CK-MB FS

Diagnostic reagent for quantitative in vitro determination of CK-MB in serum or plasma on photometric systems

Order Information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 1641 99 10 021</td>
<td>R1 5 x 20 mL + R2 1 x 25 mL</td>
</tr>
<tr>
<td>1 1641 99 10 026</td>
<td>R1 5 x 80 mL + R2 1 x 100 mL</td>
</tr>
<tr>
<td>1 1641 99 10 930</td>
<td>R1 4 x 20 mL + R2 2 x 10 mL</td>
</tr>
<tr>
<td>1 1641 99 10 951</td>
<td>600 Tests on ADVIA 1200/1650/1800/2400</td>
</tr>
</tbody>
</table>

The following reagent is additionally required for a determination with CK-MB DS:

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 1690 99 10 065</td>
<td>3 x 3 mL</td>
</tr>
</tbody>
</table>

Summary

Creatine kinase (CK) is an enzyme which consists of isoenzymes mainly of the muscle (CK-M) and the brain (CK-B). CK exists in the human body in dimeric forms as CK-MM, CK-MB, CK-BB and as macro-enzyme. Measurement of CK-MB is a specific test for detection of cardiac muscle damage and, therefore, is used for diagnosis and monitoring of myocardial infarction.

Method

Optimized UV test according to DGKC (German Society of Clinical Chemistry) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) for CK with inhibition of CK-M isoenzymes by monoclonal antibodies

Principle

CK-MB consists of the subunits CK-M and CK-B. Specific antibodies against CK-M inhibit the complete CK-MM activity (main part of the total CK activity) and the CK-M-subunit of CK-MB. Only CK-B activity is measured, which is half of the CK-MB activity.

Reagent Preparation

**Components and Concentrations**

**R1**
- Imidazole/Good's buffer: 120 mmol/L
- Glucose: 25 mmol/L
- N-Acetylcysteine (NAC): 25 mmol/L
- Magnesium acetate: 12.5 mmol/L
- EDTA-Na2: 2 mmol/L
- NADP: 2.5 mmol/L
- Hexokinase (HK): ≥ 5 kU/L
- Monoclonal antibodies against human CK-M (mouse); inhibiting capacity: 2500 U/L

**R2**
- Imidazole/Good's buffer: 90 mmol/L
- ADP: 10 mmol/L
- AMP: 28 mmol/L
- Glucose-6-phosphate dehydrogenase (G6P-DH): ≥ 15 kU/L
- Diadenosine pentaphosphate: 50 µmol/L
- Creatine phosphate: 150 µmol/L

Waste Management

Please refer to local legal requirements.

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 if contamination is avoided. Do not freeze the reagents!

Warnings and Precautions


2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

3. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.

4. In very rare cases, samples of patients with gammopathy might give falsified results [10].

5. Sulfasalazine medication may lead to false results in patient samples. Blood collection must be done before drug administration.

6. Heterophile antibodies in patient samples may cause falsified results.

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!

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

**Serum, Plasma**

Stability [8]:

<table>
<thead>
<tr>
<th></th>
<th>Stability</th>
<th>Temp (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 days</td>
<td>at 20 – 25°C</td>
<td></td>
</tr>
<tr>
<td>7 days</td>
<td>at 4 – 8°C</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>at -20°C</td>
<td></td>
</tr>
</tbody>
</table>

Discard contaminated specimens! Freeze only once!
**Assay Procedure**

**Application sheets for automated systems are available on request.**

<table>
<thead>
<tr>
<th>Substrate Start</th>
<th>Sample or calibrator</th>
<th>Blank</th>
<th>Sample or calibrator</th>
<th>Dist. water</th>
<th>Reagent 1</th>
<th>Reagent 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample or calibrator</td>
<td>50 µL</td>
<td>1000 µL</td>
<td>250 µL</td>
<td>1000 µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mix, incubate for approx. 3 min., then add:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reagent 2</td>
<td>250 µL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mix, read absorbance after 2 min. and start the stopwatch.</td>
<td>Read absorbance again after 1, 2, 3, 4 and 5 min.</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

**Sample Start**

<table>
<thead>
<tr>
<th>Sample or calibrator</th>
<th>Blank</th>
<th>Sample or calibrator</th>
<th>Dist. water</th>
<th>Monon reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample or calibrator</td>
<td>40 µL</td>
<td>1000 µL</td>
<td>1000 µL</td>
<td></td>
</tr>
<tr>
<td>Mix, read absorbance after 5 min. and start the stopwatch.</td>
<td>Read absorbance again after 1, 2, 3, 4 and 5 min.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Calculation**

**With factor**

From absorbance readings, calculate ∆A/min and multiply by the corresponding factor from the table below:

\[ \Delta A/\text{min} \times \text{factor} = \text{CK-MB activity [U/L]} \]

**Conversion factor**

\[ \text{CK-MB [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Calibrator}} \times \text{Conc. Calibrator [U/L]} \]

**Performance Characteristics**

**Measuring range**

The test has been developed to determine CK-MB activities up to 2000 U/L. If that value is exceeded, samples should be diluted with NaCl solution (9 g/L) to activities of less than 2000 U/L.

**Specificity/Interferences**

No interference was observed by ascorbic acid up to 30 mg/dL, conjugated and unconjugated bilirubin up to 25 mg/dL and lipemia up to 900 mg/dL triglycerides. Hemoglobin interferes even in minimum concentrations as from 25 mg/dL. For further information on interfering substances refer to Young DS [9].

**Sensitivity/Limit of Detection**

The lower limit of detection is 2 U/L.

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**Method Comparison**

A comparison of DiaSys CK-MB FS (y) with a commercially available test (x) using 90 samples gave following results:

\[ y = 1.00 \times x + 2.08 \text{ U/L}; r = 1.00 \]

**Reference Range**

**Myocardial infarction:** The risk of myocardial infarction is high if the following three conditions are fulfilled [6]:

1. CK (Men) > 190 U/L (3.17 µkat/L)**
2. CK (Women) > 167 U/L (2.78 µkat/L)**
3. CK-MB activity is between 6 and 25% of total CK activity.

**Calibrated to the molar extinction coefficient.**

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**CB**

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