respons®910

CK-NAC FS* IFCC

Diagnostic reagent for quantitative in vitro determination of creatine kinase (CK) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1601 99 10 921
4 twin containers for 120 tests each

Method

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

Principle

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

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

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

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 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. Reagent R2 is toxic. R61: May cause harm to the unborn child. S53: Avoid exposure – obtain special instructions before use. S28: After contact with skin, wash immediately with plenty of water. S29: Do not empty into drains. S36/37: Wear suitable protective clothing and gloves. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the lable where possible).
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. In very rare cases, samples of patients with gammopathy might give falsified results.
4. 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, heparin plasma or EDTA plasma

Stability [1]:	2 days	at	20 - 25 °C
	7 days	at	4 - 8 °C
	4 weeks (in the dark)	at	-20 °C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation (molar extinctionscoefficient 340 nm). 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 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

Measuring range up to 1100 U/L CK (in case of higher activities re-measure samples after manual dilution or use rerun function)	
Limit of detection**	3 U/L CK
On-board stability	6 weeks
Calibration stability	3 weeks

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

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	143	167	515
Coefficient of variation [%]	1.15	1.64	0.88
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	142	190	524
Coefficient of variation [%]	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	1.009
Intercept	0.702 U/L
Coefficient of correlation	0.9998

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

Conversion factor

CK-NAC [U/L] x 0.0167 = CK-NAC [µkat/L]

Reference Range

Adults [2]

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 can be improved by additional measurement of CK-MB.
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 after 4 hours with fresh samples.

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

Children [5]

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

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
2. 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.
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. 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. 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.
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. 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.

IVD CE

Manufacturer

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respons®910

CK-NAC 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:	CK
Shortcut:	
Reagent barcode reference:	029
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]	06:48
Last reading time [min:sec]	09:36
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	0.6
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	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

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

Range	
Genre	Male
Age	
SERUM	>= <=171
URINE	
PLASMA	>= <=171
CSF	
Genre	Female
Age	
SERUM	>= <=145
URINE	
PLASMA	>= <=145
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	0.0150
Cal. 2	0.0070
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value