Components and Concentrations

Reagents

Glucose-6-phosphate + NADP

Order Information

DiaSys respons containers provide protection from light. Do not freeze the reagents!

Method

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

Principle

Creatine phosphate + ADP ➔ CK Creatine + ATP

Glucose + ATP ➔ HK Glucose-6-phosphate + ADP

Glucose-6-phosphate + NADP ➔ G6-PDH Gluconate-6-phosphate + NADPH + H+

Reagents

Components and Concentrations

R1: Imidazole pH 6.0 60 mmol/L
Glucose 27 mmol/L
N-Acetylcyesteine (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
Diadenosine pentaphosphate 55 mmol/L
Glucose-6-phosphate dehydrogenase (G6-P-DH) ≥ 14 kU/L
EDTA-Na2 2 mmol/L
Creatine phosphate 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

1. Reagent 1: Danger. H360D May damage the unborn child. P201 Obtain special instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of water/soap. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 If exposed or contacted: Get medical advice/attention.


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 infectious according to universal precautions and good laboratory practice.

5. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.

6. In very rare cases, samples of patients with gammadopathy might give falsified results [9].

7. 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.

8. For professional use only!

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]:

<table>
<thead>
<tr>
<th>Duration</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 days</td>
<td>20 – 25 °C</td>
</tr>
<tr>
<td>7 days</td>
<td>4 – 8 °C</td>
</tr>
</tbody>
</table>

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. This method has been standardized against the original IFCC formulation. For internal quality control DiaSys TruLab N and P controls should be assayed. 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-run function).

Limit of detection** 1 U/L CK

On-board stability 4 weeks

Calibration stability 4 weeks

Interferences < 10% by

Ascorbate up to 30 mg/dL
Hemoglobin up to 200 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL

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

Precision

<table>
<thead>
<tr>
<th>Method comparison (n=110)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [U/L]</td>
<td>138</td>
<td>384</td>
<td>523</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.84</td>
<td>1.21</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Method comparison (n=110)

Test x DiaSys CK-NAC FS (Hitachi 917)
Test y DiaSys CK-NAC FS (respons®920)
Slope 0.988
Intercept 0.352 U/L
Coefficient of correlation 1.00

Conversion factor

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

Page 1 - Reagent Information

* fluid stable
## 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)***

CK (Women)  
> 167 U/L (2.78 µkat/L)***

2. CK-MB  
> 24 U/L (0.40 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)

If myocardial infarction is suspected and the conditions are not fulfilled, the infarction may be fresh. In this case the measurements should be repeated after 4 hours with fresh samples.

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

**Children** [5]

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical cord blood</td>
<td>175 – 402 U/L  2.92 – 6.70 µkat/L</td>
</tr>
<tr>
<td>Newborns</td>
<td>468 – 1200 U/L  7.80 – 20.0 µkat/L</td>
</tr>
<tr>
<td>≤ 5 days</td>
<td>195 – 700 U/L   3.25 – 11.7 µkat/L</td>
</tr>
<tr>
<td>&lt; 6 months</td>
<td>41 – 330 U/L    0.68 – 5.50 µkat/L</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>24 – 229 U/L    0.40 – 3.82 µkat/L</td>
</tr>
</tbody>
</table>

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
CK-NAC FS IFCC
Application for serum and plasma

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>CK</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>CK-NAC</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
<td>U/L</td>
<td>Decimal Places : 1</td>
</tr>
<tr>
<td>Wavelength-Primary</td>
<td>340</td>
<td>Secondary : 405</td>
</tr>
<tr>
<td>Assay Type</td>
<td>RATE - A</td>
<td>Curve Type : Linear</td>
</tr>
<tr>
<td>M1 Start</td>
<td>0</td>
<td>M1 End : 0</td>
</tr>
<tr>
<td>M2 Start</td>
<td>23</td>
<td>M2 End : 32</td>
</tr>
<tr>
<td>Sample Replicates</td>
<td>1</td>
<td>Standard Replicates : 3</td>
</tr>
<tr>
<td>Control Replicates</td>
<td>1</td>
<td>Control Interval : 0</td>
</tr>
<tr>
<td>Reaction Direction</td>
<td>Increasing</td>
<td>React. Abs. Limit : 1.25</td>
</tr>
<tr>
<td>Prozone Limit %</td>
<td>0</td>
<td>Prozone Check : Lower</td>
</tr>
<tr>
<td>Linearity Limit %</td>
<td>0</td>
<td>Delta Abs./Min. : 0.0000</td>
</tr>
<tr>
<td>Technical Minimum</td>
<td>1.0</td>
<td>Technical Maximum : 1100.0</td>
</tr>
<tr>
<td>Y = aX + b</td>
<td>a= 1.0000</td>
<td>b= 0.0000</td>
</tr>
</tbody>
</table>

* Enter calibrator value.

Consumables/Calibrators:
- Blank/Level 0: 0
- Calibrator 1: *

---

Sample Volumes

<table>
<thead>
<tr>
<th>Normal</th>
<th>Increase</th>
<th>Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.00 µL</td>
<td>12.00 µL</td>
<td>3.00 µL</td>
</tr>
</tbody>
</table>

Dilution Ratio: 1 X

Reagent Volumes and Stirrer Speed

<table>
<thead>
<tr>
<th>RGT-1 Volume</th>
<th>160 µL</th>
<th>R1 Stirrer Speed : Medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>RGT-2 Volume</td>
<td>40 µL</td>
<td>R2 Stirrer Speed : High</td>
</tr>
</tbody>
</table>

---

Reference Range

<table>
<thead>
<tr>
<th>Lower Limit (U/L)</th>
<th>Upper Limit (U/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal: 0.00</td>
<td>171.00</td>
</tr>
<tr>
<td>Panic: 0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

---

Sample Types

- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other

Reference Range

<table>
<thead>
<tr>
<th>Lower Limit (U/L)</th>
<th>Upper Limit (U/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal: 0.00</td>
<td>171.00</td>
</tr>
<tr>
<td>Panic: 0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>