LiquiMAX ACE

(Angiotensin Converting Enzyme)
(FAPGG / Kinetic method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVACE-25	25 ml	Mono Reagent

INTENDED USE

LiquiMAX ACE is an in-vitro diagnostic kit for the quantitative determination of Angiotensin Converting Enzyme in human serum or plasma.

PRODUCT FEATURES:

1. Liquid Stable, Ready to use Mono Reagent with calibrator
2. 10 Minutes Fixed Time Assay (300 Sec + 300 Sec.)
3. Linearity: 150 U/L
4. Measuring Wavelength 340 nm.
5. Serum and Heparinized Plasma are the specimens
6. 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).

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 AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions are maintained.

KIT COMPONENTS

1. ACE Reagent
2. ACE Calibrator : Concentration as stated on the label

COMPOSITON

Buffer	100mM
FAPGG	1mM
Calibrator	lot specific
Control	lot specific

REAGENT RECONSTITUTION & STABILITY

All reagent are ready to use. Stable upto the expiry date when the reagent is stored properly at 2-8°C.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance less than 0.8 at 340 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

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 4°C.

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

SYSTEM PARAMETERS

Temperature	:	37°C
Primary Wavelength	:	340 nm
Assay Type	:	Fixed Time
Calibrator Conc	:	On the Label
Direction	:	Decrease
Sample Vol	:	100 µL
Reagent Vol	:	1000 µL
Delay/Lag Time	:	300 Seconds
Read Time	:	300 Seconds
Reagent Blank Limits	:	Distilled Water
Linearity	:	150 U/L

TEST PROCEDURE

Take the following in to clean glass test tube

ACE Reagent	500 µl
Serum / Plasma	50 µl

Mix well & incubate at 37°C for 5 minutes and read A1 after 300 Seconds. A2 300 seconds. As follows.

A1 - Exactly after 300 Seconds
A2 - Exactly after every 300 seconds

CALCULATIONS

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

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

EXPECTED VALUES : 8-68 U/L

QUALITY CONTROL & CALIBRATION

To ensure adequate quality control, normal and elevated control should be run as unknown samples
Recommend that this assay should be calibrated using Calibrator.

PERFORMANCE CHARACTERISTICS

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.

1. Linearity

Linearity : 150 U/L

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 1 U/L

3. Interferences
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

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

Intra-Assay

N=20	Mean (U/L)	SD (U/L)	CV%
Control serum 1	46.03	0.53	1.16
Control serum 2	79.09	0.78	0.99

Inter-Assay

Sample	Mean (U/L)	SD (U/L)	CV%
Control serum 1	49.34	1.03	2.09
Control serum 2	83.62	2.97	3.55

5. Method Comparison:
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

LIMITATIONS
Measuring range: 1-150 U/L. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES
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.

REFERENCE
1. Ferlitsch, A. et al.: Angiotensin converting enzyme (ACE), a blood test for diagnosis of sarcoidosis. Klin. Wochenschrift 58, 195-198 (1980).
2. Baur, X. et al.: Value of angiotensin I - converting enzyme in the diagnosis of sarcoidosis. Klin. Wochenschrift 58, 199 (1980).
3. Holmquist B, Bunning P, Riordan JF: A continuous spectrophotometric assay for angiotensin converting enzyme. Anal Biochem , 540 (1979).
4. Liebermann, J., Beutler, E.: Elevation of serum angiotensin converting enzyme in Gaucher's disease. N.Engl. J. Med. 294, 1442-1444 (1976). 5. Kamoun, P.P. et al.: Measurements of angiotensin

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
Σ	Contains sufficient no. of test		

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