BioMajesty®

CK-NAC FS*

Order Information

Cat. No.	Kit size
1 1601 99 10 962	Σ 1890 (R1: 6 x 315, R2: 6 x 315)

Intended Use

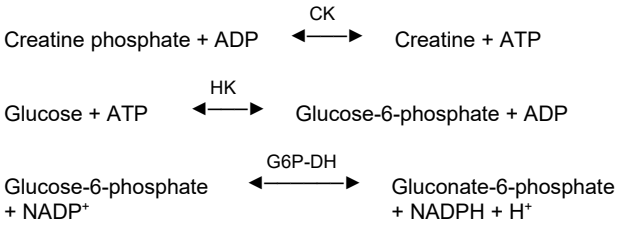
Diagnostic reagent for quantitative in vitro determination of creatinkinase (CK) in human serum or lithium heparin plasma on automated BioMajesty®-JCA BM6010/C.

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 from 12 up to 1300 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**	7 U/L
Onboard stability	15 weeks
Calibration stability	15 weeks

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Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	120
	65 mg/dL	296
Bilirubin (conjugated)	55 mg/dL	120
	65 mg/dL	298
Bilirubin (unconjugated)	48 mg/dL	120
	65 mg/dL	285
Hemoglobin	100 mg/dL	140
	180 mg/dL	304
Lipemia (triglycerides)	1600 mg/dL	120
	1800 mg/dL	262

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]	106	166	727
CV [%]	0.866	0.341	1.06
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	103	167	731
CV [%]	1.29	1.03	0.813

Method comparison (n= 164)	
Test x	Competitor CK-NAC (cobas®c 501)
Test y	CK-NAC FS (BioMajesty®JCA-BM6010C)
Slope	1.02
Intercept	1.52 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

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

BioMajesty

CK-NAC FS

Chemistry code 10 160

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	3.0
Sample vol (U)	3.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CK
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	3	3
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	28
M-DET.P.n	40
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	3
Factor	3
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.15
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999