ACE
Hitachi® Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
AUD309	4 x 20 ml	ACE	2-8°C

INTENDED USE:

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

SUMMARY AND EXPLANATION: [2]

ACE is a peptidyl-dipeptidase that catalyses the conversion of active 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: [1]

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

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

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:

This assay is designed to run on Hitachi® clinical chemistry analysers. Refer to relevant user's manual or Laboratory internal practice for routine maintenance procedures. See enclosed application sheet.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent	Borate Buffer pH 8.3	80 mmol/l
	FAPGG	0.75 mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 is ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, unopened component is stable until expiry date stated on the label.
Stability On Board the Instrument: 28 days.

TYPE OF SPECIMEN: [2]

Serum, free of haemolysis and lipemia, 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 [2]: up to 4 weeks at 4°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
ACE Calibrator	AD968	Hitachi® Analyser	N/A
ACE Control Level 1	AQC306	Hitachi® Consumables	N/A
ACE Control Level 2	AQC316	General Laboratory Equipment	N/A

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

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.
- When Quality Controls are out of range.

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.
- At intervals established by the laboratory QC Programme.

CALCULATION:

The analyser automatically calculates the ACE activity in the sample.
(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 – 1.08

It is strongly recommended that each laboratory 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 164 U/l (2.74 µkat/l).
For samples with higher activity:
- Re-assay using, when available, "Rerun" function. Refer relevant user's manual for instructions.
- *Or*, 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 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	28.5	0.96	3.37	Level 1	29.4	1.49	5.05
Level 2	45.9	1.51	3.28	Level 2	45.2	2.85	6.30

Method Comparison:
Using 50 samples, a comparison, between this ACE test (y) and another commercially available test (x), gave the following results:

y = 1.020x + 5.148	r = 0.980	Sample range: 1 to 81 U/l

BIBLIOGRAPHY:

1. Price CP. Maguire GA. Ann. Clinical Biochemistry. 1985; 22.204-210.
2. Burtis CA., Ashwood ER.Tietz Fund. Of Clin. Chem. 5th ed.; 30-54 and 385.

SYMBOLS:

The following symbols are used in the labelling of Audit Diagnostics systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	CE	CE Mark - Device comply with the Directives 98/79/EC
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

anufactured By: AUDIT DIAGNOSTICS, Business & Technology Park, Carrigtwohill, Co. Cork (Ireland)
Tel: 00353 - (0) 21 – 4533 652 *Fax:* 00353 - (0) 21 – 4533 653
E-mail: info@auditdiagnostics.ie *Website:* www.auditdiagnostics.ie

CE

Revision No. 05. Issued on 04 December 2006

ACE Hitachi® Instruments Settings
Catalogue No(s): AUD309

Audit Diagnostics

HITACHI 704®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	[ACE]
ASSAY CODE	[2(2point)] - [14] - [32]
SAMPLE VOLUME	[20]
R1 VOLUME	[330] - [__] - [NO]
R2 VOLUME	[0] - [__] - [NO]
WAVELENGTH	[700] - [340]
CALIB. METHOD	[LINEAR]
STD (1) CONC. POS.	[__] - [__]
STD (2) CONC. POS.	[__] - [__]
STD (3) CONC. POS.	[0] - [0]
STD (4) CONC. POS.	[0] - [0]
STD (5) CONC. POS.	[0] - [0]
STD (6) CONC. POS.	[0] - [0]
UNITS	[__]
SD LIMIT	[0.1]
DUPLICATE LIMIT	[220]
SENSITIVITY LIMIT	[0]
ABS LIMIT (INC/DEC)	[0] - [DECREASE]
PROZONE LIMIT	[0] - [LOWER]
EXPECTED VALUE	[__] - [__]
INSTRUMENT FACTOR	[1.00]

[__] User Defined.

HITACHI 717®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	[ACE]
ASSAY CODE	[2(2point)] - [22] - [50]
SAMPLE VOLUME	[25] - [2]
R1 VOLUME	[250] - [__] - [NO]
R2 VOLUME	[0] - [__] - [NO]
WAVELENGTH	[700] - [340]
CALIB. METHOD	[LINEAR]
STD (1) CONC. POS.	[__] - [__]
STD (2) CONC. POS.	[__] - [__]
STD (3) CONC. POS.	[0] - [0]
STD (4) CONC. POS.	[0] - [0]
STD (5) CONC. POS.	[0] - [0]
STD (6) CONC. POS.	[0] - [0]
SD LIMIT	[0.1]
DUPLICATE LIMIT	[220]
SENSITIVITY LIMIT	[0]
ABS LIMIT (INC/DEC)	[0] - [DECREASE]
PROZONE LIMIT	[0] - [LOWER]
EXPECTED VALUE	[__] - [__]
PANIC VALUES	[__] - [__]
INSTRUMENT FACTOR	[1.00]

[__] User Defined.

HITACHI 911®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST CODE		[ACE/G]
ASSAY CODE		[2 Point End] - [10]
WAVELENGTH (SUB-MAIN)		[700] - [340]
ASSAY POINT		[14] - [31]
DILUTION		[__] - [__]
SAMPLE VOLUME (µL)		[25] - [__]
ABS LIMIT		[32000] - [DECREASE]
PROZONE LIMIT		[32000] - [UPPER]
REAGENT (µL)	R1	[250] - [0] - [0]
	R2	[0] - [0] - [0]
	R3	[0] - [0] - [0]
	R4	[0] - [0] - [0]
CALIBRATION TYPE		[LINEAR] - [2] - [2]
SD LIMIT		[999]
DUPLICATE LIMIT		[32000]
SENSITIVITY LIMIT		[__]
SI ABS. LIMIT		[-32000] - [32000]
UNIT		[__] - [__]
INSTRUMENT A		[1.00]
FACTOR (Y=AX+B) B		[0] - [0]
STD 1		[__] - [__]
STD 2		[__] - [__]
STD 3		[__] - [__]
STD 4		[__] - [__]
STD 5		[__] - [__]
STD 6		[__] - [__]

[__] User Defined.

HITACHI 917/MODULAR P®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST NO		[__]
TEST NAME		[ACE]
TEST CODE		[__]
MODULE P		[__]
ASSAY CODE		[2POINT END] - [10] - [__]
MEASUREMENT POINTS		[17] - [30] - [0] - [0]
WAVELENGTH (SUB-MAIN)		[700] - [340]
SAMPLE VOLUME (µL)		[25]
S VOLUME (DECREASE/INCREASE)		[__] - [__]
REAGENT (µL)	R1	[250] - [__] - [__]
	R2	[0] - [__] - [__]
	R3	[0] - [__] - [__]
	R4	[0] - [__] - [__]
ABS LIMIT		[32000] - [INCREASE]
PROZONE LIMIT		[-32000] - [LOWER]
TECHNICAL LIMIT (LOW/HIGH)		[__] - [__]
REPEAT LIMIT (LOW/HIGH)		[__] - [__]
CALIBRATION		[LINEAR] - [2] - [2]
SD LIMIT		[999]
DUPLICATE LIMIT		[32000]
SENSITIVITY LIMIT (LOW/HIGH)		[__] - [__]
S1 ABS. LIMIT (LOW/HIGH)		[-32000] - [32000]
STD 1		[__] - [__]
STD 2		[__] - [__]
STD 3		[0] - [0]
STD 4		[0] - [0]
STD 5		[0] - [0]
STD 6		[0] - [0]

HITACHI 902®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST NAME		[ACE]
ASSAY CODE		[2 POINT END] - [10] - [__]
ASSAY POINTS		[17] - [30] - [0] - [0]
WAVELENGTH (SUB-MAIN)		[700] - [340]
SAMPLE VOLUME (µL)		[25]
REAGENT (VOL-POS-BOTTLE SIZE)	R1	[250] - [__] - [__]
	R2	[0] - [__] - [__]
	R3	[0] - [__] - [__]
CALIBRATION		[LINEAR] - [2] - [2]
CALIB 1 (CONC/POS)		[__] - [__]
CALIB 2 (CONC/POS)		[__] - [__]
CALIB 3 (CONC/POS)		[0] - [0]
CALIB 4 (CONC/POS)		[0] - [0]
CALIB 5 (CONC/POS)		[0] - [0]
CALIB 6 (CONC/POS)		[0] - [0]
S1 ABS		[0]
K FACTOR		[10000]
K 2 FACTOR		[10000]
K 3 FACTOR		[10000]
K 4 FACTOR		[10000]
K 5 FACTOR		[10000]
A FACTOR		[0]
B FACTOR		[0]
C FACTOR		[0]
SD LIMIT		[0.1]
DUPLICATE LIMIT		[500]
SENSITIVITY LIMIT		[0]
S1 ABS. LIMIT (LOW/HIGH)		[-32000] - [32000]
ABS LIMIT		[9000] - [DECREASE]
PROZONE LIMIT		[0] - [MIN]
PROZONE (END POINT)		[35]
EXPECTED VALUES		[__] - [__]
INST FACTOR (A - B)		[1] - [0]
KEY SETTING		.....

[__] User Defined.

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