

ACE Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL309AC	10 x 10 ml 1 x 1 ml	ACE ACE - Calibrator	2-8°C

INTENDED USE:

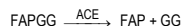
In Vitro Diagnostic reagent pack for the quantitative determination of Angiotensin Converting Enzyme (ACE) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: ¹

ACE is a peptidyl-dipeptidase that catalyses the conversion of inactive angiotensin I to the biologically active angiotensin II. ACE is an important enzyme in the Renin – Angiotensin – Aldosterone cycle. A number of ACE inhibitors are used in the control of hypertension. ACE is most frequently measured in patients with suspected Sarcoidosis in which, levels of three times the upper normal limit can be found. Successful subsequent treatment of this condition correlates well to declining ACE levels. Elevated ACE levels are also encountered in a number of other conditions including histoplasmosis, alcoholic cirrhosis, idiopathic pulmonary fibrosis, Hodgkin's disease and hyperthyroidism.

PRINCIPLE OF THE TEST: ²

Furylacryloylphenylalanylglucylglycine (FAPGG) is hydrolysed to Furylacryloylphenylalanine (FAP) and Glycylglycine (GG) as per equation. 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.



WARNINGS AND 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.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent	Boric Acid Buffer pH 8.3 FAPGG	80 mmol/l 0.75 mmol/l
Calibrator	ACE	Lot specific

REAGENT PREPARATION AND STABILITY:

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.

TYPE OF SPECIMEN: ¹

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 sample container, with proper specimen identification. Serum/Plasma should be separated from cells within 2 hours after collection.

Stability: up to 4 weeks at 4°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
ACE Control Level 1	GQC306	Photometer	N/A
ACE Control Level 2	GQC316	General Laboratory Equipment	N/A

Assay procedure:

Wavelength: λ: 340 nm

Temperature: 30°C or 37°C

Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	100 µl
Calibrator	----	100 µl	----

Gently mix and Incubate for 4 minutes, then measure the Optical Density (OD).
Incubate for a further 5 minutes, mix and read OD.

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.

N.B. ACE Calibrator can also be purchased as a separate item (Cat No AD968)

Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify 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 intervals established by the laboratory QC Program.

CALCULATION:

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

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

EXPECTED VALUES:

	U/l	µkat/l
Over 14 years of age	8 – 65	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:

Within Run N = 20	Mean (U/l)	SD	% CV	Between Run N = 20	Mean (U/l)	SD	% CV
Level 1	26.3	0.90	3.42	Level 1	27	1.01	3.80
Level 2	88.9	1.79	2.01	Level 2	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
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BIBLIOGRAPHY:

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

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Antibody
	Calibrator		Substrate
	Buffer		Aqueous Standard
	CE Mark - Device comply with the Directives 98/79/EC		Storage temperature
	Expiry Date (Last day of the month)		Reconstitute with
	Biological risk		Manufactured By
			Consult Instruction for Use

Manufactured By:



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