Pariksha Biotech
A game changer in IVD

ACE Estimation Kit

High-Q Angiotensin Converting Enzyme (ACE)
(FAPGG / Kinetic method)

HIGH®
Command on Quality

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

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 Composition:

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

Stability And Preparation Of Reagents
All the reagents are ready to use and are stable up to the expiry date when stored at 2-8°C

Calibrator:
Calibrator is available as Lyophilized Calibrator. Add 1 ml Distilled water to reconstitute. Reconstituted Calibrator is stable for I month at 2-8°C and for 3 Months once frozen at --20° in small aliquotes

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 (Lot Specific)
Direction	Decrease
Sample Vol	100 µL
Reagent Vol	1000 µL
DelayTime	300 Seconds
Read Time	300 Seconds
Linearity	1 -150 U/L
Low Normal	8.0 U/L
High Normal	68.0 U/L

Test Procedure:

Reagent	Calibrator	Sample
FAPGG Reagent	500 µl	500 µl
Reconstituted ACE Calibrator	50 µl	----
Sample	-----	50 µl

Mix and immediately aspirate in to the analyzer.

Delay 300 Sec (A1)

Measuring 300 Sec (A2)

Calculate the change absorbance A=A1-A2 for Calibrator and Sample

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

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

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.

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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:

1. Muller BR. Ann Clin Biochem 2002;39:436-43
2. Studdy PR and Bird R. Ann Clin Biochem 1989;26:13-18
3. Beneteau B et al. Clin Chem 1986;32:884-6
4. Butter J and Stuart S. CLin Chem 1993;39:312-6
5. Maguire GA and Price CP Ann Clin Biochem 1985;22:204-10
6. Young DS, Effects of Drugs on Clinical Laboratory Tests. Third Edition.1990; 3-37

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**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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