ACE

Angiotensin Converting Enzyme - Liquid Reagent

CE

In Vitro Diagnostic reagent for the quantitative determination of Angiotensin Converting Enzyme (ACE) in serum and plasma. Store at 2-8ºC .

REF: ACE-101L

Summary:

Angiotensin converting enzyme is a glycoprotein peptidyldipeptide hydrolase that cleaves histidylleucine dipeptide from angiotensin I to angiotensin II, a potent vasoconstrictor. ACE also inactivates bradykinin. Elevated levels of ACE activity occur in serum of patients with active sarcoidosis, and occasionally in premature children with respiratory distress syndrome, in adults with tuberculosis, Gaucher's disease, leprosy, and in many other pathologic conditions involving lung and liver diseases.

Principle:

Furylacryloylphenylalanylglycylglycine (FAPGG) is hydrolysed to Furylacryloylphenylalanine (FAP) and Glycylglycine (GG). Hydrolysis of FAPGG results in a decrease in absorbance at 340nm. The rate of decrease in absorbance is directly proportional to ACE activity in the sample.

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

Composition:

Reagent: Boric Acid Buffer pH 8.3 - 80 mmol/l, FAPGG - 0.75 mmol/l
Calibrator: ACE - Lot specific

Precautions:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Colourless clear liquid.
Any significant changes could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.

Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

Instruments:

Instrument applications are available upon request.

Preparation:

Reagent is ready to use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, component is stable until expiry date stated on the label.

Samples:

Serum, is the preferred sample. Heparinised plasma can also be used.
It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding sample handling. Sample should be collected in an appropriate sample container, with proper sample identification. Serum/Plasma should be separated from cells within 2 hours after collection.
Stability: up to 4 weeks at 4°C.

Equipment:

- ACE Control Level 1
- ACE Control Level 2
- Photometer
- General Laboratory Equipment

Procedure:

1. Assay conditions:
Wavelength: . . . . . 340 nm
Cuvette: . . . . . 1 cm. light path
Temperature . . . . . 30°C or 37°C

	Blank	Calibrator	Sample
R1 (µL)	1000	1000	1000
Sample (µL)	-	-	100
Calibrator (µL)	-	100	-

2.Gently mix and Incubate for 4 minutes, then measure the Optical Density (OD). Incubate for a further 5 minutes, mix and read OD
3. Calibration: Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Calculations:

$$\frac{OD_{Sample} - OD_{Blank}}{OD_{Calibrator} - OD_{Blank}} \times \text{Concentration of Calibrator} = \text{ACE Activity}$$

(Conversion factor: Qty in µKat/l = Qty in U/l x 0.0167).

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference values:

Over 14 years of age
U/l: 8 – 65
µkat/l: 0.13 – 1.10
Each laboratory should establish its own reference range. ACE results should always be reviewed with the patient's medical examination and history.

Performance characteristics:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.
Linearity:
This assay is linear up to 166 U/l (2.8 µkat/l)
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.
Interfering substances:
Results of study are as follows:
Bilirubin (mixed isomers): Less than 10% interference up to 600 µmol/l Bilirubin
Haemolysis: Less than 10% interference up to 1.25 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 1.25 g/l Intralipid.
Sensitivity:
The Lowest Detectable Level of ACE was estimated at 5.4 U/l (0.09 µkat/l).
Precision:

	Intra-assay			Inter-assay		
N=20	Mean (µmol/L)	SD	%CV	Mean (µmol/L)	SD	%CV
level 1	26.3	0.90	3.42	27	1.01	3.80
level 2	88.9	1.79	2.01	94	3.71	3.97

Method comparison:
Using 50 samples, a comparison, between this ACE test (y) and another commercially available test (x), gave the following results:
y = 1.015x + 7.690
r = 0.991
Sample range: 12 to 124 U/l

References:

1. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352, 384-385 and 965.
2. Maguire GA, Price CP. Ann. Clin. Biochem. 1985; 22:204-210.

Sorachim