**CK-MB**

**CREATIVE KINASE-MB**

For discrete analyzers

**Method:** Enzymatic immunoassay

**Product Code:** 4118-0297

**Packaging:** 6 x lyophil. + 6 x 10 ml (R1)

**Store at:** 2 – 8°C

**For in vitro use**

---

**INTENDED USE**

MEDICON CK-MB is a set of reagents for the quantitative determination of CK-MB in human serum, with BECKMAN COULTER AU400/560/600-IVD/640/270/5400 and other discrete analyzers. For in vitro diagnostic use only.

**CLINICAL SIGNIFICANCE**

Creative Kinase consists of the M and B subunits and is found in the MM, MB, and BB isomorphs. The CK-MB isomorph is found mainly in the cardiac muscle. CK-MB activity is specifically increased in myocardial infarction and this increase is very specific for the laboratory diagnosis of myocardial infarction.

**METHOD PRINCIPLE**

The enzymatic immunoinhibition of the M subunit is applied. The anti-CK-M antibody present in the CK-MB reagent inhibits the catalytic activity of the M subunit of CK-MB enzyme. The observed activity is only due to the B subunit of the enzyme. The activity is measured as the increase of the signal at 340 nm observed during the following reactions:

Phosphoglycerate + ADP → CK → 2 ATP + Glucose 6-Phosphate + ADP

Glucose 6-Phosphate + NAD+ → 6-Phosphogluconate + NADH + H+

**REAGENT COMPOSITION**

The reagent contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build-up in the drain pipes.

**METHOD LIMITATIONS**

The CK-BB isoenzyme is also measured with this method. Its activity is usually negligible but the presence of CK-BB may be given falsely elevated CK-MB values. A macromorph of the CK-BB isoenzyme may be present during the determination of CK-MB. If the activity of the CK-BB isoenzyme surpasses the 20% of total CK activity, then the presence of CK-BB macromorph may be supposed.

Overestimation of CK-MB may occur in cases of CK macromorph presence in the sample. Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".

**SAMPLE**

Lipemic, haemolysed and strongly icteric samples should be avoided.

CK-MB activity remains steady for 24 hours in room temperature (18 – 20°C) and for 14 days at 2 – 6°C, or –20°C. Samples should be tested shortly after collection.

**CALIBRATION**

 Determination takes place in MB Calibration Mode. The calibration factor is derived by the mean of at least three separate analyses series, on different days, in single point calibration mode (AB). MEDICON provides the MEDICON CK-MB Calibrator (1578-0293) or the BECKMAN COULTER ODR30034 CK-MB CONTROL SERUM LEVEL 1 (MEDICON code: 4476-0095) and BECKMAN COULTER ODR30306 CK-MB CONTROL SERUM LEVEL 2 (MEDICON code: 4476-0096).

Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for CK-MB should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**

CK-MB calibrator

Quality control material

Automated biochemistry analyzer

Common laboratory equipment

**REFERENCE INTERVALS**

- **Serum:**
  - **CK-MB:** < 24 U/L, when total CK is within normal limits.
  - **CK:**
    - **Women:** < 167 U/L (37°C)
    - **Men:** < 190 U/L (37°C)

A CK-MB fraction more than 6% of the total activity is regarded as diagnostic for myocardial infarction. A fraction less than 6% indicates skeletal muscle damage. If CK-MB is normal for a patient with suspected heart attack, repeat testing with new sample collection 4 hours later.

Each laboratory should determine its own expected values as dictated by good laboratory practice.

**WASTE DISPOSAL**

This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build-up in the drain pipes.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

- **Linearity**

  The assay is linear up to 1200 U/L. When values exceed this range, samples should be diluted accordingly.

  Inhibition of the M subunit applies up to 2000 U/L of total CK at 37°C. If during the determination of total CK, its value surpasses 2000 U/L at 37°C, dilute the sample accordingly and repeat the measurement. Multiply the result with the dilution factor to determine the exact value of the isoenzyme.

- **Sensitivity**

  The lowest detectable level of CK-MB is estimated at 1 U/L.

  The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean ± three standard deviations.

  **Precision**

  Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-02 (20 consecutive days, 2 runs per day, 2 repeats per run).

<table>
<thead>
<tr>
<th>Level</th>
<th>SD (Within Run)</th>
<th>%CV (Within Run)</th>
<th>SD (Total)</th>
<th>%CV (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>61.7</td>
<td>0.29</td>
<td>0.47</td>
<td>0.75</td>
<td>1.21</td>
</tr>
<tr>
<td>22.1</td>
<td>0.66</td>
<td>0.54</td>
<td>1.34</td>
<td>1.07</td>
</tr>
</tbody>
</table>

  Precision is defined as the %CV.

  **Interference**

  Lipemic: insignificantly up to 100 mg/dL triglycerides

  Hemoglobin: insignificantly up to 50 mg/dL

  Non-Con: Bilirubin: insignificantly up to 20 mg/dL

  Conj: Bilirubin: insignificantly up to 20 mg/dL

  Acetonic acid: insignificantly up to 3 mg/dL

  Refer to "Young" for further information on interfering substances.

**Method Comparison**

A comparison was performed between this reagent and another commercially available product. The results were as follows:

Y = 1.0583X – 0.3456

R² = 0.9904

N = 307

Sample range: 3.07 – 192 U/L

**BIBLIOGRAPHY**


**SYMBOLS**

- **Temperature Limits (2°C – 8°C):**

  - **NDA STERILE** (ISO 15223:2013)

  - **Batch Code:** (ISO 15223:2014 / ISO 16885)

  - **Catalogue Number:** (ISO 15223:2014 / ISO 16885)

  - **Date of Expiry:** (ISO 15223:2014 / ISO 16885)

**MEDICON HELLAS S.A.**

Melittina 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 – Fax: +302106612666 – www.mediconsa.com

MEDICON HELLAS S.A. reserves the right to change the information contained in the insert without prior notice.