CK-MB FS*

Diagnostic reagent for quantitative in vitro determination of CK-MB in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size		Number of tests	
1 1641 99 10 972	R1	3 x 10.7 mL	BX-3010	3 x 80 tests
			BX-4000	3 x 55 tests
	R2	3 x 4.7 mL	BX-3010	3 x 80 tests
			BX-4000	3 x 55 tests

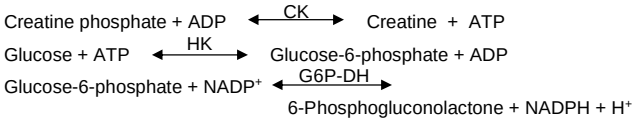
Method

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

Principle

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.

Reaction Principle



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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1 and 2: Danger. H360D May damage the unborn child. P201 Obtain special instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face 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 material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. In very rare cases, samples of patients with gammopathy might give falsified results [10].
5. Heterophile antibodies in patient samples may cause falsified results.
6. Sulfasalazine medication may lead to false results in patient samples. Blood collection must be done before drug administration.
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

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum or plasma

Stability [1]:

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

Freeze only once. Discard contaminated specimens.

Calibrators and Controls

For calibration the DiaSys TruCal CK-MB calibrator is recommended. The assigned values of the calibrator 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. Please take care to use controls and calibrators containing exclusively human CK-MB. For internal quality control DiaSys TruLab N and P controls should be assayed. 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

Measuring range up to 2000 U/L (33.3 µkat/L) CK-MB (in case of higher activities re-measure samples after manual dilution with NaCl (9 g/L) or use rerun function)	
Limit of detection**	4 U/L (0.067 µkat/L) CK-MB
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	43.2 U/L (0.720 µkat/L)
Hemoglobin	Hemoglobin interferes	
Bilirubin, conjugated	up to 15 mg/dL	29.3 U/L (0.488 µkat/L)
Bilirubin, unconjugated	up to 20 mg/dL	27.0 U/L (0.450 µkat/L)
Lipemia (triglycerides)	up to 1200 mg/dL	27.5 U/L (0.459 µkat/L)
For further information on interfering substances refer to Young DS [9].		

Precision (BX-4000)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	33.2	43.7	151
Mean [µkat/L]	0.554	0.728	2.52
Coefficient of variation [%]	2.12	1.80	0.853
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	32.5	40.1	138
Mean [µkat/L]	0.542	0.668	2.30
Coefficient of variation [%]	2.97	3.07	2.90

Method comparison (n=120)	
Test x	CK-MB FS (BioMajesty 6010C)
Test y	CK-MB FS (BX-4000)
Slope	1.01
Intercept	–1.72 U/L (0.029 µkat/L)
Coefficient of correlation	0.99997

** lowest measurable activity which can be distinguished from zero
mean + 3 SD (n=20) of an analyte free specimen

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 the following three conditions are fulfilled [2]:

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 [2,3].

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
2. Stein W. Strategie der klinisch-chemischen Diagnostik des frischen Myokardinfarkts. Med Welt 1985; 36: 572-7.
3. 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.
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. 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.
6. 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.
7. 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.
8. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 2: Reference procedure for the measurement of catalytic concentration of creatine kinase. Clin Chem Lab Med 2002; 40: 635-42.
9. 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.
10. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	CK MB	Reagent Name	Reagent (µL)	Water (µL)
Print Name	CK MB	MethodColor		R1 CK MB	100	
Sample Type	Serum			R2 CK MB	25	
Unit	U/L			Diluent Disable		
Assay Type	Rate			Sample Ppt. Wash Disable		

Measuring points

	Start		End
1	37	–	45
2	Disable	–	

Stirring Speed R1: Middle R2: Middle

Wave Length: Prim. 340 Sec. 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

Normal	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)	Technical Range		
						(Conc)	4 –	2000
☐ Diluent	0.0 <	5.0 <	0.0			(mAbs/10)	* –	*
Rerun (High/Prozone)								
☐ Diluent	0.0 <	5.0 <	0.0			Previous Result Comparison (%)	*	* %
Rerun (Low)								
☐ Diluent	0.0 <	5.0 <	0.0			Abnormal Range (Conc)	* –	*
						Panic Range (Conc)	* –	*

Decimal Point 0 Profile SI Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name CK MB Sample Serum

Limit Checks

✓ Duplicate Limit	10	mAbs/10
✓ Sensitivity Limit	110	mAbs/10
✓ Linearity Limit	10	%
	230	(mAbs/10)/min
☐ Prozone Limit	Higher	%
SL1-S	–	SL1-F
SL2-S	–	SL2-F
Sensitivity		mAbs/10
✓ Absorbance Limit		
Abs. in reaction	Increase	
Limit	17000	mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

CK-MB FS

Chemistry Code 100 23

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name CK MB

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration

Disable

Calibration Type Linear

Reagent Lot New Add

Calibrator Name TruCal CK-MB

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry

☐ C1 Blank

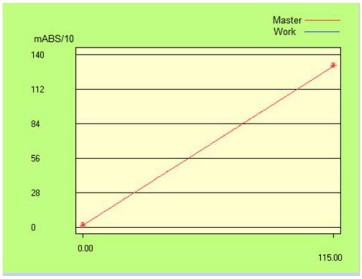
☐ Reagent Blank for C1

Reagent Lot No.

(R1) *

(R2) *

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

***Entered by user**

CK-MB FS

Chemistry Code 100 23

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	CK MB	Reagent Name	Reagent (µL)	Water (µL)
Print Name	CK MB			R1	CK MB	150	
Sample	Serum			R2 ✓ Enable	CK MB	38	
Unit	U/L						
Assay Type	Rate			Diluent ☐ Enable			

Measuring points — Start — End — Decimal Points: 0

1: 54 – 67

☐ Enable 2: –

Wave Length: Prim. 340 Sec ☐ Disable 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	7.5		
Rerun (High/Prozone) ☐ Dilution	7.5		
Rerun (Low) ☐ Dilution	7.5		

Technical Range: (Conc) 4 – 2000; (mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed: R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name CK MB Sample Serum

Limit Checks

- ✓ Duplicate Limit: 10 mAbs/10
- ✓ Sensitivity Limit: 110 mAbs/10
- ✓ Linearity Limit: 10 % 230 (mAbs/10)/min
- ☐ Prozone Limit: % Upper
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity: mAbs/10
- ✓ Absorbance Limit
  - Reaction: Increase
  - Limit: 17000 mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:
✓ Duplicate Limit: 10 mAbs/10

Instrument Factor: a 1.00 b 0.00

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method * Name CK MB

Sample Serum

Sampling Duplicate

Check Interval 42 days

Auto Change Lot Full Calibration

Auto Interval hours

Type Linear Lot New

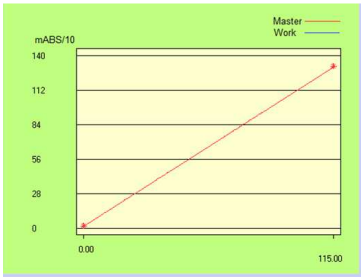
Material Name TruCal CK-MB

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1 * Last
R2 *



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Type Conc.

Absorbance mAbs/10 Recalculation