CK-MB

Creatinin Kinase MB. Liquid

Product information

24CKMB01-UN	**Meditest CK-MB**	**4x40 mL 2x20 mL**
24CKMB01-AU	**Meditest CK-MB**	**4x40 mL 2x20 mL**
24CKMB01-AB	**Meditest CK-MB**	**4x40 mL 2x20 mL**
24CKMB01-ER	**Meditest CK-MB**	**4x40 mL 2x20 mL**
24CKMB01-AR	**Meditest CK-MB**	**4x40 mL 2x20 mL**

Purpose

In vitro assay for the quantitative determination of the catalytic activity of the creatinine kinase MB subunit in human serum and plasma.

Summary

CK-MB is an enzyme formed by the union of two subunits from muscle (M) and nerve cells (B). CK-MB is usually found in low concentration in serum; It increases after acute myocardial infarction, and then decreases to normal levels. It also rarely increases in skeletal muscle damage.

Test principle

Creatinin Phosphate + ADP —CK→ Creatinin+ATP

ATP + Glucose —HK→ ADP+ Glucose-6-phosphate (G-6-P)

G-6-P + NADP —G6P-DH→ 6-phosphogluconate+NADPH+H+

Reagents - working solutions

R 1	Imidazole Buffer pH 6.7	<100 mmol/L
	Glucose	<20 mmol/L
	Magnessium Acetate	>10 mmol/L
	EDTA	<2.0 mmol/L
	AMP	<5.0 mmol/L
	NADP	<2.0 mmol/L
R 2	Creatinin Phosphate	30 mmol/L
	G6P-DH	>1.5 u/mL
	Diadenosine pentaphosphate	10 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

Sample collection and preparation

Use serum that does not contain hemolysis, heparin, or EDTA plasma. It is recommended to follow NCCLS procedures (or similar standard conditions) related to sample handling. Immediately after collection, the serum/plasma should be separated from the cells and stored in the dark.
Stability: Up to 7 days at 2-8°C.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 340 nm
Cuvette: . . . . . 1 cm light path
Temperature: . 30^{0C}/25 or 37^{0C} 2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

	Blank	Calibrator	Sample
R1 (µL)	800	800	800
Sample (µL)	-		40
Calibrator (µL)	-	40	-

4. Mix slowly and incubate at 37°C for 5 minutes.
5. Add

R2(µL)	200	200	200

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6. Mix slowly and incubate at 37°C for 2 min, then measure the change in Optical Density (ΔOD/min) per minute for the next 4 minutes.

Calculation

$$\frac{\Delta OD\ Sample - \Delta OD\ Blank}{} \times Concentration\ of\ Calibrator. = CK\ MB\ Activity$$

$$\Delta OD\ Calibrator - \Delta OD\ Blank$$

(Conversion factor: Qty in µKat/l = Qty in U/l x 0.0167).

Conversion factor: mg/dL x 88.4 = µmol/L

Expected values

When the following 3 conditions are met, there is a high probability of myocardial injury

			U/L at 25° C	µkat/l at 25°C	U/L at 30°C	µkat/l at 30°C	U/L at 37°C	µkat/l at 37°C
1.	CK	Men	> 80	> 1.33	> 130	> 2.17	190>	> 3.17
		Women	> 70	> 1.17	> 110	> 1.83	> 167	> 2.87
2.	CK- MB		> 10	> 0.17	> 15	> 0.25	> 24	> 0.40
3.	CK-MB activity accounts for 6 – 25% of the total CK activity							

These values are for orientation purposes; Each laboratory should establish its own reference range

Limitations

Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l Bilirubin.
Hemolysis: Less than 10% interference up to 1.25 g/l Hemoglobin.
Lipemia: Less than 10% interference up to 2.5 g/l Intralipid value.

Performance characteristics

Measuring range: 0-318 U/L
If the results obtained are greater than the linearity limit, dilute the sample by 1/2 with 9 g/L NaCl and multiply the result by 2.

Precision

	Intra-assay			Inter-assay		
N=20	Mean (U/L)	SD	%CV	Mean (U/L)	SD	%CV
Level 1	172.1	4.88	2.83	165.4	5.58	3.37
Level 2	776.4	13.46	1.73	740.2	15.26	2.06

Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:
Correlation coefficient $(r)^2$: 0.999
Regression equation = 0.976x – 0.269
The results of the performance characteristics depend on the analyzer used.

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).

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