BioMajesty®

CK-MB FS*

Order Information

Cat. No.	Kit size
1 1641 99 10 964	Σ 900 (R1: 6 x 150, R2: 6 x 150)

Intended Use

Diagnostic reagent for quantitative in vitro determination of CK-MB in human serum or lithium heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Creatine kinase (CK) is an enzyme, which consists of isoenzymes mainly of the muscle (CK-M) and the brain (CK-B). CK exists in the human body in dimeric forms as CK-MM, CK-MB, CK-BB and as macro-enzyme. Measurement of CK-MB is a specific test for the detection of cardiac muscle damage and, therefore, is used for diagnosis and monitoring of myocardial infarction. [1,2,3]

Method [4]

Optimized UV test according to DGKC (German Society of Clinical Chemistry) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) for CK with inhibition of CK-M isoenzymes by monoclonal antibodies.

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

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

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NADP}^+ \xrightarrow{\text{G6P-DH}} \text{6-Phosphogluconolactone} + \text{NADPH} + \text{H}^+$$

Reagents

Components and Concentrations

R1:	Imidazole/Good's buffer	120 mmol/L
	Glucose	25 mmol/L
	N-Acetylcysteine (NAC)	25 mmol/L
	Magnesium acetate	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 (mouse); inhibiting capacity	≥ 2500 U/L
R2:	Imidazole/Good's buffer	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

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Protect from light.

Warnings and Precautions

1. ⚠ Reagent 1 and 2: Danger. Contains: Imidazole. H360D May damage the unborn child. P201 Obtain special instructions before use. P280 Wear protective gloves/protective clothing/eye protection. P308+P313 If exposed or concerned: Get medical advice/attention.
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. The reagents contain animal and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
5. Sulfasalazine medication may cause false results in patient samples. Blood collection must be performed prior to drug administration.
6. Heterophile antibodies in patient samples may cause falsified results.
7. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or lithium heparin plasma

Stability [6]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
4 weeks	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal CK-MB is recommended for calibration. TruCal CK-MB calibrator values have been made traceable to the molar extinction coefficient. Control sera and calibrators containing non-human CK-MB fractions are not suitable to be applied with this test due to the monoclonal antibody used in the reagent. Only use controls and calibrators containing exclusively human CK-MB. Use DiaSys TruLab N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal CK-MB	5 9450 99 10 074	6 x 1 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range from 9 up to 1900 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	8 U/L
Onboard stability	11 weeks
Calibration stability	11 weeks

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	30 mg/dL	33.0
	60 mg/dL	98.4
Bilirubin (conjugated)	36 mg/dL	33.0
	32 mg/dL	91.6
Bilirubin (unconjugated)	36 mg/dL	33.0
	45 mg/dL	89.6

Hemoglobin	10 mg/dL	33.0
	45 mg/dL	104
Lipemia (triglycerides)	1000 mg/dL	33.0
	1700 mg/dL	85.9
Sulfapyridin	30 mg/dL	24.2
	30 mg/dL	96.8
Sulfasalazin	2.5 mg/dL	25.2
	9 mg/dL	98.8
For further information on interfering substances refer to Young DS [7,8].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	16.0	33.8	198
CV [%]	2.57	3.47	2.36
Total (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	16.6	23.4	178
CV [%]	2.90	2.03	1.00

Method comparison (n=162)	
Test x	Competitor CK-MB FS (cobas® c 501)
Test y	DiaSys CK-MB FS (BioMajesty® JCA-BM6010/C)
Slope	0.966
Intercept	2.31 U/L
Coefficient of correlation	0.997

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor
CK-MB [U/L] x 0.0167 = CK-MB [µkat/L]

Reference Range

Myocardial infarction: the risk of myocardial infarction is high if following three conditions are fulfilled [9]:
1. CK (Men) > 190 U/L (3.17 µkat/L)***
   CK (Women) > 167 U/L (2.78 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 [9,10].

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.

Literature

1. Stein W. Creatine kinase (total activity), creatine kinase isoenzymes and variants. In: Thomas L, ed. Clinical laboratory diagnostics. Frankfurt: TH-Books Verlagsgesellschaft;1998. p. 71-80.
2. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617-721.
3. Würzburg U, Hennrich N, Orth HD, Lang H. Quantitative determination of creatine kinase isoenzyme catalytic concentrations in serum using immunological methods. J Clin Chem Clin Biochem 1977;15:131-7.
4. Recommendations of the German Society for Clinical Chemistry. Standardization of methods for the estimation of enzyme activities in biological fluids: Standard method for the determination of creatine kinase activity. J Clin Chem Clin Biochem 1977;15:255-60.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in June 2021. Published by AACC Press and John Wiley and Sons, Inc.
9. Stein W. Strategie der klinisch-chemischen Diagnostik des frischen Myokardinfarkts. Med Welt 1985:36:572-7.
10. Myocardial infarction redefined – a consensus document of the Joint European society of Cardiology/America College of Cardiology Committee for the redefinition of myocardial Infarction. Eur Heart J 2000;21:1502-13.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

BioMajesty

CK-MB FS

Chemistry code 10 164

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	4
Sample vol (U)	4
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CKMB
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	4	4
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	32
M-DET.P.n	41
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	3
Factor	3
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.25
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999