

# CK-NAC FS\* IFCC

Diagnostic reagent for quantitative in vitro determination of creatinase (CK) in serum or plasma on Sysmex BX-Series

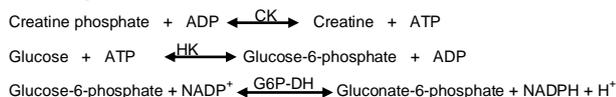
## Order information

Cat. No.	Kit size	Number of tests
1 1601 99 10 972	R1 3 x 13.0 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests
	R2 3 x 5.5 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests

## Method

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

## Principle



## Reagents

### Components and Concentrations

<b>R1:</b>	Imidazole	pH 6.0	60 mmol/L
	Glucose		27 mmol/L
	N-Acetylcysteine (NAC)		27 mmol/L
	Magnesium acetate		14 mmol/L
	EDTA-Na <sub>2</sub>		2 mmol/L
	NADP		2.7 mmol/L
	Hexokinase (HK)		≥ 5 kU/L
<b>R2:</b>	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 <sub>2</sub>		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. Do not freeze the reagents!

### Warnings and Precautions

- Reagent 1: Danger. H360D May damage the unborn child. P201 Obtain special instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face protection. P308+P313 If exposed or concerned: Get medical advice/attention.
- Reagent 2: Danger. 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/face 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.
- Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [9].
- 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.
- For professional use only!

## Waste Management

Please refer to local legal requirements.

## Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

## 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

Only freeze once. Discard contaminated specimens.

## Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. 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 (18.3 μkat/L) CK (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	3 U/L (0.05 μkat/L) CK
On-board stability	12 weeks
Calibration stability	12 weeks

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

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	121 U/L (2.02 μkat/L)
Hemoglobin	up to 150 mg/dL	175 U/L (2.92 μkat/L)
Bilirubin, conjugated	up to 60 mg/dL	153 U/L (2.54 μkat/L)
Bilirubin, unconjugated	up to 60 mg/dL	145 U/L (2.42 μkat/L)
Lipemia (triglycerides)	up to 1400 mg/dL	164 U/L (2.74 μkat/L)

For further information on interfering substances refer to Young DS [8].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	57.9	139	469
Mean [μkat/L]	0.965	2.32	7.82
Coefficient of variation [%]	0.858	0.461	0.404
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	56.5	140	466
Mean [μkat/L]	0.943	2.34	7.77
Coefficient of variation [%]	2.02	0.779	0.654

Method comparison (n=105)	
Test x	CK-NAC FS (BioMajesty 6010C)
Test y	CK-NAC FS (BX-4000)
Slope	1.01
Intercept	0.365 U/L (0.006 μkat/L)
Coefficient of correlation	0.9998

## 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 (3.17 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 [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.

## Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
2. Schumann G, Bonora R, Ceriotti F, Féraud G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 2: 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. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 617–721.
7. 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.
8. 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.
9. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

## Manufacturer



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																						
Method No.	*	Method Name	CK	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	CK	MethodColor		R1	CK 100																					
Sample Type	Serum			R2	CK 25																					
Unit	U/L			Diluent	Disable																					
Assay Type	Rate			Sample Ppt. Wash	Disable																					
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle																				
		1	33 - 44																							
		2	Disable -																							
Wave Length	Prim. 340	Sec. 415		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>			No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																							
1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																						
	Low 0.0	Normal 3.8	High 0.0	(Conc) 3	1100																					
<input type="checkbox"/> Diluent	0.0 <	3.8 <	0.0	(mAbs/10)	*	*																				
	Rerun (High/Prozone)			Previous Result Comparison (%)	*	%																				
<input type="checkbox"/> Diluent	0.0 <	3.8 <	0.0	Abnormal Range	*	*																				
	Rerun (Low)			Panic Range	*	*																				
<input type="checkbox"/> Diluent	0.0 <	3.8 <	0.0	Decimal Point	0	Profile SI Disable																				

\*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	CK	Sample	Serum	
<b>Limit Checks</b> <input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit 100 mAbs/10 <input checked="" type="checkbox"/> Linearity Limit 10 % 255 (mAbs/10)/min <input type="checkbox"/> Prozone Limit Higher % SL1-S - SL1-F SL2-S - SL2-F Sensitivity mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction Increase Limit 17000 mAbs/10				<b>Blank measurement</b> Blank measurement: Disable reagent blank and C1 blank Measurement of Reagent Blank during Run: None Reagent blank measurement at calibration: Reagent blank (No sample) The number of measurement: Duplicate Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10		
<b>Instrument Factor</b> a 1.00      b 0.00						

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer  
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

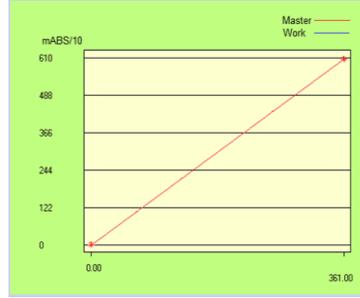
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K   C1 Blank  
 Reagent Blank for C1

Reagent Lot No.

(R1)   
(R2)

Last



The calibration curve is lot dependent

Reagent blank  mAbs/10 Last

Blank  mAbs/10 Last

Calibration Curve  Conc.

Absorbance  mAbs/10

\*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="CK"/>	Reagent Name	<input type="text"/>																				
Print Name	<input type="text" value="CK"/>	R1	<input type="text" value="CK"/>	Reagent (µL)	<input type="text" value="150"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable <input type="text" value="CK"/>	Reagent (µL)	<input type="text" value="38"/>																				
Unit	<input type="text" value="U/L"/>	Diluent	<input type="checkbox"/> Enable <input type="text"/>	<input type="text"/>	<input type="text"/>																				
Assay Type	<input type="text" value="Rate"/>	Measuring points	Start	End	Decimal Points																				
		1	<input type="text" value="48"/>	- <input type="text" value="66"/>	<input type="text" value="0"/>																				
		<input type="checkbox"/> Enable 2	<input type="text"/>	- <input type="text"/>																					
Wave Length	Prim. <input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable <input type="text" value="415"/>	Normal Range																					
				<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>		No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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1	Male-G1	*	*																						
2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
<input type="checkbox"/> Dilution	Normal Sampling <input type="text" value="5.7"/>	Sample (µL)	<input type="text"/>	Diluent (µL)	<input type="text"/>																				
<input type="checkbox"/> Dilution	Rerun (High/Prozone) <input type="text" value="5.7"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Technical Range (Conc) <input type="text" value="3"/> - <input type="text" value="1100"/>																				
<input type="checkbox"/> Dilution	Rerun (Low) <input type="text" value="5.7"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	(mAbs/10) <input type="text"/> - <input type="text"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="5.7"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	SPT Wash <input type="checkbox"/> Enable <input type="text"/>																				
					Stirring Speed R1 <input type="text" value="Middle"/> R2 <input type="text" value="Middle"/>																				

\*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	* <input type="text"/>	Name	<input type="text" value="CK"/>	Sample	<input type="text" value="Serum"/>
Limit Checks		Blank measurement			
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/> mAbs/10	Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/>			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="100"/> mAbs/10	Measurement of Reagent Blank during Run: <input type="text" value="None"/>			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/> % <input type="text" value="255"/> (mAbs/10)/min	Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/>			
<input type="checkbox"/> Prozone Limit	<input type="text"/> % <input type="text" value="Upper"/>	The number of measurement: <input type="text" value="Duplicate"/>			
	SL1-S <input type="text"/> - SL1-F <input type="text"/>	Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10			
	SL2-S <input type="text"/> - SL2-F <input type="text"/>	Instrument Factor			
Sensitivity	<input type="text"/> mAbs/10	a <input type="text" value="1.00"/> b <input type="text" value="0.00"/>			
<input checked="" type="checkbox"/> Absorbance Limit	Reaction <input type="text" value="Increase"/>				
	Limit <input type="text" value="17000"/> mAbs/10				

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer  
Analytical Parameters

Method  Name

Sample

Sampling

Check Interval  days

Auto

Auto Interval  hours

Type  Lot

Material Name

R Lot No. R1   
R2

Last



The calibration curve is lot dependent

Reagent blank  mAbs/10 Last

Blank  mAbs/10 Last

Type  Conc.

Absorbance  mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K   S1 Blank  Reagent Blank for S1

\*Entered by user