



## Stability in serum/plasma [14]:

1 day	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

**Caution/Note:** When interpreting the results, it must be taken into account that ACE inhibitors significantly lower ACE-activity depending on the dose administered.

## Calibrators and Controls

DiaSys TruCal ACE is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient of the FAPGG method from Beneteau B, Baudin B et al. [15]. Lot specific uncertainties can be obtained on request. Use DiaSys TruLab ACE Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal ACE	1 7600 99 10 046	3 x 1 mL
TruLab ACE Level 1	5 9300 99 10 046	3 x 1 mL
TruLab ACE Level 2	5 9310 99 10 046	3 x 1 mL

## Performance Characteristics

Measuring range from 5 U/L up to 175 U/L. Linearity  $\leq 5$  U/L is given within  $\pm 30\%$ , linearity  $> 5$  U/L within  $\pm 10\%$ . In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	5 U/L
Limit of quantitation**	5 U/L
Onboard stability	12 weeks
Calibration stability	9 days

Interference by	Interferences $\leq 15\%$ up to	Analyte concentration [U/L]
<b>Ascorbic acid</b>	50 mg/dL	38.0
	50 mg/dL	93.9
<b>Bilirubin (conjugated)</b>	30 mg/dL	32.4
	30 mg/dL	85.1
<b>Bilirubin (unconjugated)</b>	12.5 mg/dL	37.1
	12.5 mg/dL	97.7
<b>Hemoglobin</b>	200 mg/dL	32.3
	200 mg/dL	86.1
<b>Hemolysis</b>	600 mg/dL	33.0
	600 mg/dL	87.2
<b>L-Cysteine</b>	35 mg/dL	34.9
	35 mg/dL	88.1
<b>Lipemia (triglycerides)</b>	1000 mg/dL	33.2
	1000 mg/dL	91.2
<b>Magnesium</b>	30 mg/dL	35.3
	30 mg/dL	96.0
<b>N-acetylcysteine (NAC)</b>	500 mg/L	35.1
	500 mg/L	95.5
<b>Uric acid</b>	23.5 mg/dL	35.3
	23.5 mg/dL	88.5
<b>Zinc</b>	200 $\mu$ g/dL	35.1
	200 $\mu$ g/dL	96.2

Precision			
Repeatability (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	29.1	64.6	121
CV [%]	1.60	1.38	1.60
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	29.1	64.6	121
CV [%]	3.58	2.87	2.77
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	38.0	55.2	145
CV [%]	5.30	4.67	2.80

Method comparison (n=100)	
Test x	Competitor ACE (ARCHITECT)
Test y	DiaSys ACE FS (BioMajesty® JCA-BM6010/C)
Slope	0.845
Intercept	8.84 U/L
Coefficient of correlation	0.970

Trueness	
Since neither a reference material nor a reference method is available for the measurement of ACE activity, the trueness is demonstrated by a method comparison with an established method on the market (refer to the section Method comparison).	

\*\* according to CLSI document EP17-A2, Vol. 32, No. 8

## Conversion Factor

ACE [U/L] x 0.0167 = ACE [ $\mu$ kat/L]

## Reference Range

In a healthy population, ACE values are usually expected to be  $< 14.7$  IU/L (95th percentile) [16].

In this study, the cut-off value of 14.7 IU/L was defined for optimum sensitivity (78.1%) and specificity (81.7%) for detecting sarcoidosis. With a 14% sarcoidosis prevalence in the genotype DD, this results in a PPV of 23% and an NPV of 98.2% [16].

Positive likelihood LR+ = (Sensitivity/(1-Specificity))  $\geq 4.27$

Negative likelihood LR- = ((1-Sensitivity)/Specificity)  $\leq 0.27$

**NOTE:** Serum ACE activity is strongly dependent on the genotype of the patient.

A study of 150 apparently healthy individuals (19 - 66 years) addressed this topic and investigated reference intervals for ACE activity depending on the genotype. The general reference range was defined at 13.3 - 63.9 U/L and the corresponding intervals for different genotypes were 12.3 – 65.6 U/L (DD), 9.5 – 49.5 U/L (ID) and 9.6 – 28.7 U/L (II) [6]. Due to the relationship between ACE genotype frequencies in different populations and geographic regions, the reference intervals given are for orientation purposes only.

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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\* Fluid Stable

## ACE FS

Chemistry code 10 760

### Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	6.0
Sample vol (U)	6.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	ACE
Digits	1
M-wave L.	505
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	6.0	6.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	38
M-DET.P.n	38
S-DET.P.p	24
S-DET.P.r	24
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	3
Factor	3.0
E2 corre	Not do
Blank (u)	1.6000
Blank (d)	-9.999
Sample (u)	1.6000
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999

# entered by user