ACE Estimation Kit

Angiotensin Converting Enzyme (ACE)

(FAPGG / Kinetic method)

Intended Use

Kit for the quantitative determination of Angiotensin Converting Enzyme (ACE, EC3.4.15.1, dipeptidyl carboxypeptidase I) in human serum or plasma.

Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P - ACE-10	10 ml	Mono Reagent
P - ACE-25	25 ml	
P - ACE-50	2 x 25 ml	

PRODUCT FEATURES:

- Liquid Stable, Ready to use Mono Reagent with calibrator
- 10 Minutes Fixed Time Assay (300 Sec + 300 Sec.)
- Linearity: 150 IU/L
- Measuring Wavelength 340 nm.
- Serum and Heparinized Plasma are the specimens
- Available as multipurpose reagents and dedicated system packs

Clinical Significance

Angiotensin converting enzyme (ACE, EC3.4.15.1, dipeptidyl carboxypeptidase) is a glycoprotein peptidyldipeptide hydrolase that cleaves histidylleucine dipeptide from angiotensin I, a relatively inactive decapeptide. The latter is converted to the potent vasoconstrictor, angiotensin II. ACE also inactivates bradykinin. Elevated levels of ACE activity occur in serum of patients with active sarcoidosis, and occasionally in premature infants with respiratory distress syndrome, in adults with tuberculosis, Gaucher's disease, leprosy, and in many other patogic conditions involving lung and liver diseases. Significantly low levels were reported by Siefkin et al., in many acute and chronic cases of lung injuries. Serial measurements of ACE in 71 patients showed that significantly decreasing levels over successive days were associated with a very high mortality rate. A single ACE measurement does not necessarily predict the presence or extent of lung injury, or aid in diagnosis of prognosis. However, serial levels are of value prognostically. Several methods have been devised for measuring ACE activity including radioimmunoassay and competitive enzyme-linked immunoassay. The procedure described herein is a rapid, convenient spectrophotometric method utilizing the synthetic tripeptide substrate N-[3-(2-furyl)acryloyl]-L-phenylalanylglycylglycine (FAPGG).

ASSAY 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.

TYPE OF SPECIMEN:

Serum is the preferred specimen. Heparinised plasma can also be used.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. **Serum/Plasma should be separated from blood cells within 2 hours after collection. (Mandatory).**

Stability: up to 4 weeks at 4C.

Test the specimen for ACE Values immediately after separating it from the blood cells.

REAGENT COMPOSITON

Contents	Concentration of Solutions
Buffer	100mM
FAPGG	1mM
Calibrator	lot specific
Control	lot specific

Stability And Preparation Of Reagents

All reagents are ready to use. Stable up to the expiry date when stored at 2-8°C
The assay kit reagents are table for 30 days on board.

Calibration

Recommend that this assay should be calibrated using Calibrator.

QUALITY CONTROL

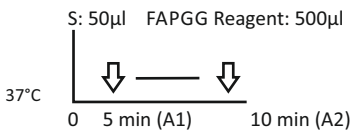
To ensure adequate quality control, normal and elevated control should be run as unknown samples

SYSTEM PARAMETERS

Temperature		37°C
Primary Wavelength		340 nm
Assay Type		Fixed Time
Calibrator Conc		On the Label
Direction		Decrease
Sample : Reagent		Ratio 1 : 10
Eg:	**Sample Vol** 100 µL	
	Reagent Vol	1000 µL
Delay/Lag Time		300 Seconds
Read Time		300 Seconds
Reagent Blank Limits		Low 0.0 AU
(340nm, 1cm lightpath)	High 2.0 AU	
Linearity		1 -150 U/L

Assay Procedure

Wave Length (main): 340 nm



1. Incubate 50 µl sample with 500 µl reagent at 37°C for 5 minutes and read A1 at 340 nm (Delay)
2. Incubate for 5 min and read A2 at 340 nm (Measuring)
3. Calculate the change absorbance A=A1-A2

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CALCULATIONS

Results are calculated, usually automatically by the instrument, as follows:

$$ACE = \frac{\text{A1-A2 of Sample}}{\text{A1-A2 of Calibrator}} \text{ - x Calibrator Concentration}$$

SENSITIVITY: The minimum detectable concentration of ACE with an acceptable level of precision was determined as 8 U/L.

Correlation: This method (Y) was compared with another commercially available method (x) and the following linear regression equation

obtained: Y=0.9995X-2.2779, and a correlation coefficient of 0.9751, 100 patient samples were analyzed.

Safety Precautions And Warnings

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.

2. Solution contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

3. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

Limitations:

Studies to determine the level of interference from haemoglobin, bilirubin and lipaemia were carried out. The following results were obtained:

Haemoglobin: No interference from haemoglobin up to 725 mg/dL.

Conjugated Bilirubin: No interference from conjugated bilirubin up to 25 mg/dL).

Lipaemia: No interference from lipaemia, measured as triglycerides, up to 1000 mg/dL

Ascorbic Acid: No interference from Ascorbic Acid up to 5 mg/dL

Reference Range: 8-68 U/L

ACE will be higher when the age is below 18.Each laboratory should establish an expected range with a set of standards

Performance Data:

The following data was obtained using the Infinity ACE Liquid Stable Reagent on a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser used.

Imprecision:

Imprecision was evaluated over a period of 20 days using two levels of commercial control and following the NCCLS EP5-T procedure

Within Run:

N=20	LEVEL I	LEVEL II
Mean (umol/L)	46.03	79.09
SD	0.53	0.78
CV (%)	1.16	0.99

Between run precision:

N=20	LEVEL I	LEVEL II
Mean (umol/L)	49.34	83.62
SD	1.03	2.97
CV (%)	2.09	3.55

Accuracy:

Comparison studies were carried out using a similar commercially available reagent as a reference. Serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Number of sample pairs	108
Range of sample results	1 - 114 U/L
Mean of reference method results	39.2 U/L
Mean of Infinity ACE results	34.3 U/L
Slope	0.961
Intercept	-3.3 U/L
Correlation coefficient	0.966

Linearity:

When run as recommended the assay is linear between 1 and 150 U/L of ACE.

Sensitivity:

When run as recommended the sensitivity of this assay is 0.084 ΔmA/min per U/L (1cm light path, 340nm).

References

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