**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.

<table>
<thead>
<tr>
<th>Tests</th>
<th>KK-ACK</th>
<th>KK-ACK4</th>
<th>KK-ACK2</th>
<th>KK-ACKX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substrate</td>
<td>1 x 26 mL</td>
<td>4 x 26 mL</td>
<td>2 x 13 mL</td>
<td>3 x 100 mL</td>
</tr>
<tr>
<td>Calibrator</td>
<td>1 x 2 mL</td>
<td>2 x 2 mL</td>
<td>2 x 2 mL</td>
<td>3 x 2 mL</td>
</tr>
<tr>
<td>Controls normal/ high</td>
<td>1 x 2 mL</td>
<td>2 x 2 mL</td>
<td>2 x 2 mL</td>
<td>3 x 2 mL</td>
</tr>
</tbody>
</table>

**Manual procedure**

Substrate has to be adjusted to room temperature.

Prepare tubes for Calibrator, Controls and patient samples

Add 25 µL of 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 Synchrone Cx®
- Beckman Coulter Synchrone Lx®/Unicel® DxC
- Beckman Coulter AU400/480/640/680
- Beckman Coulter AU2700/5400/5800
- 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
**ACE kinetic**

**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 angiotensin 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.

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

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

**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**

<table>
<thead>
<tr>
<th>Adults</th>
<th>Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>80</td>
</tr>
<tr>
<td>Age (years)</td>
<td>20 - 70</td>
</tr>
<tr>
<td>Median (U/L)</td>
<td>40.7</td>
</tr>
<tr>
<td>2.5-97.5th Percentile (U/L)</td>
<td>19.8 - 70.2</td>
</tr>
<tr>
<td>Reference range (U/L)</td>
<td>20 - 70</td>
</tr>
</tbody>
</table>

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

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