

N BIO - ANGIOTENSIN CONVERTING ENZYME (ACE)

(Kinetic method)

| KIT NAME | KIT SIZE | CAT. NO |
|-------------|----------|------------|
| N BIO - ACE | 4 X 5 ml | MACE04005M |

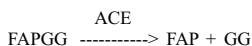


INTRODUCTION

Angiotensin converting enzyme is a central component of the rennin-angiotensin system (RAS). It assists in the conversion of angiotensin I to the active vasoconstrictor angiotensin II, which causes arteries to contract and increases blood pressure. Blood level of ACE may increase when sarcoidosis is present, so ACE test is often used to diagnose and monitor sarcoidosis. Main source of ACE are located mainly in the capillaries of the lungs, but can also be found in endothelial and kidney epithelial cells.

METHOD PRINCIPLE

The Kit utilizes enzymatic and kinetic reactions to measure the ACE level (U/L) in human serum. FAPGG has peak absorbance at 340nm. ACE breaks down the enzyme N-[3[2-Furyl]Acryloyl]-phe-gly-gly to FAP and GG and cause a change in absorbance at 340nm.



ACE level can be calculated by monitoring the rate of change of FAPGG at 340nm.

KIT CONTENTS

| | |
|---------------------|----------|
| R1 - ACE reagent | 4 x 5 ml |
| R2 - ACE calibrator | 1 vial |

R2-ACE Calibrator is in lyophilized form, Please refer the calibrator label for reconstitution and calibrator value.

WORKING REAGENT PREPARATION AND STABILITY

The reagent is ready to use.

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C, the reagents are stable for 1 month when the bottle vial has opened for usage.

CONCENTRATIONS IN THE TEST

| | |
|------------------------------------|------------|
| Tris-HCl buffer, pH8.0 | 100 mmol/l |
| N-[3[2-Furyl]Acryloyl]-phe-gly-gly | 2.5 mmol/l |
| Proclin 300 | 0.01% |
| NaCl | 0.9% |

WARNINGS AND NOTES

- Product for in vitro diagnostic use only.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 340 nm
- Thermostat at 25°C or 37°C
- General laboratory equipment

SPECIMEN

Serum free from hemolysis. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2-8°C for a day or frozen at -80°C for 1 month. Avoid repeated freeze-thaw cycle.

PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

| | |
|-------------|--------|
| Wavelength | 340 nm |
| Temperature | 37°C |
| Cuvette | 1 cm |

Pipette into the cuvette :

| Reagent | Calibrator (C) | Test (T) |
|--|----------------|----------|
| R1 ACE Reagent | 1000 µl | 1000 µl |
| Bring up the temperature of determination. Then add, | | |
| Calibrator | 100 µl | |
| Sample | | 100 µl |

Mix well and after 180 seconds incubation, measure the absorbance every 60 seconds interval for 3 readings and calculate the $\Delta A/\text{min}$ at 37°C.

CALCULATION BY CALIBRATOR

ACE concentration = $A(T)/A(C) \times \text{Calibrator concentration}$

REFERENCE VALUES

Serum upto 52 U/L

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To Ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

For Fully Automated analyzers by using dedicated GB's ACE Calibrator, can plot calibration curve and the same should be prepared every 8 weeks or with change of reagent lot number.

PERFORMANCE CHARACTERISTICS

Linearity: up to 150 U/L. For higher concentration of ACE dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

Accuracy: relative deviation $\leq 10\%$

Precision: Within Run: CV $\leq 6\%$; Run-to-Run: CV $\leq 5\%$

Blank absorbance : at 340nm, 10 mm optical diameter, OD ≤ 1.0

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Fabiny DL: et al: Clin Chem 1971, 17:696.
2. Vasiliades J: et al: Clin Chem 1976, 22:1664

SYSTEM PARAMETERS

| | |
|------------------------|-----------------------|
| Method | Kinetic |
| Wavelength | 340 nm |
| Zero Setting | Distilled water |
| Temperature Setting | 37°C |
| Incubation Temperature | 37°C |
| Incubation Time | ---- |
| Delay time | 180 secs |
| Read time | 180 secs |
| No. of Reading | 3 |
| Interval time | 60 secs |
| Sample Volume | 0.1 ml (100 ul) |
| Reagent Volume | 1.0 ml (1000 ul) |
| Standard Concentration | Refer Calibrator Vial |
| Units | U/L |
| Factor | ---- |
| Reaction slope | Decreasing |
| Linearity | 150 U/L |



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