

Creatinine PAP FS*

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

Order information

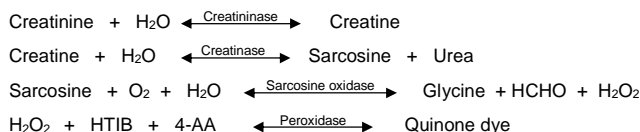
Cat. No.	Kit size	Number of tests
1 1759 99 10 972	R1 3 x 13.0 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests
	R2 3 x 8.0 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests

Method

Enzymatic colorimetric test

Principle

Creatinine is determined by the following reaction:



The absorbance of the produced red dye at 545 nm is proportional to the creatinine concentration in the sample.

Reagents

Components and Concentrations

R1:	Goods buffer	pH 8.1	25 mmol/L
	Creatininase		≥ 30 kU/L
	Sarcosine oxidase		≥ 10 kU/L
	Ascorbate oxidase		≥ 2.5 kU/L
	Catalase		≥ 350 kU/L
	HTIB (3-Hydroxy 2,4,6-triiodo benzoic acid)		2.3 mmol/L
R2:	Goods buffer	pH 8.1	25 mmol/L
	Creatininase		≥ 150 kU/L
	Peroxidase		≥ 50 kU/L
	4-Aminoantipyrine (4-AA)		2 mmol/L
	Potassium hexacyanoferrate		0.18 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

1. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. High homogentisic acid concentrations in urine samples lead to false results.
3. In very rare cases, samples of patients with gammopathy might give falsified results [9].
4. N-acetylcysteine (NAC), acetaminophen, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
5. 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.
6. 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 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

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

Calibrators and Controls

For calibration the 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

Performance Characteristics

Measuring range up to 90 mg/dL Creatinine in serum and up to 800 mg/dL 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**	0.010 mg/dL (0.884 µmol/L)
On-board stability	6 weeks
Calibration stability	6 weeks

** lowest measurable concentration 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 27 mg/dL	0.725 mg/dL (64.1 µmol/L)
Hemoglobin	up to 500 mg/dL	0.731 mg/dL (64.6 µmol/L)
Bilirubin, conjugated	up to 12.5 mg/dL	0.638 mg/dL (56.4 µmol/L)
	up to 12.5 mg/dL	1.51 mg/dL (133 µmol/L)
Bilirubin, unconjugated	up to 20 mg/dL	0.643 mg/dL (56.8 µmol/L)
	up to 25 mg/dL	1.51 mg/dL (133 µmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	0.475 mg/dL (42.0 µmol/L)
	up to 2000 mg/dL	1.52 mg/dL (134 µmol/L)

For further information on interfering substances refer to Young DS [1].

Precision (serum) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.576	1.28	8.00
Mean [µmol/L]	50.9	113	707
Coefficient of variation [%]	0.887	0.561	0.324
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.546	1.28	7.80
Mean [µmol/L]	48.2	113	690
Coefficient of variation [%]	1.39	0.900	0.865

Precision (urine) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	39.1	112	172
Mean [mmol/L]	3.45	9.91	15.2
Coefficient of variation [%]	0.958	0.690	0.809
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	38.2	105	169
Mean [mmol/L]	3.38	9.25	14.9
Coefficient of variation [%]	0.696	0.841	0.690

Method comparison (n=137)	
Test x	Creatinine PAP FS (BioMajesty 6010C)
Test y	Creatinine PAP FS (BX-4000)
Slope	0.992
Intercept	-0.028 mg/dL (-2.44 µmol/L)
Coefficient of correlation	0.9998

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] [2]

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

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

Reference Range

Serum/Plasma

	mg/dL	µmol/L
Adults [4]		
Women	0.51 – 0.95	45 – 84
Men	0.67 – 1.17	59 – 104
Children [5]		
0 – 7 days	0.6 – 1.1	53 – 97
1 week – 1 month	0.3 – 0.7	27 – 62
1 – 6 month(s)	0.2 – 0.4	18 – 35
7 – 12 months	0.2 – 0.4	18 – 35
1 – 18 year(s)	0.2 – 0.7	18 – 62

Morning urine [4]

Women	29 – 226	2.55 – 20.0
Men	40 – 278	3.54 – 24.6

24h urine [2]

Women	720 – 1510 mg/24h	6 – 13 mmol/24h
Men	980 – 2200 mg/24h	9 – 19 mmol/24h

Albumin/creatinine ratio (early morning urine) [10]:

< 30 mg/g Creatinine

Creatinine clearance [2]

66.3 - 143 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.
- 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
- 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.
- Mazzachi BC, Peake M, Erhardt V. Reference range and method comparison for enzymatic and Jaffé Creatinine assays in plasma and serum and early morning urine. Clin Lab 2000; 46: 53-5.
- Schlebusch Soldin SJ, Hicks JM. Pediatric reference ranges . Washington: AACC Press, 1995:50.
- 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.
- 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	CREA	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	Creatinine	MethodColor		R1	CREA	100	
Sample Type	Serum			R2	CREA	50	
Unit	mg/dL			Diluent	Disable		
Assay Type	End			Sample Ppt. Wash	Disable		
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle	
		1	22 - 23				
		2	45 - 46				
Wave Length	Prim. 546	Sec. 700		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)	0.01	90
<input type="checkbox"/>	Low 0.0 < 2.5	Normal < 0.0	High	(mAbs/10)	*	*	*
<input type="checkbox"/>	Diluent 0.0 < 2.5	< 0.0		Previous Result Comparison (%)	*	*	%
<input type="checkbox"/>	Diluent 0.0 < 2.5	< 0.0		Abnormal Range	(Conc)	*	*
<input type="checkbox"/>	Diluent 0.0 < 2.5	< 0.0		Panic Range	(Conc)		
				Decimal Point	2	Profile SI	Disable

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	CREA	Sample	Serum	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/>	Duplicate Limit	100	mAbs/10	Blank measurement:	Disable reagent blank and C1 blank	
<input checked="" type="checkbox"/>	Sensitivity Limit	900	mAbs/10	Measurement of Reagent Blank during Run:	None	
<input checked="" type="checkbox"/>	Linearity Limit		%	Reagent blank measurement at calibration:	Reagent blank (No sample)	
			(mAbs/10)/min	The number of measurement:	Duplicate	
<input type="checkbox"/>	Prozone Limit	Higher	%	Reagent blank limit checks:	<input checked="" type="checkbox"/>	Duplicate Limit 10 mAbs/10
				Instrument Factor	a	1.00
	SL1-S		SL1-F		b	0.00
	SL2-S		SL2-F			
	Sensitivity		mAbs/10			
<input checked="" type="checkbox"/>	Absorbance Limit					
	Abs. in reaction	Increase				
	Limit	25000	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

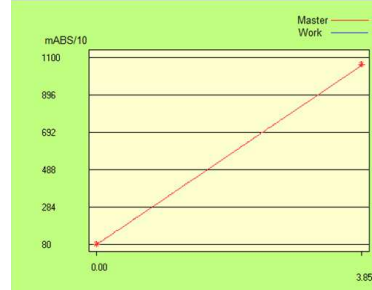
Reagent Lot

Calibrator Name

	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) 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

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text" value=""/>	Name	<input type="text" value="CREA"/>																						
Print Name	<input type="text" value="Creatinine"/>	R1	<input type="text" value="CREA"/>	<input type="text" value="150"/>	<input type="text" value=""/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="CREA"/>	<input type="text" value="75"/>																				
Unit	<input type="text" value="mg/dL"/>																								
Assay Type	<input type="text" value="End"/>	Diluent	<input type="checkbox"/> Enable	<input type="text" value=""/>	<input type="text" value=""/>																				
Measuring points		Start	End	Decimal Points	<input type="text" value="2"/>																				
	<input type="checkbox"/> Enable	1	<input type="text" value="33"/> - <input type="text" value="34"/>																						
		2	<input type="text" value="67"/> - <input type="text" value="68"/>																						
Wave Length	Prim. <input type="text" value="546"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>																					
<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	*	*																						
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3	Male-G3	*	*																						
4	Female-G1	*	*																						
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range																					
<input type="checkbox"/> Dilution	<input type="text" value="3.8"/>	<input type="text" value=""/>	<input type="text" value=""/>	(Conc) <input type="text" value="0.01"/> - <input type="text" value="90"/>																					
	Rerun (High/Prozone)			(mAbs/10) <input type="text" value=""/>	<input type="text" value=""/>																				
<input type="checkbox"/> Dilution	<input type="text" value="3.8"/>	<input type="text" value=""/>	<input type="text" value=""/>																						
	Rerun (Low)																								
<input type="checkbox"/> Dilution	<input type="text" value="3.8"/>	<input type="text" value=""/>	<input type="text" value=""/>																						
				SPT Wash	<input type="checkbox"/> Enable <input type="text" value=""/>																				
				Reagent Name	<input type="text" value=""/>																				
				Stirring Speed	R1 <input type="text" value="Middle"/> R2 <input type="text" value="Middle"/>																				
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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters					
Method No.	* <input type="text" value=""/>	Name	<input type="text" value="CREA"/>	Sample	<input type="text" value="Serum"/>		
<table border="0" style="width:100%;"> <tr> <td style="width:50%; vertical-align: top;"> <p>Limit Checks</p> <p><input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="100"/> mAbs/10</p> <p><input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="900"/> mAbs/10</p> <p><input checked="" type="checkbox"/> Linearity Limit <input type="text" value=""/> % <input type="text" value=""/> (mAbs/10)/min</p> <p><input type="checkbox"/> Prozone Limit <input type="text" value=""/> % <input type="text" value="Upper"/></p> <p>SL1-S <input type="text" value=""/> - SL1-F <input type="text" value=""/></p> <p>SL2-S <input type="text" value=""/> - SL2-F <input type="text" value=""/></p> <p>Sensitivity <input type="text" value=""/> mAbs/10</p> <p><input checked="" type="checkbox"/> Absorbance Limit</p> <p>Reaction <input type="text" value="Increase"/></p> <p>Limit <input type="text" value="25000"/> mAbs/10</p> </td> <td style="width:50%; vertical-align: top;"> <p>Blank measurement</p> <p>Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/></p> <p>Measurement of Reagent Blank during Run: <input type="text" value="None"/></p> <p>Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/></p> <p>The number of measurement: <input type="text" value="Duplicate"/></p> <p>Reagent blank limit checks:</p> <p><input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="10"/> mAbs/10</p> <hr/> <p>Instrument Factor</p> <p>a <input type="text" value="1.00"/> b <input type="text" value="0.00"/></p> </td> </tr> </table>						<p>Limit Checks</p> <p><input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="100"/> mAbs/10</p> <p><input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="900"/> mAbs/10</p> <p><input checked="" type="checkbox"/> Linearity Limit <input type="text" value=""/> % <input type="text" value=""/> (mAbs/10)/min</p> <p><input type="checkbox"/> Prozone Limit <input type="text" value=""/> % <input type="text" value="Upper"/></p> <p>SL1-S <input type="text" value=""/> - SL1-F <input type="text" value=""/></p> <p>SL2-S <input type="text" value=""/> - SL2-F <input type="text" value=""/></p> <p>Sensitivity <input type="text" value=""/> mAbs/10</p> <p><input checked="" type="checkbox"/> Absorbance Limit</p> <p>Reaction <input type="text" value="Increase"/></p> <p>Limit <input type="text" value="25000"/> mAbs/10</p>	<p>Blank measurement</p> <p>Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/></p> <p>Measurement of Reagent Blank during Run: <input type="text" value="None"/></p> <p>Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/></p> <p>The number of measurement: <input type="text" value="Duplicate"/></p> <p>Reagent blank limit checks:</p> <p><input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="10"/> mAbs/10</p> <hr/> <p>Instrument Factor</p> <p>a <input type="text" value="1.00"/> b <input type="text" value="0.00"/></p>
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<u>Registration Calibration</u>	Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																
Method <input type="text" value="*"/> Name <input type="text" value="CREA"/>	R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/> R2 <input type="text" value="*"/>																																																
Sample <input type="text" value="Serum"/>	<p>The calibration curve is lot dependent</p>																																																
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<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:5%;"></th> <th style="width:15%;">Conc.</th> <th style="width:15%;">WORK</th> <th style="width:15%;">MASTER</th> <th style="width:15%;">Lot No. (S)</th> <th style="width:10%;">All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td>0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td><input type="checkbox"/></td> </tr> <tr> <td>S2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Conc.	WORK	MASTER	Lot No. (S)	All	S1	0	Automatic entry	Automatic entry		<input type="checkbox"/>	S2	*	Automatic entry	Automatic entry			S3	*					S4	*					S5	*					S6	*					S7	*					Type <input type="text"/> Conc. <input type="text"/>
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K <input type="text" value="Automatic entry"/> <input type="checkbox"/> S1 Blank <input type="checkbox"/> Reagent Blank for S1	Absorbance <input type="text"/> mAbs/10 <input type="button" value="Recalculation"/>																																																
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Chemistry Parameters 1			Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																						
Method No.	* []	Method Name	[CREA]	Reagent Name	Reagent (μL) Water (μL)																				
Print Name	[Creatinine]	MethodColor		R1	[CREA] [100] []																				
Sample Type	[Urine]			R2	[CREA] [50] []																				
Unit	[mg/dL]			Diluent	[Disable] []																				
Assay Type	[End]			Sample Ppt. Wash	[Disable]																				
Measuring points		Start	End	Stirring Speed R1	[Middle] R2 [Middle]																				
		1 [22]	- [23]																						
		2 [45]	- [46]																						
Wave Length	Prim. [546]	Sec.	[700]	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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2	Male-G2	*	*																						
3	Male-G3	*	*																						
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Normal	Sample Volume (μL)	Diluted Sample (μL)	Diluent (μL)	Technical Range																					
	Low Normal High			(Conc)	[0.03] - [800]																				
<input type="checkbox"/> Diluent	[0.0] < [2.5] < [0.0]	[10.0]	[90]	(mAbs/10)	[*] - [*]																				
Rerun (High/Prozone)				Previous Result Comparison (%)	[*] [*] %																				
<input type="checkbox"/> Diluent	[0.0] < [2.5] < [0.0]	[10.0]	[90]	Abnormal Range	(Conc) [*] - [*]																				
Rerun (Low)				Panic Range	(Conc) [*] - [*]																				
<input type="checkbox"/> Diluent	[0.0] < [2.5] < [0.0]	[10.0]	[90]	Decimal Point	[2] Profile SI [Disable]																				

*Entered by user

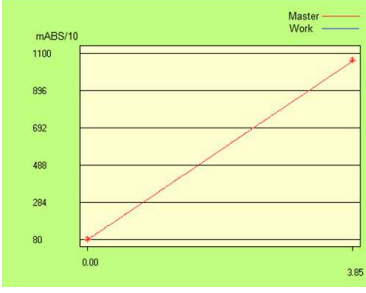
Chemistry Parameters 2		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters	
Method No.	* []	Method Name	[CREA U]
		Sample	[Urine]
Limit Checks		Blank measurement	
<input checked="" type="checkbox"/> Duplicate Limit	[100] mAbs/10	Blank measurement:	[Disable reagent blank and C1 blank]
<input checked="" type="checkbox"/> Sensitivity Limit	[900] mAbs/10	Measurement of Reagent Blank during Run:	[None]
<input type="checkbox"/> Linearity Limit	[] %	Reagent blank measurement at calibration:	[Reagent blank (No sample)]
	[] (mAbs/10)/min	The number of measurement:	[Duplicate]
<input type="checkbox"/> Prozone Limit	[Higher] %	Reagent blank limit checks:	
	[]	<input checked="" type="checkbox"/> Duplicate Limit	[10] mAbs/10
SL1-S [] - SL1-F []		Instrument Factor	
SL2-S [] - SL2-F []		a [1.00] b [0.00]	
Sensitivity [] mAbs/10			
<input type="checkbox"/> Absorbance Limit			
Abs. in reaction	[Increase]		
Limit	[25000] mAbs/10		

<u>Calibration Registration</u>		Sysmex BX-3010 Chemistry Analyzer																																															
		Analytical Parameters																																															
<p>Method No. <input style="width: 80%;" type="text" value="*"/></p> <p>Method Name <input style="width: 80%;" type="text" value="CREA U"/></p> <p>Sample Type <input style="width: 80%;" type="text" value="Urine"/></p> <p>Replication <input style="width: 80%;" type="text" value="Duplicate"/></p> <p>Check Interval <input style="width: 80%;" type="text" value="42"/></p> <p>Test without calibration <input style="width: 80%;" type="text" value="Disable"/></p> <p>Calibration Type <input style="width: 80%;" type="text" value="Linear"/></p> <p>Reagent Lot <input style="width: 40%;" type="text" value="New"/> <input style="width: 40%; background-color: #cccccc;" type="button" value="Add"/></p> <p>Calibrator Name <input style="width: 80%;" type="text" value="TruCal U"/></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 20%;">Conc.</th> <th style="width: 20%;">WORK</th> <th style="width: 20%;">MASTER</th> <th style="width: 20%;">Calibr. Lot No.</th> <th style="width: 15%; text-align: right;">□ All</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>0.0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> <td></td> </tr> <tr> <td>C2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> <td></td> </tr> <tr> <td>C3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>C7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p style="margin-top: 5px;">K <input style="width: 80%;" type="text" value="Automatic entry"/> <input type="checkbox"/> C1 Blank <input type="checkbox"/> Reagent Blank for C1</p>		Conc.	WORK	MASTER	Calibr. Lot No.	□ All	C1	0.0	Automatic entry	Automatic entry	*		C2	*	Automatic entry	Automatic entry	*		C3	*					C4	*					C5	*					C6	*					C7	*					<p>Reagent Lot No. (R1) <input style="width: 80%;" type="text" value="*"/> (R2) <input style="width: 80%;" type="text" value="*"/> Last <input style="width: 80%;" type="text"/></p> <div style="text-align: center; margin: 10px 0;"> <p style="font-size: small;">The calibration curve is lot dependent</p> </div> <p>Reagent blank <input style="width: 80%;" type="text"/> mAbs/10 Last <input style="width: 80%;" type="text"/></p> <p>Blank <input style="width: 80%;" type="text" value="Automatic entry"/> mAbs/10 Last <input style="width: 80%;" type="text"/></p> <p>Calibration Curve <input style="width: 80%;" type="text"/> Conc. <input style="width: 80%;" type="text"/></p> <p>Absorbance <input style="width: 80%;" type="text"/> mAbs/10 <input style="background-color: #cccccc;" type="button" value="Recalculation"/></p>
	Conc.	WORK	MASTER	Calibr. Lot No.	□ All																																												
C1	0.0	Automatic entry	Automatic entry	*																																													
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C7	*																																																
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Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																						
Method	*	Name	CREA U	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Creatinine		R1	CREA	150																					
Sample	Urine		R2 <input checked="" type="checkbox"/> Enable	CREA	75																					
Unit	mg/dL																									
Assay Type	End		Diluent <input type="checkbox"/> Enable																							
Measuring points	Start	End	Decimal Points	2																						
	1	33 - 34																								
<input checked="" type="checkbox"/> Enable	2	67 - 68																								
Wave Length	Prim.	546	Sec	<input type="checkbox"/> Disable	700																					
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3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range																						
<input type="checkbox"/> Dilution	3.8	10.0	90	(Conc)	0.03	- 800																				
	Rerun (High/Prozone)			(mAbs/10)																						
<input type="checkbox"/> Dilution	3.8	10.0	90																							
	Rerun (Low)																									
<input type="checkbox"/> Dilution	3.8	10.0	90																							
				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	CREA	Sample	Serum	
Limit Checks						
<input checked="" type="checkbox"/> Duplicate Limit	100	mAbs/10				
<input checked="" type="checkbox"/> Sensitivity Limit	900	mAbs/10				
<input type="checkbox"/> Linearity Limit		%		(mAbs/10)/min		
<input type="checkbox"/> Prozone Limit		%	Upper			
	SL1-S	-	SL1-F			
	SL2-S	-	SL2-F			
	Sensitivity	mAbs/10				
<input type="checkbox"/> Absorbance Limit						
	Reaction	Increase				
	Limit	25000 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

<u>Registration Calibration</u>			Sysmex BX-4000 Chemistry Analyzer																																									
			Analytical Parameters																																									
Method <input style="width: 80%;" type="text" value="*"/>	Name <input style="width: 80%;" type="text" value="CREA U"/>	R Lot No. <input style="width: 80%;" type="text" value="*"/>	Last <input style="width: 80%;" type="text"/>																																									
Sample <input style="width: 80%;" type="text" value="Urine"/>		R2 <input style="width: 80%;" type="text" value="*"/>																																										
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Check Interval <input style="width: 40%;" type="text" value="42"/> days																																												
Auto <input style="width: 80%;" type="text" value="Change Lot"/> <input style="width: 80%;" type="text" value="Full Calibration"/>																																												
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Type <input style="width: 80%;" type="text" value="Linear"/> Lot <input style="width: 80%;" type="text" value="New"/>		The calibration curve is lot dependent																																										
Material Name <input style="width: 80%;" type="text" value="NaCl / TruCal U"/>		Reagent blank <input style="width: 80%;" type="text"/> mAbs/10	Last <input style="width: 80%;" type="text"/>																																									
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