h 30min | Overnight + 1h | N/A | |
| Ready to use reagents | Yes | Yes | No | N/A | |
| Dynamic Range, pg/mL | 10–1000 | 5.7–1000 | 4.7–250 | 40–1000 | |
| Sample size, µL | 50 | 50 | 100 | 600 | |
| Sample pre-treatment | | | | | |
| Serum, Plasma | No | No | Yes | Yes | |
| Urine | No | Yes | Yes | Yes | |
| Sensitivity, pg/mL | 9.1 | 5.7 | 4.7 | 40 | |
| Precision, CV% | | | | | |
| Intra-assay | 5.5–9.4 | 3.8–9.7 | 4.5–6.6 | | |
| Inter-assay | 7.6–12.8 | 8.6–11.5 | 10.8–16.3 | | |

Comparative analysis of serum samples results between the new DBC Aldosterone kit (CAN-ALD-500) and LC-MS/MS performed at Mayo Clinic.



PERFORMANCE

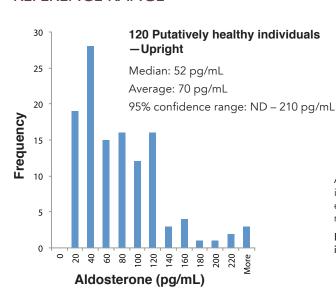
Evaluation of International Controls

The RfB international controls were assayed with the DBC ELISA kit (CAN-ALD-500). The results for the kit are the mean ± SD of 4 independent experiments (pg/mL).

The results match both LC-MS/MS results from Mayo Clinic and fall within the range of results established from all methods.

| RfB lot | HM 2/15 A | HM 2/15 B | |
|------------------------|-----------------|-----------|--|
| LC-MS/MS (Mayo Clinic) | 570 | 110 | |
| | Target | | |
| | 634 | 122 | |
| LC-MS/MS (RfB) | Range (16P–84P) | | |
| | 419–764 | 111–172 | |
| | Target | | |
| All Methods (RfB) | 529 | 110 | |
| , , | Range (16P–84P) | | |
| | 468–658 | 90–144 | |
| CAN-ALD-500 (DBC) | 636 ± 70 | 105 ± 16 | |

REFERENCE RANGE



Aldosterone concentration range in the population depends on the ethnic and social composition and nutritional factors.

Each laboratory must determine its own reference ranges!

LITERATURE

- 1. Spence JD. Lessons from Africa: the importance of measuring plasma renin and aldosterone in resistant hypertension. *Can J Cardiol*. 2012; 28(3):254–7.
- 2. Spence JD. Physiologic tailoring of therapy for resistant hypertension: 20 years' experience with stimulated renin profiling. *Am J Hypertens*. 1999; 12:1077–83.
- 3. Spence JD. Physiologic tailoring of treatment in resistant hypertension. *Current Cardiology Reviews*. 2010; 6:119–123.
- 4. Jones ES, et al. Physiologically Individualized Therapy for Resistant Hypertension in Africa. Hypertension Teaching Seminar Organized by the International Society of Hypertension (ISH) Africa Regional Advisory Group in collaboration with the European Society of Hypertension (ESH), the International Forum for Hypertension Control and Prevention in Africa (IFHA) and the Mozambican Heart Association (AMOCOR); April 18–19, 2016; Maputo, Mozambique 2016.





Catalogue number: CAN-ALD-500

Number of test wells: 96

Sensitivity: 9.1 pg/mL
Sample Volume: 50 µL
Total assay time: 80 mins.
Validated against: LC-MS/MS



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