CE IVD DIALAB

**Liquid Reagents – ready to use**

# CK-MB

## (Creatine Kinase - MB)

**opt. DGKC / IFCC**

2 Reagents

**Diagnostic reagent for quantitative in vitro determination of creatine kinase (CK-MB) in human serum or plasma on photometric systems**

REF Cont.

| | | | |
|---|---|---|---|
| **D10587** | **5 x 25 ml** | 4 x 25 ml | Reagent 1 |
| | | 1 x 25 ml | Reagent 2 |

Additionally offered (optional):

| | | | |
|---|---|---|---|
| D98485 | 5 x 3 ml | Calibrator | Diacal Auto |
| D98481 | 12 x 5 ml | Control normal | Diacon N |
| D98482 | 12 x 5 ml | Control abnormal | Diacon P |

## TEST PARAMETERS

| | |
|---|---|
| Method: | UV, Kinetic, Increasing Reaction, opt. DGKC / IFCC |
| Wavelength: | 340 nm, Hg 334 nm |
| Temperature: | 37°C |
| Sample: | Serum, plasma |
| Linearity: | up to 2000 U/L |
| Sensitivity: | The lower limit of detection is 2 U/L. |

## REAGENT COMPOSITION

| COMPONENTS | CONCENTRATION |
|---|---|
| **Reagent 1** | |
| Imidazole | 120 mmol/L |
| Glucose | 25 mmol/L |
| N-Acetylcysteine (NAC) | 25 mmol/L |
| Magnesiumacetate | 12.5 mmol/L |
| EDTA-$Na_2$ | 2 mmol/L |
| NADP | 2.5 mmol/L |
| Hexokinase (HK) | ≥ 5 kU/L |
| Monoclonal antibodies against human CK-M; inhibiting capacity | 2500 U/L |
| **Reagent 2** | |
| Imidazole | 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 mmol/L |
| Stabilisers | |

## REAGENT PREPARATION

**Substrate Start:**
Reagents are ready for use.

**Sample Start:**
Mix 4 parts of Reagent 1 + 1 part of Reagent 2
( = Working Reagent)
Protect from light!

## REAGENT STABILITY AND STORAGE

Conditions: protect from light!
close immediately after use
avoid contamination
do not freeze the reagents!

**Substrate Start:**
Storage: at 2 – 8°C
Stability: up to the expiration date

**Sample Start (Working Reagent):**
Stability: at 2 – 8°C 2 weeks
at 15 – 25°C 24 hours

## SAMPLE STABILITY AND STORAGE

Serum, Plasma Stability [8]: at 20 – 25 °C 2 days
at 4 – 8 °C 7 days
at - 20 °C 4 weeks

Discard contaminated specimens.

## INTERFERING SUBSTANCES

no interference up to:

| | |
|---|---|
| ascorbic acid | 30 mg/dL |
| conj. and unconj. bilirubin | 25 mg/dL |
| triglycerides | 900 mg/dL |

hemoglobin interferes at a concentration of 25 mg/dL

## MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

**Substrate Start**

| Pipette into test tubes | Blank | Sample |
|---|---|---|
| Sample | - | 50 µl |
| Dist. water | 50 µl | - |
| Reagent 1 | 1000 µl | 1000 µl |
| Mix. Incubate for approximately 3 minutes. Then add: | | |
| Reagent 2 | 250 µl | 250 µl |
| Mix. Read initial absorbance after 2 min at 37°C and start a timer. Read abs. again after exactly 1, 2, 3, 4, 5 min. at 37°C<br>ΔA/min = [ΔA/min sample] – [ΔA/min blank] | | |

**Sample Start**

| Pipette into test tubes | Blank | Sample |
|---|---|---|
| Sample | - | 40 µl |
| Dist. water | 40 µl | - |
| Working reagent | 1000 µl | 1000 µl |
| Mix. Read initial absorbance after 5 min. at 37°C and start a timer. Read abs. again after exactly 1, 2, 3, 4, 5 min. at 37°C<br>ΔA/min = [ΔA/min sample] – [ΔA/min blank] | | |

## CALCULATION (light path 1 cm)

**With factor:**

CK-MB (U/L) = ΔA/min x Factor

**Factor for 340 nm** 8254
**Factor for 334 nm** 8414

**With calibrator :**

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

## UNIT CONVERSION

U/L x 0.01667 = µkatal/L

## REFERENCE RANGE (U/L)

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

1. CK (men) > 190 U/L (3.12 µkat/L)*
   CK (women) > 167 U/L (2.87 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 [6,7].
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.

## TEST PRINCIPLE

CK-MB consists of the subunits CK-M and CK-B. Specific polyclonal 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.

$$\text{Creatine phosphate} + \text{ADP} \xleftarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xleftarrow{\text{HK}} \text{ADP} + \text{Glucose-6-Phosphate (G-6-P)}$$

$$\text{G-6-P} + \text{NADP}^+ \xleftarrow{\text{G6P-DH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^+$$

## PERFORMANCE CHARACTERISTICS

### LINEARITY

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 sodium chloride in dist. water) and reassayed, multiplying the result by the dilution factor.

### PRECISION (at 37°C)

| Intra-assay, n = 20 | Mean [U/L] | SD [U/L] | CV [%] |
|---|---|---|---|
| Sample 1 | 26.7 | 0.70 | 2.61 |
| Sample 2 | 46.6 | 0.85 | 1.82 |
| Sample 3 | 106 | 1.03 | 0.97 |

| Inter-assay, n = 20 | Mean [U/L] | SD [U/L] | CV [%] |
|---|---|---|---|
| Sample 1 | 28.2 | 1.05 | 3.72 |
| Sample 2 | 52.7 | 1.66 | 3.15 |
| Sample 3 | 109 | 2.32 | 1.13 |

### METHOD COMPARISON

A comparison between Dialab CK-MB (y) and a commercially available test (x) using 90 samples gave following results: y = 1.00 x + 2.08 U/l; r= 1.00.

## QUALITY CONTROL

All human based control sera with CK-MB values determined by this method can be used. Please take care to use controls containing exclusively human CK-MB. Do not use control sera from animal source! We recommend:

| REF | Cont. | | |
|---|---|---|---|
| **D98481** | 12 x 5 ml | **DIACON N** | Assayed Control Serum Normal |
| **D98482** | 12 x 5 ml | **DIACON P** | Assayed Control Serum Abnormal |

## CALIBRATION

The use of a CK-MB Calibrator (for automated Systems) is optional. All human based calibrators with CK-MB values determined by this method may be used. Please take care to use calibrators containing exclusively human CK-MB. Do not use calibrators from animal source! We recommend:

| REF | Cont. | | |
|---|---|---|---|
| **D98485** | 5 x 3 ml | **DIACAL AUTO** | Assayed Multi Calibration Serum |

## AUTOMATION

Special adaptations for automated analyzers can be made on request.

## WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

## WASTE MANAGEMENT

Please refer to local legal requirements.

## REFERENCES


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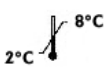


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