ACE kinetic

Procedure

KK-ACK

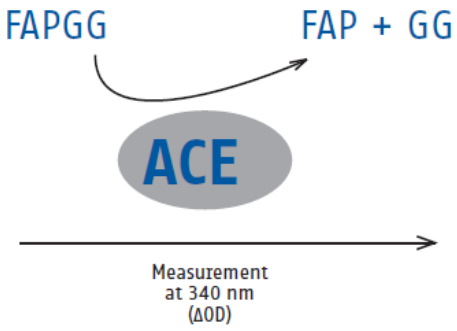
A Commitment to Diagnostics

INTENDED USE

BÜHLMANN ACE kinetic is an *in vitro* diagnostic bio-chemical 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.

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-gly-cyl-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 calibra-tion 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 appli-cation notes describing installation and analysis on specific instruments are available from BÜHLMANN upon request. Corresponding instrument manuals must be considered for instrument setup, maintenance, operation and precautions.

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 info@buhlmannlabs.com.

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

Pre-Analytics

Sample required:	~200 µL serum
Sample collection	Gel separator tubes (SST) are recommended
	Optionally, Li-Heparin and Citrate Plasma can be used*
	EDTA Plasma inhibits ACE ac-tivity
	Serum collection tubes wi-thout anti-coagulants
Sample storage:	at 2-8°C up to 30 days at -20°C at least 6 months

*Plasma samples not validated. Plama testing is at discretion of the laboratory.

Special Equipment

Open clinical chemistry analyzer:
validated applications are available

For manual procedure:
kinetic spectrophotometer with 340 and 415 nm filter and incubation chamber at 37°C

Kit Components

ACE kinetic is available in different package sizes.

	KK-ACK	KK-ACK4	KK-ACK2	KK-ACKX
Tests	100	400	2 x 50	1200
Sub-strate	1 x 26 mL	4 x 26 mL	2 x 13 mL	3 x 100 mL
Calibra-tor	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

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ACE kinetic

Characteristics KK-ACK

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Assay Performance

Data obtained on the Roche cobas® c501. Refer to specific application notes for performance on other clinc chem 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.com/products-solutions/clinical-chemistry/ace-kinetic).

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%

*Plasma samples not validated. Plama testing is at discretion of the laboratory.

Ordering codes:

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

ACE kinetic is FDA 510(k) Exempt. For *in vitro* Diagnostic Use.

CE 0123

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