

Creatinine FS*

Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on Sysmex BX-Series

Order information

Cat. No.	Kit size	Number of tests
1 1711 99 10 972	R1 3 x 11.8 mL	BX-3010 3 x 90 tests
		BX-4000 3 x 62 tests
	R2 3 x 5.1 mL	BX-3010 3 x 90 tests
		BX-4000 3 x 62 tests

Method

Kinetic test without deproteinization according to the Jaffé method

Principle

Creatinine forms a colored orange-red complex in an alkaline picric acid solution. The difference in absorbance at fixed times during conversion is proportional to the concentration of creatinine in the sample.



Reagents

Components and Concentrations

R1:	Sodium hydroxide	0.2 mol/L
R2:	Picric acid	20 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 – 25°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- Reagent 1: Warning. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. P234 Keep only in original container. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of water/soap. P332+P313 If skin irritation occurs: Get medical advice/attention. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P390 Absorb spillage to prevent material damage.
- Reagent 2: Warning. H290 May be corrosive to metals. P234 Keep only in original container. P280 Wear protective gloves/protective clothing/eye protection/face protection. P390 Absorb spillage to prevent material damage.
- High homogentisic acid concentrations in urine samples lead to false results.
- In very rare cases, samples of patients with gammopathy might give falsified results [11].
- Eltrombopag medication leads to falsely low or high results in patient samples.
- 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 rotors.

Specimen

Serum, heparin plasma or urine

Stability in serum and plasma [1]:

7 days	at	4 – 25°C
3 months	at	-20°C

Stability in urine [1]:

2 days	at	20 – 25°C
6 days	at	4 – 8°C
6 months	at	-20°C

Only freeze once! Discard contaminated specimens. TruLab Urine controls must be prediluted the same way as patient samples.

Calibrators and Controls

For calibration DiaSys TruCal U calibrator is recommended. The calibrator values have been made traceable to NIST (National Institute for Standardization) Standard Reference Material SRM 967 using level 1 and 2 and, therefore, to GC-IDMS (gas chromatography-isotope dilution mass spectrometry). For internal quality control DiaSys TruLab N, TruLab P and TruLab Urine 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
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Compensated method [2,3]

Picric acid which forms the coloured complex reacts unspecifically with interfering serum components, so-called pseudo-creatinines. This leads to falsely elevated creatinine values in serum and plasma samples especially in the low measuring range. To compensate these interferences the calibrator value for the compensated method indicated in the value sheet of TruCal U has to be used for calculation. Additionally 0.3 mg/dL (27 µmol/L) has to be subtracted from the calculated creatinine value.

When using the compensated method, calibration with the calibrator TruCal U is explicitly recommended. The method is applicable only for serum and plasma samples.

The compensated method is traceable to GC-IDMS.

Performance Characteristics

Measuring range up to 15 mg/dL (1326 µmol/L) creatinine in serum (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) or use the rerun function)	
Limit of detection**	0.1 mg/dL (9 µmol/L) creatinine
On-board stability	4 days
Calibration stability	4 days

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	0.719 mg/dL (63.5 µmol/L)
Hemoglobin	up to 400 mg/dL	0.793 mg/dL (70.1 µmol/L)
Hemoglobin	up to 600 mg/dL	1.67 mg/dL (148 µmol/L)
Bilirubin, conjugated	up to 3 mg/dL	0.670 mg/dL (59.2 µmol/L)
Bilirubin, conjugated	up to 5 mg/dL	1.77 mg/dL (156 µmol/L)
Bilirubin, unconjugated	up to 7 mg/dL	0.900 mg/dL (79.6 µmol/L)
Bilirubin, unconjugated	up to 7 mg/dL	1.90 mg/dL (168 µmol/L)
Lipemia (triglycerides)	up to 1800 mg/dL	0.628 mg/dL (55.5 µmol/L)
Lipemia (triglycerides)	up to 1800 mg/dL	1.67 mg/dL (147 µmol/L)

For further information on interfering substances refer to Young DS [10].

Precision (Serum) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.731	1.31	7.69
Mean [µmol/L]	64.6	115	680
Coefficient of variation [%]	1.65	1.01	0.605
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.898	1.57	7.61
Mean [µmol/L]	79.4	138	672
Coefficient of variation [%]	0.798	1.16	0.866

Method comparison (n=106) Serum	
Test x	Creatinine FS (BioMajesty 6010C)
Test y	Creatinine FS (BX-4000)
Slope	0.982
Intercept	0.044 mg/dL (3.89 µmol/L)
Coefficient of correlation	0.9998

Measuring range up to 1200 mg/dL (106 mmol/L) creatinine in urine (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) or use the rerun function)

Precision (Urine) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	66.9	99.3	169
Mean [µmol/L]	5910	8781	14905
Coefficient of variation [%]	1.07	0.644	0.799
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	65.5	99.3	167
Mean [µmol/L]	5786	8780	14753
Coefficient of variation [%]	1.96	2.50	2.42

Method comparison (n=90) Urine	
Test x	Creatinine FS (BX-4000)
Test y	Creatinine FS (BX-3010)
Slope	0.975
Intercept	0.032 mg/dL (2.80 µmol/L)
Coefficient of correlation	0.9999

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

Conversion factor

Creatinine [mg/dL] x 88.4 = Creatinine [µmol/L]

Creatinine [mg/dL] x 0.0884 = Creatinine [mmol/L]

Calculation of Creatinine Clearance [mL/min/1.73 m²] [5]

$$= \frac{\text{mg Creatinine} / 100 \text{ mL Urine} \times \text{mL Urine}}{\text{mg Creatinine} / 100 \text{ mL Serum} \times \text{min Urine collection time}}$$

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m²).

Reference Range

Serum/plasma, Jaffé method not compensated

	mg/dL	µmol/L
Adults [6]		
Women	0.6 – 1.1	53 – 97
Men	0.7 – 1.3	62 – 115
Children [7,8]		
Neonate	0.5 – 1.2	44 - 106
Infant	0.4 – 0.7	35 - 62
Child	0.5 – 1.2	44 - 106

Serum/plasma, Jaffé method compensated

	mg/dL	µmol/L
Adults [2]		
Women	0.5 – 0.9	44 - 80
Men	0.7 – 1.2	62 - 106
Children [9]		
Neonate	0.24 – 1.04	21 – 92
Infant	0.17 – 0.42	15 – 37
Child	0.24 – 0.87	21 - 77

Urine

24h urine [6]

Women 11 – 20 mg/kg/24h 97 – 177 µmol/kg/24h

Men 14 – 26 mg/kg/24h 124 – 230 µmol/kg/24h

Albumin/creatinine ratio (early morning urine) [12]:

< 30 mg/g Creatinine

Creatinine clearance [7]

Women 95 – 160 mL/min/1.73 m²

Men 98 – 156 mL/min/1.73 m²

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

- Guder WG, Zawta B. Recommendations of the Working group on Preanalytical Quality of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine: The Quality of Diagnostic Samples. 1st ed Darmstadt: GIT Verlag 2001; p. 24-5,50-1
- Mazzachi BC, Peake MJ, Ehrhardt V. Reference Range and Method Comparison Studies for Enzymatic and Jaffé Creatine Assays in Plasma and Serum and Early Morning Urine. Clin. Lab. 2000; 46: 53-55.
- Swanson AF, Swartzentruber M, Nolen PA et al. Multicenter Evaluation of the Boehringer Mannheim Compensated, Rate-Blanked Creatinine/Jaffe Application on BM/Hitachi Systems. Advances in Clinical Diagnostics. 1993. Boehringer Mannheim Corporation.
- Levey AS, Coresh J, Greene T, Marsh J et al: Expressing the Modification of Diet in Renal Disease Study Equation for Estimating Glomerular Filtration Rate with Standardized Serum Creatinine Values. Clin Chem 2007; 53 (4): 766-72.
- Junge W, Wilke B, Halabi A, Klein G. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and a modified Jaffé method. Clin Chim Acta 2004; 344: 137-148
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- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.
- Soldin SJ, Brugnara C, Wong EC, eds. Pediatric Reference Intervals. 6th ed. AACC Press, 2007: p. 77-78
- Schlebusch H, Liappis N, Klein G. Ultrasensitive CRP and Creatinine: Reference intervals from infancy to childhood. Clin Chem Lab Med. 2001; 39 Special supplement pp S1-S448; May 2001. PO-T042
- 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.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
- Dati F, Metzmann E. Proteins-Laboratory testing and clinical use. 1st ed. Holzheim: DiaSys Diagnostic Systems; 2005: p. 93.

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	CREAJ	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	Creatinine	MethodColor		R1	CREAJ	150	
Sample Type	Serum			R2	CREAJ	38	
Unit	mg/dL			Diluent	Disable		
Assay Type	Rate			Sample Ppt. Wash	Disable		
Measuring points		Start	End	Stirring Speed R1	Middle	R2	Middle
		1	29 - 38				
		2	Disable -				
Wave Length	Prim. 510	Sec. 570		Normal Range			
				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	(Conc)	0.10	15.00
	Low	Normal	High		(mAbs/10)	*	*
<input type="checkbox"/> Diluent	0.0 <	9.5 <	0.0		Previous Result Comparison (%)	*	* %
	Rerun (High/Prozone)				Abnormal Range	(Conc)	* - *
<input type="checkbox"/> Diluent	0.0 <	9.5 <	0.0		Panic Range	(Conc)	0.10 - 15.00
	Rerun (Low)				Decimal Point	2	Profile SI
<input type="checkbox"/> Diluent	0.0 <	9.5 <	0.0				Disable

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	*	Method Name	CREAJ	Sample	Serum		
Limit Checks	Blank measurement						
<input checked="" type="checkbox"/> Duplicate Limit	20	mAbs/10		Blank measurement:			
<input checked="" type="checkbox"/> Sensitivity Limit	200	mAbs/10		Disable reagent blank and C1 blank			
<input checked="" type="checkbox"/> Linearity Limit	10	%		Measurement of Reagent Blank during Run:			
	140	(mAbs/10)/min		None			
<input type="checkbox"/> Prozone Limit	Higher	%		Reagent blank measurement at calibration:			
				Reagent blank (No sample)			
				The number of measurement:			
				Duplicate			
	SL1-S	-	SL1-F	Reagent blank limit checks:			
	SL2-S	-	SL2-F	<input checked="" type="checkbox"/> Duplicate Limit			
	Sensitivity			10 mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit	Instrument Factor						
	Abs. in reaction	Increase		a	1.00	b	0.00
	Limit	8000 mAbs/10					

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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

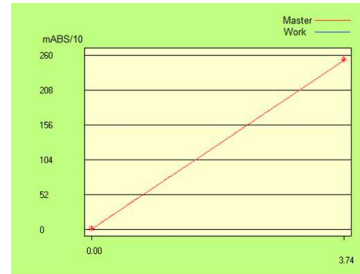
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

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

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																									
Method	* <input type="text"/>	Name	<input type="text" value="CREAJ"/>		Reagent Name	Reagent (μL)	Water (μL)																				
Print Name	<input type="text" value="Creatinine"/>		R1	<input type="text" value="CREAJ"/>	<input type="text" value="150"/>																						
Sample	<input type="text" value="Serum"/>		R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="CREAJ"/>	<input type="text" value="38"/>																					
Unit	<input type="text" value="mg/dL"/>																										
Assay Type	<input type="text" value="Rate"/>		Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																					
Measuring points	Start	End	Decimal Points	<input type="text" value="2"/>																							
	1	<input type="text" value="42"/>	-	<input type="text" value="54"/>																							
<input type="checkbox"/> Enable	2	<input type="text"/>	-	<input type="text"/>																							
Wave Length	Prim.	<input type="text" value="510"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="570"/>																						
<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	Sampling	Sample (μL)	Diluent (μL)	Technical Range	(Conc)	<input type="text" value="0.10"/>	-	<input type="text" value="15.00"/>																			
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>		(mAbs/10)	<input type="text"/>	-	<input type="text"/>																			
Rerun (High/Prozone)																											
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>																								
Rerun (Low)																											
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>																								
				SPT Wash	<input type="checkbox"/> Enable	<input type="text" value="Reagent Name"/>																					
				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="CREAJ"/>		Sample	<input type="text" value="Serum"/>
Limit Checks	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="200"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text" value="10"/> % <input type="text" value="140"/> (mAbs/10)/min <input type="checkbox"/> Prozone Limit <input type="text"/> % <input type="text" value="Upper"/>					
	SL1-S	<input type="text"/>	-	SL1-F	<input type="text"/>	
	SL2-S	<input type="text"/>	-	SL2-F	<input type="text"/>	
	Sensitivity	<input type="text"/> mAbs/10				
<input checked="" type="checkbox"/> Absorbance Limit	Reaction	<input type="text" value="Increase"/>				
	Limit	<input type="text" value="8000"/> mAbs/10				
Blank measurement						
Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/>						
Measurement of Reagent Blank during Run: <input type="text" value="None"/>						
Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/>						
The number of measurement: <input type="text" value="Duplicate"/>						
Reagent blank limit checks:						
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="10"/> mAbs/10					
Instrument Factor						
	a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>		

<u>Registration Calibration</u>		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																	
Method	<input type="text" value="*"/>	Name	<input type="text" value="CREAJ"/>																																																
Sample	<input type="text" value="Serum"/>	R Lot No. R1	<input type="text" value="*"/>																																																
Sampling	<input type="text" value="Duplicate"/>	R2	<input type="text" value="*"/>																																																
Check Interval	<input type="text" value="4"/> days	Last	<input type="text"/>																																																
Auto	<input type="text" value="Change Lot"/>	<input type="text" value="Full Calibration"/>																																																	
Auto Interval	<input type="text"/> hours																																																		
Type	<input type="text" value="Linear"/>	Lot	<input type="text" value="New"/>																																																
Material Name	<input type="text" value="TruCal U"/>																																																		
The calibration curve is lot dependent																																																			
Reagent blank	<input type="text"/>	mAbs/10	Last <input type="text"/>																																																
Blank	<input type="text" value="Automatic entry"/>	mAbs/10	Last <input type="text"/>																																																
Type	<input type="text"/>	Conc.	<input type="text"/>																																																
Absorbance	<input type="text"/>	mAbs/10	<input type="button" value="Recalculation"/>																																																
<table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th></th> <th>Conc.</th> <th>WORK</th> <th>MASTER</th> <th>Lot No. (S)</th> <th><input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td><input type="text" value="0"/></td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S2</td> <td><input type="text" value="*"/></td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S3</td> <td><input type="text" value="*"/></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td><input type="text" value="*"/></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td><input type="text" value="*"/></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td><input type="text" value="*"/></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td><input type="text" value="*"/></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					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="*"/>				
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S7	<input type="text" value="*"/>																																																		
K	<input type="text" value="Automatic entry"/>	<input type="checkbox"/> S1 Blank	<input type="checkbox"/> Reagent Blank for S1																																																
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Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																							
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="CREAJ"/>	Reagent Name	Reagent (µL)	Water (µL)																					
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Sample Type	<input type="text" value="Urine"/>			R2	<input type="text" value="CREAJ"/>	<input type="text" value="38"/>																					
Unit	<input type="text" value="mg/dL"/>			Diluent	<input type="text" value="Disable"/>																						
Assay Type	<input type="text" value="Rate"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>																						
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2	<input type="text" value="Middle"/>																				
		1	<input type="text" value="29"/> - <input type="text" value="38"/>																								
		2	<input type="text" value="Disable"/> - <input type="text" value=""/>																								
Wave Length	Prim. <input type="text" value="510"/>	Sec. <input type="text" value="570"/>		Normal Range																							
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1	Male-G1	*	*																								
2	Male-G2	*	*																								
3	Male-G3	*	*																								
4	Female-G1	*	*																								
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																							
	Low Normal High			(Conc)	<input type="text" value="0.10"/>	-	<input type="text" value="1200"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="9.5"/> < <input type="text" value="0.0"/>	<input type="text" value="4.0"/>	<input type="text" value="196"/>	(mAbs/10)	<input type="text" value="*"/>	-	<input type="text" value="*"/>																				
	Rerun (High/Prozone)			Previous Result Comparison (%)	<input type="text" value="*"/>		<input type="text" value="*"/> %																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="9.5"/> < <input type="text" value="0.0"/>	<input type="text" value="4.0"/>	<input type="text" value="196"/>	Abnormal Range	(Conc) <input type="text" value="*"/>	-	<input type="text" value="*"/>																				
	Rerun (Low)			Panic Range	(Conc) <input type="text" value="0.10"/>	-	<input type="text" value="1200"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="9.5"/> < <input type="text" value="0.0"/>	<input type="text" value="4.0"/>	<input type="text" value="196"/>	Decimal Point	<input type="text" value="2"/>	Profile SI	<input type="text" value="Disable"/>																				

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters				
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="CREAJ"/>	Sample	<input type="text" value="Serum"/>			
Limit Checks				Blank measurement	Blank measurement: <input type="text" value="Disable reagent blank and C1 blank"/>			
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10		Measurement of Reagent Blank during Run:	<input type="text" value="None"/>			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="200"/>	mAbs/10		Reagent blank measurement at calibration:	<input type="text" value="Reagent blank (No sample)"/>			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%		The number of measurement:	<input type="text" value="Duplicate"/>			
	<input type="text" value="140"/>	(mAbs/10)/min		Reagent blank limit checks:	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="10"/> mAbs/10			
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%		Instrument Factor				
	<input type="text" value=""/>				a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>
	SL1-S <input type="text" value=""/>	-	SL1-F <input type="text" value=""/>					
	SL2-S <input type="text" value=""/>	-	SL2-F <input type="text" value=""/>					
	Sensitivity <input type="text" value=""/>	mAbs/10						
<input checked="" type="checkbox"/> Absorbance Limit								
	Abs. in reaction	<input type="text" value="Increase"/>						
	Limit	<input type="text" value="8000"/> mAbs/10						

Calibration Registration

**Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters**

Method No.

Method Name

Sample Type

Replication

Check Interval

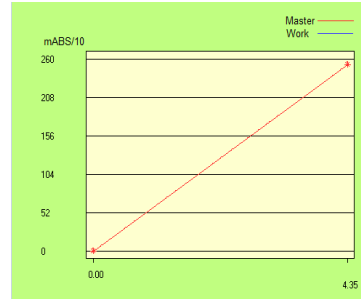
Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

Reagent Lot No.
(R1)
(R2) Last



The calibration curve is lot dependent

	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	*				

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

K C1 Blank
 Reagent Blank for C1

*Entered by user

Creatinine FS

Chemistry Code 100 27

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters						
Method	*	Name	CREAJ	Reagent Name	Reagent (µL)	Water (µL)		
Print Name	Creatinine	R1	CREAJ	150				
Sample	Urine	R2	CREAJ	38				
Unit	mg/dL							
Assay Type	Rate	Diluent	<input type="checkbox"/> Enable					
Measuring points		Start	End	Decimal Points	2			
	1	42	54					
<input type="checkbox"/> Enable	2							
Wave Length	Prim. 510	Sec	<input type="checkbox"/> Disable 570	Normal Range				
				No.	Normal Range Name	Min	Max	
				1	Male-G1	*	*	
				2	Male-G2	*	*	
				3	Male-G3	*	*	
				4	Female-G1	*	*	
<input type="checkbox"/> Dilution	9.5	Sample (µL)	4.0	Diluent (µL)	196	Technical Range	4.0	
						(Conc)	0.10 - 1200	
						(mAbs/10)		
<input type="checkbox"/> Rerun (High/Prozone)								
<input type="checkbox"/> Dilution	9.5	4.0	196	4.0				
<input type="checkbox"/> Rerun (Low)								
<input type="checkbox"/> Dilution	9.5	4.0	196	4.0				
				SPT Wash	<input type="checkbox"/> Enable	Reagent Name		
				Stirring Speed	R1	Middle	R2	Middle

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	*	Name	CREAJ	Sample	Urine
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	20	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	200	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit	10	%	140	(mAbs/10)/min	
<input type="checkbox"/> Prozone Limit		%	Upper		
	SL1-S		SL1-F		
	SL2-S		SL2-F		
Sensitivity		mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit					
	Reaction	Increase			
	Limit	8000	mAbs/10		
Blank measurement					
Blank measurement:	Disable reagent blank and S1 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	10	mAbs/10			
Instrument Factor					
	a	1.00	b	0.00	

Creatinine FS

Chemistry Code 100 27

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer Analytical Parameters

Method Name

Sample

Sampling

Check Interval days

Auto

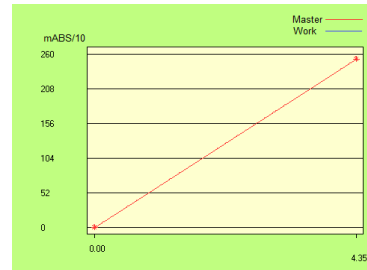
Auto Interval hours

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	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K S1 Blank Reagent Blank for S1

*Entered by user