


CK-NAC FS*

Order Information

Cat. No.

1 1601 99 10 921

Kit size

 480 (4 x 120)

Intended Use

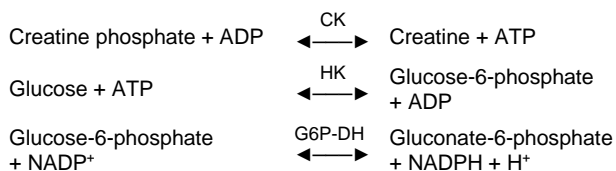
Diagnostic reagent for quantitative in vitro determination of creatine kinase (CK) activity in human serum or lithium heparin plasma on automated respons[®]940.

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. CK-MB appears in high proportions exclusively in myocardial tissue; thus measurement of the heterodimer may detect myocardial cell wall injury [1]. Comparison of CK-MB with other cardiac biomarkers as for example troponin I reveals a shorter half-life and a different kinetic profile after a myocardial necrosis. CK-MB determination is used for temporal differentiation of the cardiac damage as an aid in the diagnosis of a myocardial infarction or reinfarction [2].

Method

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



One unit of CK is the amount of enzyme that converts 1.0 μmol of phosphate from creatine phosphate per minute at the enzyme specific conditions [3].

Reagents

Components and Concentrations

R1:	Imidazole Glucose N-Acetylcysteine (NAC) Magnesium acetate EDTA-Na ₂ NADP Hexokinase (HK)	pH 6.0 ≥ 5 kU/L	60 mmol/L 27 mmol/L 27 mmol/L 14 mmol/L 2 mmol/L 2.7 mmol/L
R2:	Imidazole ADP AMP Diadenosine pentaphosphate Glucose-6-phosphate dehydrogenase (G6P-DH) EDTA-Na ₂ Creatine phosphate	pH 9.0 ≥ 14 kU/L	160 mmol/L 11 mmol/L 28 mmol/L 55 μmol/L ≥ 14 kU/L 2 mmol/L 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. Do not freeze and protect from light.

The open-vial stability of the reagent is 15 months until expiry date.

Warnings and Precautions

- Components contained in CK-NAC FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ 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.



⚠ 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.

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

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

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

4 hours	at	20 – 25°C
1 month	at	4 – 8°C
1 month	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 from 6 U/L up to 1300 U/L. Linearity < 10 U/L is given with ± 1.8 U/L, between 10 U/L up to 70 U/L within ± 10%, linearity > 70 U/L within ± 5%. In case of higher activity re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	6 U/L
Limit of quantitation**	6 U/L
Onboard stability	16 weeks
Calibration stability	8 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	70 mg/dL	119
	70 mg/dL	306
Bilirubin (conjugated)	70 mg/dL	99.6
	70 mg/dL	288
Bilirubin (unconjugated)	70 mg/dL	96.4
	70 mg/dL	280
Hemolysis	150 mg/dL	104
	150 mg/dL	291
Lipemia (triglycerides)	1300 mg/dL	95.9
	1300 mg/dL	268
Sulfapyridine	36 mg/dL	84.6
	36 mg/dL	264
Sulfasalazine	9 mg/dL	103
	9 mg/dL	299
Temozolomide	25 mg/L	98.6
	25 mg/L	296
For further information on interfering substances, refer to the literature [6-8].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	110	244	509
CV [%]	0.506	0.342	0.668
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	98.4	259	498
CV [%]	2.02	1.58	1.90
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	91.8	159	463
CV [%]	2.98	2.56	2.54

Method comparison (n=152)	
Test x	Competitor CK (cobas c 501)
Test y	DiaSys CK-NAC FS (respons [®] 940)
Slope	1.04
Intercept	3.56 U/L
Coefficient of correlation	0.999

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor

CK [U/L] x 0.0167 = CK [µkat/L]

Reference Range

Myocardial infarction: The risk of myocardial infarction is high if following three conditions are fulfilled [9,10]:

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 [9,11].

Children [12]	Female		Male	
	[U/L]	[µkat/L]	[U/L]	[µkat/L]
0 – 90 day(s)	29 – 303	0.48 – 5.05	43 – 474	0.72 – 7.90
3 – 12 months	25 – 172	0.42 – 2.87	27 – 242	0.45 – 4.03
3 – 24 months	28 – 162	0.47 – 2.70	25 – 177	0.42 – 2.95
2 – 10 years	31 – 152	0.52 – 2.53	25 – 177	0.42 – 2.95
11 – 14 years	31 – 152	0.52 – 2.53	31 – 172	0.52 – 2.87
15 – 18 years	34 – 147	0.57 – 2.45	28 – 142	0.47 – 2.37

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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