SPECTRUM

The Creative Approach to Bioscience

Angiotensin Converting Enzyme (ACE)

REF: 212 001 (1 X 23 ml) 50 Test
REF: 212 002 (1 X 45 ml) 100 Test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum reagent for the quantitative in vitro determination of angiotensin converting enzyme activity in serum.

Background

Angiotensin converting enzyme (ACE), also known as kininase II, is a dipeptidyl carboxypeptidase (EC 3.4.15.1) with amolecular weight of at least 129,000. The structure of this glycoprotein shows a single polypeptide chain, a polysaccharide residue and a zinc atom. ACE is present in many different cell types such as neuronal cells and renal proximal tubular cells, but is mostly found in endothelial cells. It is attached to the endothelial surface membrane by an anchor peptide and can be cleaved to be released into the blood circulation as soluble enzyme. Serum ACE activity issignificantly elevated in patients with untreated active disease. Spontaneous orcorticosteroid-induced remission of sarcoidosis is indicated by decreasing serum ACE values. Only few patients with lung diseases such as tuberculosis, fibrosis and tumors, show elevated serum ACE values. Measurement of serum ACE activity is therefore extremely useful as an aid in the diagnosis and in the management of sarcoidosis. The determination of ACE activity in Gaucher's disease is not used as a screening procedure, but its value is significantly increased in most cases if sarcoidosis can be excluded6.ACE is inhibited by drugs from the family of Captopril. Agents acting through this mechanism are now well established inthe treatment of heart failure and hypertension. Serum ACE activity can be a useful parameter for monitoring the effectof these hypotensive drugs inhibiting ACE.

Method

FAPGG substrate method.

Assay Principle

FAPGG $\xrightarrow{ACE}$ FAP + GG

The decrease in absorbance at 340 nm is directly related to the activity of ACE.

Reagents

Reagent (R)

Buffer	100 mmol/L
FAPGG	1 mmol/L

Calibrator (C)

Actual concentration is stated on the vial label.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

The reagent is ready to use.
Stable up to the expiry date when stored at 2-8°C.
The assay kit reagents are stable for 30 days on board.
ACE Calibrator: Dissolve the contents with distilled water as mentioned on vial label. Cap vial and mix gently to dissolve contents. Wait for 30 minutes before use.
Stability of Calibrator once reconstituted 2 weeks at -20°C.

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Specimen Collection and Preservation

Serum samples. EDTA will inhibit the activity of ACE.
Serum samples are stable for a month at 2-8^{O}C, or for half a year at -20^{O}C.

Procedure

Wavelength	340 nm
Optical path	1 cm
Temperature	37 ^{O}C
Sensitivity	5 U/L
Linearity	150 U/L

Procedure

Pipette in a test tube:

Reagent	450 µl
Specimen	50 µl

Incubate at 37 ^{O}C for 3 minutes

Read initial absorbance A1 , After exactly 7 minutes later, read absorbance A2 of standard or specimen.

ΔA= A2-A1

Calculation

$$U/l = \frac{\Delta A \text{ specimen}}{\Delta A \text{calibrator}} \times \text{calibrator value}$$

Quality Control

Normal & abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatiblity)

	Level 1	Level 2
n	20	20
Mean (U/L)	46.03	79.09
SD	0.53	0.78
CV%	1.15	0.99

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	49.7	78.98
SD	0.90	1.16
CV%	1.81	1.47

Methods Comparison

A comparison between Spectrum Diagnostics Angiotensin converting enzyme and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.976 was obtained.

Sensitivity

When run as recommended, the sensitivity of this assay is 5 U/l.

Linearity

The reaction is linear up to Angiotensin converting enzyme concentration of 150 U/l. Specimens showing higher concentration should be diluted 1+1 with physiological saline and repeat the assay (result×2).

Interfering substances

No significance interferance was observed bythe presence of:

Haemoglobin 12.5 mg/dl
Intralipid 150 mg/dl
Total bilirubin 5 mg/dl

Expected Values

12- 68 U/L

ACE will be higher when the age is below 18.

Each laboratory should establish appropriate reference intervals related to its population.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
P501: Dispose of contents according to national/interna-tional regulations.

References

1.Baur, X. et al.: Value of angiotensin I - converting enzyme in the diagnosis of sarcoidosis. Klin. Wochenschrift 58, 199 (1980).
2.Kamoun, P.P. et al.: Measurements of angiotensin converting enzyme in captopril treated patients. Clin Chim. Acta 118, 333-336 (1982).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
212 001	50 test
212 002	100 test

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