respons®910

CK-NAC FS*

Order Information

Cat. No.	Kit size
1 1601 99 10 921	Σ 480 (4 x 120)

Intended Use

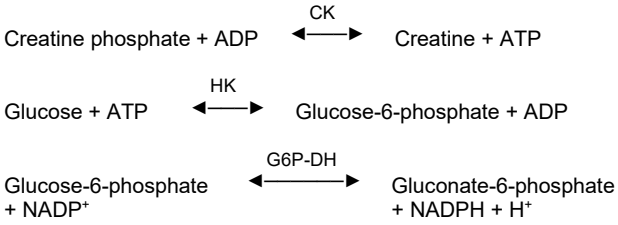
Diagnostic reagent for quantitative in vitro determination of creatinkinase (CK) in human serum or lithium heparin plasma on automated DiaSys respons®910.

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 serum in dimeric form as CK-MM, CK-MB, CK-BB and as macroenzyme. Elevated CK values are observed in cardiac muscle damages and in skeletal muscle diseases. Measurement of CK is used especially in conjunction with CK-MB for diagnosis and monitoring of myocardial infarction. [1,2]

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry).



Reagents

Components and Concentrations

R1:	Imidazole	pH 6.0	60 mmol/L
	Glucose		27 mmol/L
	N-Acetylcysteine (NAC)		27 mmol/L
	Magnesium acetate		14 mmol/L
	EDTA-Na_2		2 mmol/L
	NADP		2.7 mmol/L
	Hexokinase (HK)		≥ 5 kU/L
R2:	Imidazole	pH 9.0	160 mmol/L
	ADP		11 mmol/L
	AMP		28 mmol/L
	Diadenosine pentaphosphate		55 µmol/L
	Glucose-6-phosphate dehydrogenase (G6P-DH)		≥ 14 kU/L
	EDTA-Na_2		2 mmol/L
	Creatine phosphate		160 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: 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. ⚠ Reagent 2: Danger. Contains: Imidazole. H315 Causes skin irritation. H319 Causes serious eye irritation. H360D May damage the unborn child. P201 Obtain special instructions before use. P280 Wear protective gloves/ protective clothing/eye protection. P302+P352 If on skin: Wash with plenty of water/soap. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 If exposed or concerned: Get medical advice/attention.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
5. Reagent 2 contains animal and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
6. In very rare cases, samples of patients with gammopathy might give falsified results [3].
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 [4]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
4 weeks (in the dark)	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. This method has been standardized against the original IFCC formulation. 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 U	5 9100 99 10 063	20	x	3 mL
	5 9100 99 10 064	6	x	3 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 up to 1100 U/L. In case of higher activity re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	3 U/L
Onboard stability	6 weeks
Calibration stability	3 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	99.0
Bilirubin (conjugated)	60 mg/dL	92.0
	60 mg/dL	175
Bilirubin (unconjugated)	70 mg/dL	96.7
	70 mg/dL	307
Hemoglobin	100 mg/dL	143
	100 mg/dL	197
Lipemia (triglycerides)	1000 mg/dL	90.5
	2000 mg/dL	158
For further information on interfering substances refer to Young DS [5,6].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	143	167	515
CV [%]	1.15	1.64	0.878
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	142	190	524
CV [%]	1.59	1.65	1.19

Method comparison (n=108)	
Test x	DiaSys CK-NAC FS (Hitachi 917)
Test y	DiaSys CK-NAC FS (respons®910)
Slope	1.01
Intercept	0.702 U/L
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

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

Reference Range

Adults [7]

Women	< 145 U/L	< 2.42 µkat/L
Men	< 171 U/L	< 2.85 µkat/L

These reference ranges ensure high diagnostic sensitivity. The diagnostic specificity is low; however, it may be improved by additional measurement of CK-MB.

Myocardial infarction: The risk of myocardial infarction is high if following three conditions are fulfilled [8]:

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 [8,9].

Children [1]

Umbilical cord blood	175 – 402 U/L	2.92 – 6.70 µkat/L
Newborns	468 – 1200 U/L	7.80 – 20.0 µkat/L
≤ 5 days	195 – 700 U/L	3.25 – 11.7 µkat/L
< 6 months	41 – 330 U/L	0.68 – 5.50 µkat/L
> 6 months	24 – 229 U/L	0.40 – 3.82 µkat/L

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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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
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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:	CK
Shortcut:	
Reagent barcode reference:	029
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.000
1 st reading time [min:sec]	06:48
Last reading time [min:sec]	09:36
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance li	0.6000
Linearity: Maximum deviation [%]	100
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	3
Concentration technical limits-Upper	1100
SERUM	
Normal volume [µL]	6
Normal dilution (factor)	1
Below normal volume [µL]	12
Below normal dilution (factor)	1
Above normal volume [µL]	6
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	6
Normal dilution (factor)	1
Below normal volume [µL]	12
Below normal dilution (factor)	1
Above normal volume [µL]	6
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	6
Normal dilution (factor)	1
Below normal volume [µL]	12
Below normal dilution (factor)	1
Above normal volume [µL]	6
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	6
Normal dilution (factor)	1
Below normal volume[µL]	12
Below normal dilution (factor)	1
Above normal volume [µL]	6
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	6
Normal dilution (factor)	1
Below normal volume[µL]	12
Below normal dilution (factor)	1
Above normal volume [µL]	6
Above normal dilution (factor)	6

Results	
Decimals	0
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	Male
Age	
SERUM	>= <=171
URINE	
PLASMA	>= <=171
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=145
URINE	
PLASMA	>= <=145
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	0.007
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value