respons®910

CK-MB FS*

Diagnostic reagent for quantitative in vitro determination of CK-MB in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1641 99 10 921
4 twin containers for 120 tests each

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

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

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

Glucose-6-phosphate + $NADP^+$ $\xleftarrow{G6P\text{-}DH}$ 6-Phosphogluconolactone + NADPH + 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; 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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. In very rare cases, samples of patients with gammopathy might give falsified results.
3. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum or plasma

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, 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 CK-MB (in case of higher activities re-measure samples after manual dilution or use rerun function)	
Limit of detection**	4.3 U/L CK-MB
On-board stability	28 days
Calibration stability	7 days

Interfering substance	**Interferences < 10%**	**CK-MB [U/L]**
Ascorbate	up to 30 mg/dL	43.2
Hemoglobin	up to 10 mg/dL	28.1
	up to 25 mg/dL	88.4
Bilirubin, conjugated	up to 15 mg/dL	28.4
	up to 25 mg/dL	91.7
Bilirubin, unconjugated	up to 25 mg/dL	24.9
	up to 35 mg/dL	161
Lipemia (triglycerides)	up to 1400 mg/dL	24.8
	up to 1400 mg/dL	79.4
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	32.6	45.1	80.1
Coefficient of variation [%]	1.85	1.89	1.24
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	32.2	46.6	81.6
Coefficient of variation [%]	3.52	2.29	2.05

Method comparison (n=96)	
Test x	DiaSys CK-MB FS (Hitachi 917)
Test y	DiaSys CK-MB FS (respons®910)
Slope	0.948
Intercept	0.614 U/L
Coefficient of correlation	0.9996

** according to NCCLS document EP17-A, vol. 24, no. 34

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 [3]:

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 with fresh samples after 4 hours.

In healthy individuals different values are found depending on race and age [3,4].

Each laboratory should check if 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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
2. 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.
3. Stein W. Strategie der klinisch-chemischen Diagnostik des frischen Myokardinfarkts. Med Welt 1985; 36: 572-7.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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 5: Reference procedure for the measurement of catalytic concentration of creatine kinase. Clin Chem Lab Med 2002; 40: 635-42.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®910

CK-MB FS

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

Identification	
This method is usable for analysis:	Yes
Name:	CKMB
Shortcut:	
Reagent barcode reference:	030
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.000
1 st reading time [min:sec]	07:00
Last reading time [min:sec]	11:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	1.0
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0
Concentration technical limits-Upper	2000
SERUM	
Normal volume [µL]	11
Normal dilution (factor)	1
Below normal volume [µL]	16
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
URIN	
Normal volume [µL]	11
Normal dilution (factor)	1
Below normal volume [µL]	16
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	11
Normal dilution (factor)	1
Below normal volume [µL]	16
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	11
Normal dilution (factor)	1
Below normal volume[µL]	16
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1

Results	
Decimals	2
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>= <=24
URINE	
PLASMA	>= <=24
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.015
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value