Creatine Kinase-MB (CK-MB)
(IFCC/DGKC Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **MB0011**	R.1: 2x 50 ml R.2 1x20ml total 120 ml	2-8°C
Cat. No.: **MB0017**	R.1: 2 x 50 ml R.2 1x 20ml total 120 ml	2-8°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Creatine Kinase-MB in human serum/plasma on automated and semi-automated photometric systems.

- **Summary and Explanation:**
The Creatine Kinase is the dimer enzyme which exist in 4 types. The one iso enzyme is in mitochondria and three iso enzymes in cytoplasm: CK-MM (muscular enzyme), CK-BB (brain enzyme) and CK-MB (heart enzyme). The iso enzyme of MB is an ingredient of CK enzyme which may increase in myocardial cell injuries so the measurements of this enzyme is critical to compare of CK alone. The measurement of CK-MB activity joint with CPK value is an exclusive test for diagnostic of heart muscle damage and determine the early (previous occur) diagnostic of myocardial infarction.

Principle of the Method:
CK-MB is divided in two subunits CK-M and CK-B. The activity of CK-MM is a major part of CPK activity. CK-M is a subunit of CK-MB, control and suppress by some exclusive anti body against CK-M. So, the CK-B activity alone is the half of CK-MB in measurement.

$$\text{Creatine Phosphate + ADP} \xrightarrow{\text{CK}} \text{Creatine + ATP}$$

$$\text{ATP + Glucose} \xrightarrow[\text{HK-Mg}^{2+}]{} \text{ADP + Glucose-6-phosphate (G-6-P)}$$

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

- **Reagent Preparation and Stability:**
Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from direct light. For assay the mixture should mix by with 1 volume of R2 and 5 volumes of R1. R1 is transparent and colorless also R2 is same as well. The mixture ready to use, stability at 2-8°C is 5 days. Avoid direct sunlight.

Waste Management:
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use fresh serum/plasma non- heamolysied, heparinized with EDTA. The stability of CK-MB in the samples at 2-8°C for 7 days and at-20°C for 30 days.
The serum / plasma should have collected immediately after blood collection. Avoid any contamination. The CK-MB activity 10 percent decreased at 2-8°C after 24 hours. At room temperature 10 percent decreased after 1 hour. Keep th e samples in refrigerator make some metabolic changes on samples compare to fresh samples. The quantity activity of CK-MB and total CK should be measured together.

Required but not Supplied:
CK-MB calibrator from TKS or other valid calibrators.
CK-MB Control from TKS or other valid Controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

Maximum determination in this assay is 1000U/L
LOD: 2 U/L
For samples with a higher concentration (1000U/L), dilute 1:4 with 0.9 % NaCl and re-assay. Multiply result by 5.
Precision:
Intra Assay-Within run CK-MB

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	172. 1	4.88	2.83
2	20	776.4	13.46	1.73

Inter Assay-Between run CK-MB

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	165.4	5.58	3.37
2	20	740.2	15.26	2.06

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.999
Regression equation: Y = 0.976 (X) – 0.269 U/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**
the less concentration of below items are not interfering in this assay.

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/L Bilirubin
Lipemia	Less than 10% interference up to 2.5 g/L Intralipid
Hemolysis	Less than 10% interference up 1.25g/L Hemoglobin.

- **Reference Values:**

CK men	**>80U/L at 25°C**	**>130U/L at 30°C**	**>190U/L at 37°C**
CK women	**>70U/L at 25°C**	**>110U/L at 30°C**	**>167U/L at 37°C**
CK-MB	**>10U/L at 25°C**	**>15U/L at 30°C**	**>24U/L at 37°C**
CK-MB activity amounts for 6-25% of the total CK activity.			

Each laboratory should establish its own expected values. The CK-MB results should always be reviewed with the patient's medical examination and history.
If the three situations occurred in the same time for patient, the high possibility is heart attacked proceed for patient.

- **Assay Procedure:**

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Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result

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ISO 13485:2016
ISO 9001:2015

IVD

Assay conditions:

334-365 (340)nm	**Wavelengths**
30°C (25°C or 37°C)	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R1**
40 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minute at 37°C. Then added R2.		

200 µl	**200** µl	**R2**
Gently mix and incubate for 2 minute at 37°C. Measure the sample and calibrator. Turn on the counter exactly 1,2 and 3 min after start reaction measure the absorbance. **ΔOD/min.**		

- **ΔA/min=ΔA/sample or calibrator – ΔA/min Blank**
- **Calculations:**

CK-MB (U/L) = OD Sample x Cal Conc. (U/L)
OD calibrator

- **Conversion units:**

CK-MB (µKat/l) = CK-MB (U/L) x 0.0167

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352-390 and 974-975.
2-GuderWG, NarayananS, WisserH, ZawtaB. List of Anal; Preanal Variables. From the Patient to the Laboratory. Darmstdt: GIT Verlag 1996.
3-Wurzburg U, Hennrich N, Lang H, Prellwitz W, Neumeier D, Knedel M. Klin. Wschr. 1976: 54 and 357.
4-Szasz G, Busch EW. Third European Congress of Clinical Chemistry, Brighton, England, 3-8 June 1979 (abstract).

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight