Angiotensin Converting Enzyme (ACE)
ACE Reagent Test Kit

Intended Use
For in vitro quantitative determination of angiotensin converting enzyme activity in serum.

Order Information

Item Code.	Pack Size
117219934841	R: 1 x 10 mL
117219934840	R: 10 x 10 mL

Summary
Angiotensin converting enzyme (ACE), also known as kininase II, is a dipeptidyl carboxypeptidase (EC 3.4.15.1) with a molecular 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 is significantly 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 excluded.ACE is inhibited by drugs from the family of Captopril. Agents acting through this mechanism are now well established in the treatment of heart failure and hypertension. Serum ACE activity can be a useful parameter for monitoring the effect of these hypotensive drugs inhibiting ACE.

Method
FAPGG substrate

Principle

$$\text{FAPGG} \xrightarrow{\text{ACE}} \text{FAP} + \text{GG}$$

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

Storage Instruction and Reagent Stability
Reagents are stable until their expiration date when stored at 2-8^{0}c. Onboard stability is 28 days.

Reagent Preparation
ACE reagent comes in a single reagent system, ready –to-use for both manual method and automated chemistry analyzers.

Reagent Composition

Content	Concentration
Angiotensin	5 mmol/L
Boric acid buffer	200 mmol/L

Sample Material
Ideal for serum sample. Avoid using plasma samples containing EDTA. Serum ACE activity shall be stable for 7 days at 2-8°C.

Note: In order to prevent lipemia, blood samples should be taken from patients on an empty stomach. Lipid blood serum needs pretreatment because lipid blood Interfernin testing.

Traceability
The assigned value of the standard has been traceable to the reference method.

Assay Procedure
Application sheets for automated systems are available on request.

Wavelength (Main)	340 nm
Optical path	1 cm
Temperature	37^{0}C

Measurement

	Blank	Sample /Calibrator
Sample /Calibrator	-	25µL
Dist.water	25 µL	-
Reagent 1	225 µL	225 µL
Mix, Incubate for 3 mins & read absorbance A1		
Incubate for another 7 mins & read absorbance A2		

Calibrator and Controls
1. For the calibration use the DiaSys TruCal ACE calibrator. Calibrator values are traceable to fibrinogen which was degraded by plasmin.
2. For internal quality control, DiaSys TruLab ACE controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Reference Range

Adults	
18-70 yrs	12-68 µ/L

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

Performance Characteristics
Measuring Range
The test have been developed to determine the ACE concentration within a measuring range from 3 - 150 U/L.

Sensitivity/Limit of Detection
The lower limit of detection is 3 U/L.

Precision
Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 1 days, and each batch was measured for 5 times. The results are as follows:
A) Precision (N=10)

	Mean(U/L)	CV(%)
Level 1	42.28	3.24
Level 2	103.18	0.90

B) Intraday precision (N=5)

	Mean(U/L)	CV(%)
Level 1	36.97	1.96
Level 2	94.86	1.58

Method Comparison
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained: Y=0.9995X-1.5846, R2=0.9761; 91 patient samples were analyzed.

Specificity/Interferences
A Reagent blank may be performed by replacing sample or standard with double deionized water. The following analyze were tested up to the levels indicated and found not to interfere: Hemoglobin: 12.5 mg/dL, Intra-lipid: 150 mg/dL, Total bilirubin: 0.56 mg/dL.

Warning and Precautions

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose of test tubes and other instruments that have been in contact with test specimens in accordance with relevant medical waste disposal regulations. The following treatment methods can be selected:
   Use an autoclave to autoclave at 121°C for 15 minutes (but do not use autoclave to treat waste containing hypochlorous acid solution), or soak in hypochlorous acid solution (effective concentration greater than 1000ppm) for one hour the above.

Limitations

Do not use haemolysed samples.

Literature

1. Zhou Yongnian, etc. The detection and clinical significance of angiotensin converting enzyme, Practical Medical Technology, 2001, 8(6): 427~428
2. Li Zhongxin, etc., The Clinical Significance of Angiotensin Converting Enzyme Determination, Laboratory and Clinic, 1991, 6(1): 26-28
3. Sun Fengxiang, et al., Discussion on the effect of activator and different types of inhibitors on the catalytic reaction of angiotensin-converting enzyme, Journal of Mathematical Medicine, 2003, 16(2): 157~159

Notes on Symbols and Marks

	Consult instructions for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	*In vitro diagnostic* medical device
	Temperature limit
	Do not re-use
CONT.	The pack contains
	Recycle
	Date of manufacturer

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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