respons®920

CK-NAC FS*

Order Information

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

Intended Use

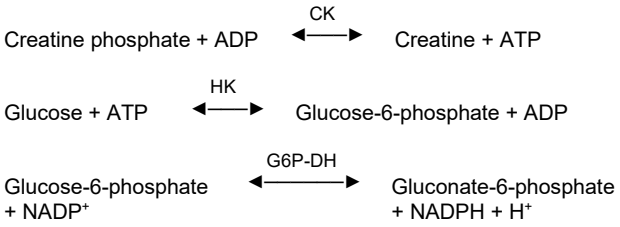
Diagnostic reagent for quantitative in vitro determination of creatinkinase (CK) in human serum or lithium heparin plasma on automated DiaSys respons®920.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
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 [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**	1 U/L
Onboard stability	4 weeks
Calibration stability	4 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	200 mg/dL
Lipemia (triglycerides)	2000 mg/dL
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]	129	337	500
CV [%]	0.80	0.85	1.01
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	138	364	523
CV [%]	0.84	1.21	0.74

Method comparison (n=110)	
Test x	DiaSys CK-NAC FS (Hitachi 917)
Test y	DiaSys CK-NAC FS (respons®920)
Slope	0.988
Intercept	0.352 U/L
Coefficient of correlation	1.00

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

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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IVD CE

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* Fluid Stable

respons®920

CK-NAC FS IFCC

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CK				Auto Rerun	☐	
Report Name	:	CK-NAC				Online Calibration	☐	
Unit	:	U/L	Decimal Places	:	1	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	405	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	CK R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	CK R2
M2 Start	:	23	M2 End	:	32			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	1.25	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	1.0	Technical Maximum	:	1100.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	CK				
Sample Type	:	Serum				

Sample Volumes

Normal	:	6.00 µL	Dilution Ratio	:	1 X	
Increase	:	12.00 µL	Dilution Ratio	:	1 X	
Decrease	:	3.00 µL	Dilution Ratio	:	1 X	
Standard Volume	:	6.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CK		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (U/L)	Upper Limit (U/L)
Normal	:	0.00	171.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other