Gcell

Angiotensin Converting Enzyme Assay Kit (ACE)

Method: Colorimetric

Cat . No.	Size	Instrument
ACE010	1×100 ml	For Hitachi917/717 &OlympusAU640/400/600 & SYNCHRON CX4-5-7-9/LX20/DXC600-800
Calibrator	1×1 ml	
Quality Control (LEVEL 1)	1×1 ml	
Quality Control (LEVEL 2)	1×1 ml	

INTENDED USE

For the quantitative *in vitro* determination of angiotensin converting enzyme activity in serum.

CLINICAL SIGNIFICANCE

Angiotensin converting enzyme (ACE), also known as kininase II, is a dipeptidyl carboxypeptidase (EC 3.4.15.1) with amolecular weight of at least 129,000. The structure of this glycoprotein shows a single polypeptide chain, a polysaccharide residue and a zinc atom. ACE is present in many different cell types such as neuronal cells and renal proximal tubular cells, but is mostly found in endothelial cells. It is attached to the endothelial surface membrane by an anchor peptide and can be cleaved to be released into the blood circulation as soluble enzyme. Serum ACE activity issignificantly elevated in patients with untreated active disease. Spontaneous orcorticosteroid-induced remission of sarcoidosis is indicated by decreasing serum ACE values. Only few patients with lung diseases such as tuberculosis, fibrosis and tumors, show elevated serum ACE values. Measurement of serum ACE activity is therefore extremely useful as an aid in the diagnosis and in the management of sarcoidosis. The determination of ACE activity in Gaucher's disease is not used as a screening procedure, but its value is significantly increased in most cases if sarcoidosis can be excluded6.ACE is inhibited by drugs from the family of Captopril. Agents acting through this mechanism are now well established inthe treatment of heart failure and hypertension. Serum ACE activity can be a useful parameter for monitoring the effectof these hypotensive drugs inhibiting ACE.

ASSAY 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.

SAMPLE COLLECTION AND PREPARATION

Serum samples. EDTA will inhibit the activity of ACE.

Serum samples are stable for a month at 2-8°C, or for half a year at -20°C.

REAGENT COMPOSITON

Contents	Concentration of Solutions
Buffer	100 mmol/L
FAPGG	1mmol/L
Calibrator	lot specific
Control	lot specific

STABILITY AND PREPARATION OF REAGENTS

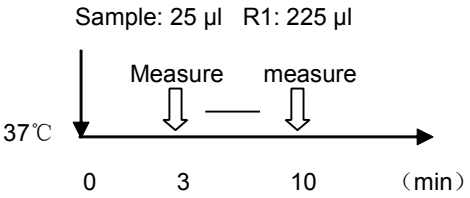
All reagents are ready to use.

Stable up to the expiry date when stored at 2-8°C.

The assay kit reagents are stable for 30 days on board .

ASSAY PROCEDURE

Wave Length (main): 340 nm



1. Incubate 25 µl sample with 225 µl R1 at 37℃ for 3 minutes.
2. Read A_1 at 340 nm, incubate for 7min;read A_2 at 340nm.
3. Calculate the change absorbance $\Delta A=A_1-A_2$

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using the matching Calibrator.

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QUALITY CONTROL

For quality control, use Randox complex Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

REFERENCE VALUE

Serum: 12-68 U/L.

ACE will be higher when the age is below 18. It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

INTERFERENCE

A Reagent blank may be performed by replacing sample or standard with double deionized water. The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin:	12.5 mg/dl
Intralipid:	150 mg/dl
Total bilirubin:	50 μmol/L
H-Val-Trp:	5 μmol/L
EDTA:	300 μmol/L

PRECISION

The CV of the test should be less than 5%

Intra assay precision		
N=20	Level1	Level 2
Mean (U/L)	46.03	79.09
SD	0.53	0.78
Cv	1.16%	0.99%
Inter assay precision		
N=5	Level1	Level 2
Mean (U/L)	49.69	78.98
SD	0.90	1.16
Cv	1.98%	1.47%

LINEARITY

The method is linear up to 150 U/L. If the samples above this concentration should be diluted 1:1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

SENSITIVITY

The minimum detecctable concentration of ACE with an acceptable level of precision was determined as 5 U/L.

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
$Y=0.9995X-1.5846$, $R^2=0.9761$; 91 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

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.

REFERENCES

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 converting enzyme in captopril treated patients. Clin Chim. Acta 118, 333-336 (1982).

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INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by (Expiration date)
IVD	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention: See instruction for use
EC REP	Authorized Representative in the European Company

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INSTRUMENT SETTINGS FOR HITACHI 917

Hitachi 7170 Parameter Application — **Gcell**

ACE
Cat. No: ACE010

Analysis

Test / Type	ACE				Ser/Pl			
Assay/Time/Point	Rate A	A	10	A	4	34	0	0
Wave (Sub/Main)	405	A	340	A				
S.Vol (Normal)	18	0.0	0					
S.Vol (Decrease)	5	0.0	0					
S.Vol (Increase)	20	0.0	0					
Diluent	Water	0						
Reagent (R1) T1	225	0	*	0				
Reagent (R2) T2	0	0	00000	0				
Reagent (R3) T3		0	*	0				
Reagent (R4) T4	0	0	00000	0				
Abs. Limit	0	Decrease	A					
Prozone Limit	0	34	Lower	A				
Cell Detergent	Detergent 1	A						

Range

Application Code	*	Unit	U/L	A
Report Name	ACE			
Data Mode	On Board	A		
Control Interval	0			
Instrument Factor (Y=aX+b)	a= 1.0	b= 0		
Technical Limit	0	162		
Expected Value				

							Qualitative	
(Male)	0	Y	A				Cancel	A
	100	Y	A			(1)	0	
				18	55	(2)	0	
(Female)	0	Y	A			(3)	0	
	100	Y	A			(4)	0	
						(5)	0	

Calibration

Calibration type	Linear	A		A
Point	2	Span Point	2	
Weight	0			
Auto calibration				
Time Out			Change Over	
Blank	0		Blank	A
Span	0		Blank	A
2Point	0			
Full	0			
SD Limit	999.9			
Duplicate limit	1000			
Sensitivity limit	0			
S1 Abs limit	-32000	32000		

STD Conc

<Standard>	(1)	(2)	(3)	(4)	(5)	(6)
Concentration	0	*	0	0	0	0
Position	Water	*	0	0	0	0
Volume	18	18	0	0	0	0
<Pre-Diluent>						
Volume	0	0	0	0	0	0
Diluent	0	0	0	0	0	0
Cal. Code	0	0	0	0	0	0

Attention: * entered by operato

INSTRUMENT SETTINGS FOR Olympus400/640/2700

Olympus AU640/400/2700 Instrument Settings — **Gcell**

ACE
Cat. No: ACE010

Specific Test Parameters

Test Name:	ACE			Type:	Serum	Operation:	Yes
Sample: Volume	20	Dilution	0	Pre-Dilution Rate:			
Reagents: R1 Volume	250	Dilution	0	Min OD		Max OD	
R2 Volume	0	Dilution	0	L	-2.0000	H	2.5000
				Reagent OD Limit:			
Wavelength: Pri.	340	Sec.	410	First L	-2.0000	First H	2.5000
Method:	RATE			Last L	-2.0000	Last H	2.5000
Reaction Slope:	-			Dynamic Range:			
Measuring Point 1: First	3	Last	27	L	0	H	162
Measuring Point 2: First		Last		Correlation Factor:			
Linearity:	30%			A	1.0	B	0.0
No-Lag-Time:	YES			Onboard Stability Period:			

Calibration Specific

Test No.:		Name:	ACE	Type:	SER
Cal. Type:	AB			Counts:	2
Formula:		Y = AX + B		Process:	CONC
Calibration Selection:					

	Cal. No.	OD	Conc.	Factor/OD-L	Factor/OD-H
Point 1	*		*	-9999999	9999999
Point 2					
Point 3					
Point 4					
Point 5					
Point 6					
Point 7					

1-Point Cal..Point:
MB Type Factor:
Cali. Stability Period:

Attention: * Entered By Operator

INSTRUMENT SETTINGS FOR HITACHI 902

Hitachi 7020 Instrument Settings — **Gcell**

ACE

Cat. No: ACE010

No.	<Chemistry>	
1	Test Name	ACE
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	*
4	Reaction Time	10
5	Assay Point 1	4
6	Assay Point 2	35
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	405
10	Wave Leng. (MAIN)	340
11	Sample Volume	24
12	**R1** VOLUME	300
13	R1 Pos.	*
14	R1 Bottle Size	Large
15	**R2** VOLUME	50
16	R2 Pos.	*
17	R2 Bottle Size	Small
18	**R3** VOLUME	0
19	R3 Pos.	0
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	99
25	Calib. Conc. 2	*
26	Calib. Pos. 2	*
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	999
45	Duplicate Limit	1000
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	0
50	ABS Limit (D/I)	Decrease
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower
53	Prz. (End Point)	35
54	Expect. Value (L)	18
55	Expect. Value (H)	55
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	*

* **Data entry by the user**

INSTRUMENT SETTINGS FOR CX4/5/7/9

Synchron CX-4/5/7/9 User-defined Chemistries — **Gcell**

ACE

Cat. No: ACE010

USER ID:
Chemistry Name: ACE
Test Name: ACE

Calculate Factor:

Reaction Type: Rate 1
Reaction Direction: Negative
Units: U/L

Math Model: Linear
Cal Time Limit: 336 **Hrs**
No. Of Calibrators: 2

Decimal Precision: X

Primary Wavelength: 340 **nm**
Secondary Wavelength: 410 **nm**

Sample Volume: 18 **µl**
Primary Inject Rgt:
A: 225 **µl**
None: **µl**
Secondary Inject Rgt:
B: 0 **µl**
Add Time: 0 **sec**

CALIBRATORS
#1: 0.0
#2: *
#3:
#4:
#5:

MULTIPOINT SPAN
1 - 2 -0.001
2 - 3
3 - 4
4 - 5
5 - 1

REAGENT BLANK
Start Read: 256 **sec**
End Read: 304 **sec**
Low ABS Limit:
High ABS Limit:

REACTION
Start Read: 60 **sec**
End Read: 600 **sec**
Low ABS Limit:
High ABS Limit:

USABLE RANGE
Lower Limit: 0
Upper Limit: 162

SUBSTRATE DEPLETION
Initial Rate: -99. 999
Delta ABS: 1. 5

RECOVERY/SENSITIVITY
Std Dev (conc):
CV (%):
Std Dev (mA):
Threshold:

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