ACE kinetic

Procedure KK-ACK

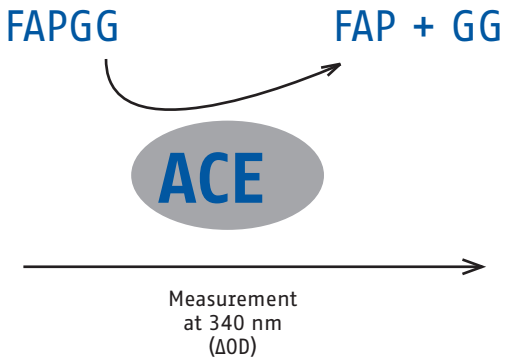
A Commitment to Diagnostics

INTENDED USE

BÜHLMANN ACE kinetic is an *in vitro* diagnostic biochemical assay for the quantitative determination of angiotensin converting enzyme (ACE) activity in serum samples. The assay aids the assessment of disease activity in patients with sarcoidosis in conjunction with other clinical and laboratory findings.
For laboratory use only.

PRINCIPLE OF THE ASSAY

The assay is a quantitative enzymatic test which can be easily applied on clinical chemistry analyzers or run by manual method. ACE catalyzes the conversion of angiotensin I to angiotensin II. The enzyme also mediates the cleavage of the synthetic substrate FAPGG (N-[3-(2-furyl)acryloyl]-L-phenylalanyl-L-glycyl-L-glycine) into the amino acid derivative FAP and the dipeptide GG. The linear kinetic of this cleavage reaction is measured by recording the decrease in absorbance at 340 nm. The final ACE activity in U/L in the patient sample is determined using a calibration curve generated from the measured calibrator value (Ronca-Testoni, Clin Chem 1983; Bénéteau, Clin Chem 1986).



ASSAY PROCEDURE

Application notes / assay installation

Assay procedures for the ACE kinetic are established on several clinical chemistry analyzers. Validated application notes describing installation and analysis on specific instruments are available from BÜHLMANN upon request.

Validated Applications

Roche cobas®	c501/502
	c701/702
	c303 (pure)
	c503 (pro)
Abbott	Alinity c
	Architect c-series
Beckman	AU480/AU680
	AU5800/DxC700AU
Siemens	Atellica CH930
	Advia 2400
	Dimension Vista
	Dimension EXL
The Binding Site	Optilite
ThermoFisher Scientific	Indiko
IDS	iSYS
Mindray	BS480

For other clinical chemistry analyzers please contact support@buhlmannlabs.ch.

Manual procedure on microtiter plate is possible applying an MP Reader with 37°C incubation and plate shaking option and optical filter at 340 nm and 415 nm.

Pre-Analytics

Sample required:	~200 µL serum
	Gel separator tubes (SST) can be used
	Optionally, Li-Heparin and Citrate Plasma can be used
	EDTA Plasma inhibits ACE activity
Sample collection:	Serum collection tubes without anti-coagulants
Sample storage:	at 2-8°C up to 30 days at -20°C at least 6 months

Special Equipment

Open clinical chemistry analyzer

Kit Components

ACE kinetic is available in different package sizes.

	KK-ACK	KK-ACK2	KK-ACK4	KK-ACKX
Tests	100	2 x 50	400	1200
Substrate	1 x 26 mL	2 x 13 mL	4 x 26 mL	3 x 100 mL
Calibrator	1 x 2 mL	2 x 2 mL	2 x 2 mL	3 x 2 mL
Controls normal/ high	1 x 2 mL	2 x 2 mL	2 x 2 mL	3 x 2 mL

BÜHLMANN

ACE kinetic

Characteristics KK-ACK

A Commitment to Diagnostics

Assay Performance

Data obtained on the Roche cobas® c501. Refer to specific application notes for performance on other analyzers.

Reproducibility **6.3-9.1% CV**
3 instruments/lots x 5 days x 5 replicates (EP05-A3)
On cobas c501, c701 and AU480

Repeatability **0.8-3.0% CV**
Within-Laboratory Precision **1.7-3.7% CV**
20 days x 2 runs x 2 replicates (EP05-A3)

Accuracy/Recovery **92.0 – 112.8%**
6 samples spiked with 20.5 U/L (10% volume) run in 4 replicates

Sample carry-over
No statistical significant carry-over (EP10-A2)

Limit of Blank (LoB) **4.3 U/L**
Limit of Detection (LoD) **6.8 U/L**
Limit of Quantification (LoQ) **11.3 U/L**
Classical approach EP17-A2; LoQ n=60; <20% CV

Linearity range **4.3-535 U/L**
Samples >150 U/L automatically re-run with reduced volume; acceptance ±4 U/L or ±10% (EP06-A)

Security zone **up to 541 U/L**
No limiting effects observed

INTERFERING SUBSTANCES

Susceptibility to interfering substances assessed according EP07-A2. Bias exceeding 20% considered as interference.

Oral pharmaceuticals
No interference detected:

• Aspirin	0.65 mg/mL
• Azathioprine	3.0 µg/mL
• Chlorambucil	7.2 µg/mL
• Cyclophosphamide	0.375 mg/mL
• Eprosartan	0.36 mg/mL
• Hydroxychloroquine	up to 0.06 mg/mL
• Ibuprofen	0.5 mg/mL
• Losartan	0.09 mg/mL
• Methotrexate	2.0 µg/mL
• Prednisone	0.3 µg/mL

Serum indices
Interference detected at concentrations:

• triglycerides	2.24 mg/mL
• conjugated bilirubin	0.06 mg/mL
• unconjugated bilirubin	0.047 mg/mL
• hemoglobin	1.19 mg/mL

No triglycerides interference observed after short centrifugation (10 min / 12'000 x g) and separation of lipid-containing supernatant.

This document is for information purpose only, before performing the assay please carefully refer/read the respective IFU available (https: www.buhlmannlabs.ch/support/downloads/eifus/).

REFERENCE INTERVALS

Adults

2.5th – 97.5th percentile from healthy participants in three independent studies in Switzerland (n=80, age: 20 – 70), Germany (n=159, age: 18 – 64, ref. 3) and USA (n=327, age: 16 – 77):

20 – 70 U/L

Children

2.5th – 97.5th percentile from healthy pediatric participants in a single study in Germany (n=84, age: 0.5 – 18):

33 – 112 U/L

Plasma samples

Samples from healthy blood donors collected into lithium-heparin and citrate tubes compared to serum samples from the same donors:

Li-Hep Plasma (n=38) y=0.9x + 2.5 ; r=0.975
Mean bias: -1.1%

Citrate Plasma (n=44) y=0.8x + 1.7 ; r=0.990
Mean bias: -10.8%

Ordering codes:

KK-ACK	100 tests
KK-ACK2	2x50 tests
KK-ACK4	400 tests
KK-ACKX	1200 tests

CE 0123

BÜHLMANN

BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax orders +41 61 487 12 99
info@buhlmannlabs.ch
www.buhlmannlabs.ch

TF025-08 E