**Creatine Kinase MB MonlabTest®**

Anti CK-M. Immuno inhibition. Kinetic UV. Liquid

**Quantitative determination of creatine kinase MB (CK-MB)**

Only for professional in vitro diagnostic use

Store at 2-8ºC

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**PRINCIPLE OF THE METHOD**

The procedure involves measurement of CK activity in the presence of an antibody to CK-M monomer. This antibody completely inhibits the activity of CK-MM and half of the activity of CK-MB while not affecting the B subunit activity of CK-MB and CK-BB. Then it uses the CK method to quantitatively determine CK-B activity. The CK-MB activity is obtained by multiplying the CK-B activity by two.

**CLINICAL SIGNIFICANCE**

CK-MB is an enzyme formed by the association of two subunits from muscle (M) and nerve cells (B). CK-MB is usually present in serum at low concentration; it is increased after an acute infarct of myocardium and later decreases at normal levels. Also is increased, rarely, in skeletal muscle damage.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**REAGENTS**

<table>
<thead>
<tr>
<th>R 1</th>
<th>125 mmol/L</th>
<th>25 mmol/L</th>
<th>25 mmol/L</th>
<th>12.5 mmol/L</th>
<th>2.02 mmol/L</th>
<th>≥6 800 U/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iomidol, pH 6.7</td>
<td>O-Glucose</td>
<td>N-Acetyl-L-Cysteine</td>
<td>Magnesium acetate</td>
<td>NADP</td>
<td>EDTA</td>
<td>Hexokinase</td>
</tr>
<tr>
<td>R 2</td>
<td>15.2 mmol/L</td>
<td>25 mmol/L</td>
<td>103 mmol/L</td>
<td>≥8 800 U/L</td>
<td>250 mmol/L</td>
<td></td>
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<tr>
<td>ADP</td>
<td>AMP</td>
<td>dI-Adenosine-5-pentaphosphate</td>
<td>Glucose-6-phosphate dehydrogenase</td>
<td>Creatine phosphate</td>
<td></td>
<td></td>
</tr>
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</table>

Optional

| CK-Nac / CK-MB CONTROL | Lyophilized human serum Ref: MO-165110 |

**PREPARATION**

Mix 4 volumes of reagent with 1 volume of reagent 2.

**STORAGE AND STABILITY**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented. Do not use reagents over the expiration date.

**Signs of reagent deterioration:**

- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1.60.

**ADDITIONAL EQUIPMENT**

- Spectrophotometer or colorimeter measuring at 340 nm.
- Thermostatic bath at 25ºC, 30ºC or 37ºC (± 0.1ºC).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

**SAMPLES**

Serum free of hemolysis or heparin plasma; Stability 7 days at 2-8ºC, protected from light.

CK-MB activity decreases a 10% after 24 hours at 4ºC or 1 hour at 25ºC.

**PROCEDURE**

1. **Assay conditions:**
   - Wavelength: 340 nm
   - Cuvette: 1 cm light path
   - Constant temperature: 25ºC / 30ºC / 37ºC
   - Adjust the instrument to zero with distilled water or air.

2. Pipette into a cuvette:
   - WR (mL) 1.0
   - Sample (µL) 40

3. Mix and incubate 10 minutes.

4. Read initial absorbance (A) of the sample, start the stopwatch and read again after 5 minutes (A).

5. Calculate the difference between absorbances AA = A2 - A1.

**CALCULATIONS**

\[ \Delta A \times 825 = \text{U/L of CK-B} \]

\[ \Delta A \times 1651 = \text{U/L of CK-MB} \]

Calculating factor in automatic analyzers (AA/min.) is 8255 of CK-MB.

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**QUALITY CONTROL**

CK-Nac/CK-MB specific control sera (Ref. MO-165110) are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and techniques for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE VALUES**

The suspicious of myocardial damage is based on the following three factors:

- **CK-MB**
  - > 10 U/L
  - > 15 U/L
  - > 24 U/L

**TOTAL CK**

- Men, up to 80 U/L
- Women, up to 70 U/L

**CK-MB Activity**

- Men: 6-25% of CK-MB Activity in the sample

These values are for orientation purpose; each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

**Measuring range:** From detection limit of 1 U/L (on Cobas Mira) to linearity limit of 600 U/L (on manual method and on Cobas Mira).

If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.

**Precision:**

- Intra-assay: 2.62
- Inter-assay: 9.80

Sensitivity: 10 U/L (on Cobas Mira).

Accuracy: Results obtained using MONLABTEST reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained were the following:

- Correlation coefficient (r): 0.99.
- Regression equation: y = 1.0183 x + 0.308.
- Measuring range: 0.42 µL - 8.000 U/L

**LIMITATION OF THE PROCEDURE**

- The method will also measure any CK-BB isoenzyme present in serum. The activity of the isoenzyme is usually negligible, however, if a significant amount of A-creatine activity is present the CK-MB activity will be overestimated.

- No interferences were observed with glucose up to 7 g/L, hemoglobin up to 6 g/L and triglycerides 8 mmol/L. A list of drugs and other interfering substances with CK determination has been reported by Young et. al.

**BIBLIOGRAPHY**

<table>
<thead>
<tr>
<th>SYMBOLS FOR IVD COMPONENTS AND REAGENTS</th>
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<tbody>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Don't re-use</td>
</tr>
<tr>
<td>Contains sufficient for &lt;n&gt; tests</td>
</tr>
<tr>
<td>Catalogue Code</td>
</tr>
<tr>
<td>Lot Number</td>
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**PACKAGING**

Ref.: MO-165081

- R1: 1 x 60 mL
- R2: 1 x 15 mL