CK-NAC FS® IFCC

Diagnostic reagent for quantitative in vitro determination of creatine kinase (CK) in serum or plasma on DiaSys respons® 910

Order Information
Cat. No. 1 1601 99 10 921
4 twin containers for 120 tests each

Method
Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry and Laboratory Medicine) and IFCC (International Federation of Clinical Chemistry)

Principle
Creatine phosphorus + ADP → creatine + ATP
Glucose + ATP → Glucose-6-phosphate + ADP
Glucose-6-phosphate + NADP+ → Gluconate-6-phosphate + NADPH + H+

Reagents
Components and Concentrations
R1: Imidazole pH 6.0 60 mmol/L
Glucose 27 mmol/L
N-Acetylcysteine (NAC) 27 mmol/L
Magnesium acetate 14 mmol/L
EDTA-Na2 2 mmol/L
NADP 2.7 mmol/L
Hexokinase (HK) ≥ 5 kU/L
R2: Imidazole pH 9.0 160 mmol/L
ADP 11 mmol/L
AMP 28 mmol/L
Diacidinosine pentaphosphate 55 µmol/L
Glucose-6-phosphate dehydrogenase (G6P-DH) ≥ 14 kU/L
EDTA-Na 2 mmol/L
Creatine phosphorus 160 mmol/L

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. Reagent 2 contains animal material. Handle the product as potentially dangerous and take appropriate safety precautions. P308+P313 If exposed or concerned: Get medical advice/attention.
5. In very rare cases, samples of patients with gampopathy might give falsified results [9].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma
Stability [1]: 2 days at 20 – 25°C
7 days at 4 – 8°C
4 weeks (in the dark) at –20°C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. For internal quality control DiaSys TruLab N and P controls should be assessed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 1100 U/L CK (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 3 U/L CK
On-board stability 6 weeks
Calibration stability 3 weeks

Interfering substance Interferences [%] CK-NAC [U/L]

<table>
<thead>
<tr>
<th>Ascorbate up to 30 mg/dL</th>
<th>99.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin up to 100 mg/dL</td>
<td>143</td>
</tr>
<tr>
<td>Bilirubin, conjugated up to 60 mg/dL</td>
<td>92.0</td>
</tr>
<tr>
<td>Bilirubin, unconjugated up to 70 mg/dL</td>
<td>98.7</td>
</tr>
<tr>
<td>Lipemia (triglycerides) up to 1000 mg/dL</td>
<td>90.5</td>
</tr>
<tr>
<td>up to 2000 mg/dL</td>
<td>158</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [6].

Precision
Within run (n=20)
Mean [U/L] 143 167 515
Coefficient of variation [%] 1.15 1.64 0.88
Between run (n=20)
Mean [U/L] 142 190 524
Coefficient of variation [%] 1.59 1.65 1.19

Method comparison (n=108)
Test x DiaSys CK-NAC FS (Hitachi 917)
Test y DiaSys CK-NAC FS (respons® 910)
Slope 1.009
Intercept 0.702 U/L
Coefficient of correlation 0.9998

Conversion factor
CK-NAC [U/L] x 0.0167 = CK-NAC [µkat/L]

Reference Range
Adults [2]
Women < 145 U/L < 2.42 µkat/L
Men < 171 U/L < 2.85 µkat/L

These reference ranges ensure high diagnostic sensitivity. The diagnostic specificity is low; however, it can be improved by additional measurement of CK-MB.

Myocardial infarction: The risk of myocardial infarction is high if following three conditions are fulfilled [3]:
1. CK (Men) > 190 U/L (3.17 µkat/L)**
2. CK (Women) > 167 U/L (2.76 µkat/L)**
3. CK-MB activity is between 6 and 25% of total CK activity.

** calculated using temperature conversion factor 2.38 (25°C → 37°C)

In healthy individuals different values are found depending on race and age [3,4].
Children [5]

- Umbilical cord blood: 175 – 402 U/L, 2.92 – 6.70 µkat/L
- Newborns: 468 – 1200 U/L, 7.80 – 20.0 µkat/L
- ≤ 5 days: 195 – 700 U/L, 3.25 – 11.7 µkat/L
- < 6 months: 41 – 330 U/L, 0.68 – 5.50 µkat/L
- > 6 months: 24 – 229 U/L, 0.40 – 3.82 µkat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

For diagnostic purposes CK values should always be assessed in conjunction with the anamnesis, the clinical examination and other findings.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany
Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

<table>
<thead>
<tr>
<th>Identification</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>This method is usable for analysis: Yes</td>
<td>Decimals 0</td>
</tr>
<tr>
<td>Twin reaction: No</td>
<td>Units U/L</td>
</tr>
<tr>
<td>Name: CK</td>
<td>Correlation factor-Offset 0.000</td>
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<tr>
<td>Shortcut:</td>
<td>Correlation factor-Slope 1.000</td>
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<tr>
<td>Reagent barcode reference: 029</td>
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<tr>
<td>Host reference:</td>
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</table>

<table>
<thead>
<tr>
<th>Technique</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Type: Linear kinetic</td>
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<td></td>
</tr>
<tr>
<td>First reagent [µL]: 160</td>
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<td></td>
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<tr>
<td>Blank reagent: Yes</td>
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<tr>
<td>Sensitive to light:</td>
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<tr>
<td>Second reagent [µL]: 40</td>
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<tr>
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<td></td>
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<tr>
<td>Sensitive to light:</td>
<td></td>
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</tbody>
</table>

| Main wavelength [nm]: 340 | | |
| Secondary wavelength [nm]: 405 | | |
| Polychromatic factor: 1.000 | | |
| 1 st reading time [min:sec]: 09:36 | | |
| Last reading time [min:sec]: 11:48 | | |
| Reaction way: Increasing | | |

| Linear Kinetics | | |
| Substance depletion: Absorbance II 0.6000 | | |
| Linearity: Maximum deviation [%]: 100 | | |
| Fixed Time Kinetics | | |
| Substance depletion: Absorbance limit | | |
| Endpoint | | |
| Stability: Largest remaining slope | | |
| Prozone Limit [%] | | |

| Reagents | | |
| Decimals | | |
| Units | | |

| Sample | | |
| DIL A (NaCl) | | |
| Hemolysis: Agent [µL]: 0 (no hemolysis) | | |
| Cleaner Sample [µL]: 0 | | |
| Technical limits | | |
| Concentration technical limits-Lower 3 | | |
| Concentration technical limits-Upper 1100 | | |

| SERUM | | |
| Normal volume [µL]: 6 | | |
| Normal dilution (factor): 1 | | |
| Below normal volume [µL]: 12 | | |
| Below normal dilution (factor): 1 | | |
| Above normal volume [µL]: 6 | | |
| Above normal dilution (factor): 6 | | |
| URINE | | |
| Normal volume [µL]: 6 | | |
| Normal dilution (factor): 1 | | |
| Below normal volume [µL]: 12 | | |
| Below normal dilution (factor): 1 | | |
| Above normal volume [µL]: 6 | | |
| Above normal dilution (factor): 6 | | |
| PLASMA | | |
| Normal volume [µL]: 6 | | |
| Normal dilution (factor): 1 | | |
| Below normal volume [µL]: 12 | | |
| Below normal dilution (factor): 1 | | |
| Above normal volume [µL]: 6 | | |
| Above normal dilution (factor): 6 | | |
| CSF | | |
| Normal volume [µL]: 6 | | |
| Normal dilution (factor): 1 | | |
| Below normal volume [µL]: 12 | | |
| Below normal dilution (factor): 1 | | |
| Above normal volume [µL]: 6 | | |
| Above normal dilution (factor): 6 | | |

| Contaminants | | |
| Please refer to r910 Carryover Pair Table | | |

| Calibrators details | | |
| Calibrator list | Concentration |
| Cat. 1/Blank | 0 | |
| Cat. 2 | 1 | |
| Cat. 3 | | |
| Cat. 4 | | |
| Cat. 5 | | |
| Cat. 6 | | |
| Max delta abs. | | |
| Cat. 1 | 0.002 | |
| Cat. 2 | 0.007 | |
| Cat. 3 | | |
| Cat. 4 | | |
| Cat. 5 | | |
| Cat. 6 | | |
| Drift limit [%]: 0.8 | | |

<table>
<thead>
<tr>
<th>Calculations</th>
<th>Model</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
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