respons®910

CK-MB FS*

Order Information

Cat. No.	Kit size
1 1641 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of CK-MB in human serum or lithium heparin plasma on automated DiaSys respons®910.

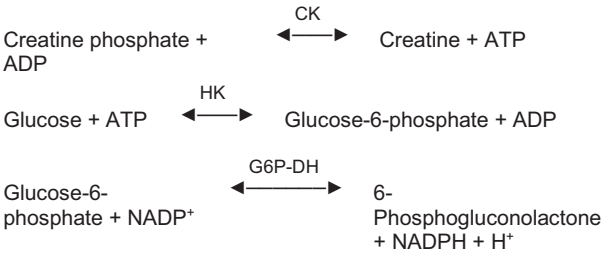
Summary

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.



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. Take special care to avoid contamination and carry-over, particularly in combination with Rheumatoid factor FS.
8. 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.
9. 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

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Performance Characteristics

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

Measuring range up to 2000 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**	4.3 U/L
Onboard stability	28 days
Calibration stability	7 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	43.2
Bilirubin (conjugated)	15 mg/dL	28.4
	25 mg/dL	91.7
Bilirubin (unconjugated)	25 mg/dL	24.9
	35 mg/dL	161
Hemoglobin	10 mg/dL	28.1
	25 mg/dL	88.4
Lipemia (triglycerides)	1400 mg/dL	24.8
	1400 mg/dL	79.4
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]	32.6	45.1	80.1
CV [%]	1.85	1.89	1.24
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	32.2	46.6	81.6
CV [%]	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	0.999

** according to CLSI 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 [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

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IVD CE

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* Fluid Stable

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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
Twin reaction:	No
Name:	CKMB
Shortcut:	
Reagent barcode reference:	030
Host reference:	030

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.0000
1 st reading time [min:sec]	07:00
Last reading time [min:sec]	11:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	1.0000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	4.3000
Concentration technical limits-Upper	2000.0000
SERUM	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	U/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>= <=24.00
URINE	
PLASMA	>= <=24.00
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.003
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value