



## Specimen

Human serum or lithium heparin plasma

Do not use EDTA as an anticoagulant as it inhibits the ACE activity [13].

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

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.

## Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	505/805 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	6.0 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance	Cycle 24/38 (354 s/546 s)
Calibration	Linear

## Calculation

With Calibrator

$$\text{ACE [U/L]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal.}} \times \text{Activity Cal. [U/L]}$$

## Conversion Factor

$$\text{ACE [U/L]} \times 0.0167 = \text{ACE [\mu kat/L]}$$

## 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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range from 5 U/L up to 175 U/L. Linearity ≤ 5 U/L is given within ± 30%, linearity > 5 U/L within ± 10%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.		
Limit of detection**	5 U/L	
Limit of quantitation**	5 U/L	
Onboard stability	12 weeks	
Calibration stability	9 days	
Interference by	Interferences ≤ 15% up to	Analyte concentration [U/L]
Ascorbic acid	50 mg/dL	38.0
	50 mg/dL	93.9
Bilirubin (conjugated)	30 mg/dL	32.4
	30 mg/dL	85.1
Bilirubin (unconjugated)	12.5 mg/dL	37.1
	12.5 mg/dL	97.7
Hemoglobin	200 mg/dL	32.3
	200 mg/dL	86.1
Hemolysis	600 mg/dL	33.0
	600 mg/dL	87.2
L-Cysteine	35 mg/dL	34.9
	35 mg/dL	88.1
Lipemia (triglycerides)	1000 mg/dL	33.2
	1000 mg/dL	91.2
Magnesium	30 mg/dL	35.3
	30 mg/dL	96.0
N-acetylcysteine (NAC)	500 mg/L	35.1
	500 mg/L	95.5
Uric acid	23.5 mg/dL	35.3
	23.5 mg/dL	88.5
Zinc	200 µg/dL	35.1
	200 µg/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

## 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)) ≥ 4.27

Negative likelihood LR- = ((1-Sensitivity)/Specificity) ≤ 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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