ACE kinetic

Procedure KK-ACK

A Commitment to Diagnostics

Pre-Analytics

Samples required:	~100 µL Serum (optionally, Heparin 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 analyser:
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
Substrate	1 x 26 mL	4 x 26 mL	2 x 13 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

Manual procedure

Substrate has to be adjusted to room temperature.

Prepare tubes for Calibrator, Controls and patient samples

Add 25 µL Calibrator, Control Serum or patient samples

Add 250 µL Substrate, vortex thoroughly

incubate 5 min at 37°C

Set Photometer to zero absorbance with distilled water (Blank)

transfer sample into a microcuvette

Measure the Absorbance at 37°C and 340 nm twice in a time interval of exactly 10 min

T=0 Pipeting/vortexing
T=5 1st Reading
T=15 2nd Reading

Automated Procedure

ACE kinetic can be performed on any open clinical chemistry analyser. Parameter settings for the following analysers are available upon request:

Validated Applications

Abbott Architect c8000

Beckman Coulter Synchron Cx®

Beckman Coulter Synchron Lx®/Unicel® DxC

Beckman Coulter AU 400/480/640/680

Beckman Coulter AU 2700/5400/5800

Horiba Medical ABX Pentra 400

Kone T-Series

Roche cobas® 6000/8000 (c501/2+c701/2)

Roche Cobas Integra 400/800

Roche Cobas Mira

Siemens Advia® 2400

Siemens Dimension RxL/Vista® 500+1500

BÜHLMANN

ACE kinetic

Characteristics KK-ACK

A Commitment to Diagnostics

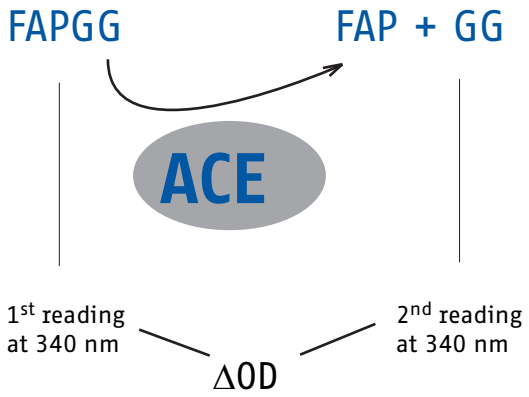
Intended Use

For *in vitro* diagnostics. Direct and quantitative determination of angiotensin converting enzyme (ACE) activity in serum by an enzymatic assay.

Principle of the Assay

In vivo, Angiotensin Converting Enzyme (ACE) catalyses the conversion of angiotensin I to angio-tensin II. *In vitro*, the enzyme also mediates the cleavage of the synthetic substrate (FAPGG =N-[3-(2-furyl)acryloyl]-L-phenylalanyl-L-glycyl-L-glycine) into an amino acid derivate and a dipeptide. The kinetic of this cleavage reaction is measured by recording the decrease in absorbance at 340 nm.

The ACE kinetic method is standardized according to the reference method of Lieberman (Am J Med 1975).



Assay Performance Data

Data obtained with the automated procedure on a Roche Cobas Mira.

Intra-assay precision 2.7 %
Samples n=3; range: 38.6-85.3 ACE U/L.
n= 20 each

Inter-assay precision 8.1 %
Samples n=3; range: 20.2-78.1 ACE U/L.
n= 20 runs; in duplicate

Dilution linearity 108.9 %
Samples n=14; range: 100-172 U/L diluted 1:2 up to 1:32
n=140; 96.5% CI: 105 - 112 %.

Spiking recovery 99.8 %
2 samples spiked ACE from human serum
recovery: 96-102%.

Analytical sensitivity <5 ACE U/L
Mean blank (water) + 3SD. The analytical sensitivity is dependent on the precision of the clinical chemical analyser in use (Cobas Mira: 2.5 U/L; Kone T30: 3.6 U/L).

Functional sensitivity ~12 ACE U/L
Defined as the concentration at 20% CV; established by repeated measurement of 45 samples with ACE values between 1.5 and 35.5 U/L (n=356).

Specificity
The ACE activity can be dose-dependently inhibited by its natural substrate Angiotensin I, by the chelator EDTA, and by H-Val-Trp-OH.

Normal Values

	Adults	Children
n	80	84
Age (years)	20 - 70	0.5 - 18
Median (U/L)	40.7	66.9
2.5-97.5th Percentile (U/L)	19.8 - 70.2	29.3 - 112.2
Reference range (U/L)	**20 - 70**	**29 - 112**

Generally, serum levels in children are substantially higher and more variable than in adults (Bénéteau et al. Clin Chem 1990). No differences related to age and gender have been observed. ACE activity levels in newborns are very low.

Ordering codes:

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

ACE kinetic kits (KK-ACK, KK-ACK2, KK-ACKX) are IVD products.

ACE kinetic (KK-ACK, KK-ACK2, KK-ACK4, KK-ACKX) is Health Canada Licensed (No. 80727).

BÜHLMANN

BÜHLMANN Laboratories AG
Switzerland
info@buhlmannlabs.ch
www.buhlmannlabs.ch
Phone +41 61 487 12 12

BUHLMANN Diagnostics Corp
USA / Canada
info@buhlmannlabs.com
www.buhlmannlabs.com
Phone 844 300 9799

TF025-07 EUS