

Creatinine FS*

Order Information

Cat. No.	Kit size	Instrument	Σ
1 1711 99 10 972	R1 3 x 11.8 mL	BX-3010	270 (3 x 90)
		BX-4000	186 (3 x 62)
	R2 3 x 5.1 mL	BX-3010	270 (3 x 90)
		BX-4000	186 (3 x 62)

Intended Use

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

Summary

Creatinine is a waste product excreted by the kidneys mainly by glomerular filtration. The concentration of creatinine in plasma of a healthy individual is fairly constant, independent from water intake, exercise and rate of urine production. Therefore, increased plasma creatinine values always indicate decreased excretion, i.e. impaired kidney function. Creatinine clearance is a good indicator for the glomerular filtration rate (GFR) which allows better detection of kidney diseases and monitoring of renal function. For this purpose, creatinine is measured simultaneously in serum and urine collected over a defined time period. [1,2]

Method

Kinetic test without deproteinization according to the Jaffé method
Creatinine forms a colored orange-red complex in an alkaline picrate 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 and Stability

The reagents are stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Protect reagents from light.

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 packaging. P264 Wash hands and face thoroughly after handling. 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. P332+P313 If skin irritation occurs: Get medical advice/attention. 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 packaging. P280 Wear protective gloves/protective clothing/eye 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 [3].
- 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

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

Serum, heparin plasma or urine

Stability in serum/plasma [4]:

7 days	at	4 – 25°C
3 months	at	-20°C

Stability in urine [4]:

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

TruLab Urine controls must be prediluted the same way as patient samples.

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values for the compensated method have been made traceable to the 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). Use DiaSys TruLab N and P or TruLab Urine controls 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
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

Picric acid which forms the colored 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. For use of the compensated method, calibration with the calibrator TruCal U is strictly recommended. The method is applicable only for serum and plasma samples. The compensated method is traceable to GC-IDMS. [5,6]

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 15 mg/dL (1326 µmol/L) in serum and up to 1200 mg/dL (106 mmol/L) in urine. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.1 mg/dL (9 µmol/L)
Onboard stability	4 days
Calibration stability	4 days

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

For further information on interfering substances refer to Young DS [7,8].

Precision in 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
CV [%]	1.65	1.01	0.605
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.898	1.57	7.61
Mean [µmol/L]	79.4	1.38	672
CV [%]	0.798	1.16	0.866

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

Precision in 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
CV [%]	1.07	0.644	0.799
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	65.5	99.3	167
Mean [µmol/L]	5786	8780	14753
CV [%]	1.96	2.50	2.42

Method comparison in urine (n=90)	
Test x	DiaSys Creatinine FS (BX-4000)
Test y	DiaSys 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

Creatinine Clearance [mL/min/1.73 m²] [9]

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

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

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 [1]		
Women	0.6 – 1.1	53 – 97
Men	0.7 – 1.3	62 – 115

Children [2,10]

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 [5]		
Women	0.5 – 0.9	44 – 80
Men	0.7 – 1.2	62 – 106

Children [11]

Neonate	0.24 – 1.04	21 – 92
Infant	0.17 – 0.42	15 – 37
Child	0.24 – 0.87	21 – 77

24h urine [1]

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 [2]

Women	95 – 160 mL/min/1.73 m ²
Men	98 – 156 mL/min/1.73 m ²

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

Literature

- Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-1270.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 366-74.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
- 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.

7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Vol. 1 and 2. Washington, CD: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed on January 2021. Published by AACC Press and John Wiley and Sons, Inc.
9. 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.
10. Soldin SJ, Brugnara C, Wong EC, eds. Pediatric Reference Intervals. 6th ed. AACC Press, 2007: p. 77-78.
11. 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.
12. Dati F, Metzmann E. Proteins-Laboratory testing and clinical use. 1st ed. Holzheim: DiaSys Diagnostic Systems; 2005: p. 93.



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www.diasys-diagnostics.com

* Fluid Stable

Creatinine FS

Chemistry Code 100 27

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																										
Method No.	* <input type="text"/>	Method Name	<input type="text" value="CREAJ"/>	Reagent Name	Reagent (µL)	Water (µL)																								
Print Name	<input type="text" value="Creatinine"/>	MethodColor		R1	<input type="text" value="CREAJ"/>	<input type="text" value="100"/>																								
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="CREAJ"/>	<input type="text" value="25"/>																								
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"/>																											
Wave Length	Prim. <input type="text" value="510"/>	Sec. <input type="text" value="570"/>																												
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4">Normal Range</th> </tr> <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>							Normal Range				No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																										
	Low <input type="text" value="0.0"/> < Normal <input type="text" value="6.3"/> < High <input type="text" value="0.0"/>			(Conc) <input type="text" value="0.10"/> - <input type="text" value="15.00"/>																										
<input type="checkbox"/> Diluent				(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="6.3"/> < <input type="text" value="0.0"/>			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="15.00"/>																										
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="6.3"/> < <input type="text" value="0.0"/>			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"/>	Method 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" value="Higher"/>	%				
	<input type="text"/>					
	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						
	Abs. in 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 C1 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"/>				

Creatinine FS

Chemistry Code 100 27

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	<input type="text" value="0"/>	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

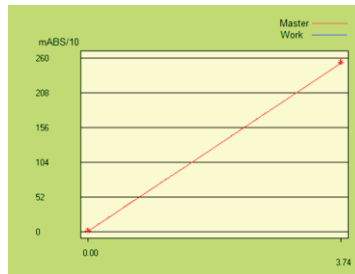
K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)

Last

(R2)



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Creatinine FS

Chemistry Code 100 27

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="CREAJ"/>	Reagent Name	<input type="text"/>																				
Print Name	<input type="text" value="Creatinine"/>	R1	<input type="text" value="CREAJ"/>	Reagent (µL)	<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"/>	Water (µL) <input type="text"/>																							
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"/>																					
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1	Male-G1	*	*																						
2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range																					
<input type="checkbox"/> Dilution	<input type="text" value="9.5"/>	<input type="text"/>	<input type="text"/>	(Conc) <input type="text" value="0.10"/>	- <input type="text" value="15.00"/>																				
Rerun (High/Prozone)					(mAbs/10) <input type="text"/>																				
<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	Reagent Name	<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="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="*"/>																																																
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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"/>																																																	
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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"/>																																																
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<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="*"/>				
	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	<input type="text" value="Automatic entry"/>	<input type="checkbox"/> S1 Blank	<input type="checkbox"/> Reagent Blank for S1																																																
*Entered by user																																																			

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																										
Method No.	* <input type="text"/>	Method Name	<input type="text" value="CREAJ"/>	Reagent Name	Reagent (µL)	Water (µL)																								
Print Name	<input type="text" value="Creatinine"/>	MethodColor		R1	<input type="text" value="CREAJ"/>	<input type="text" value="150"/>																								
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"/>	<input type="text"/>																								
Assay Type	<input type="text" value="Rate"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>	<input type="text"/>																								
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"/>																											
Wave Length	Prim. <input type="text" value="510"/>	Sec. <input type="text" value="570"/>																												
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4">Normal Range</th> </tr> <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>							Normal Range				No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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																										
	Low <input type="text" value="0.0"/> < Normal <input type="text" value="9.5"/> < High <input type="text" value="0.0"/> <input type="text" value="4.0"/>	<input type="text" value="196"/>	<input type="text" value="196"/>	(Conc) <input type="text" value="0.10"/> - <input type="text" value="1200"/>																										
<input type="checkbox"/> Diluent				(mAbs/10) <input type="text" value="*"/> - <input type="text" value="*"/>																										
<input type="checkbox"/> 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"/>	<input type="text" value="196"/>	Abnormal Range (Conc) <input type="text" value="*"/> - <input type="text" value="*"/>																										
<input type="checkbox"/> 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"/>	<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"/>	Method 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" value="Higher"/>	%				
	<input type="text"/>					
	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						
	Abs. in 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 C1 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"/>			

Creatinine FS

Chemistry Code 100 27

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	<input type="text" value="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) Last

(R2)

The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*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		<input checked="" type="checkbox"/> Enable																							
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																					
				<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																						
<input type="checkbox"/> Dilution	9.5	4.0	196	4.0	(Conc)	0.10 - 1200																				
	Rerun (High/Prozone)				(mAbs/10)																					
<input type="checkbox"/> Dilution	9.5	4.0	196	4.0																						
	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

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