

# Urea FS\*

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

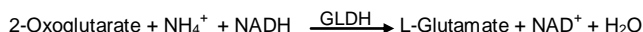
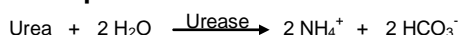
## Order information

Cat. No.	Kit size	Number of tests
1 3101 99 10 972	R1 3 x 18.6 mL	BX-3010 3 x 120 tests BX-4000 3 x 98 tests
	R2 3 x 7.1 mL	BX-3010 3 x 120 tests BX-4000 3 x 98 tests

## Method

"Urease – GLDH": enzymatic UV test

## Principle



GLDH: Glutamate dehydrogenase

## Reagents

### Components and Concentrations

R1:	TRIS	pH 7.8	150 mmol/L
	2-Oxoglutarate		9 mmol/L
	ADP		0.75 mmol/L
	Urease		≥ 7 kU/L
	GLDH (Glutamate dehydrogenase, bovine)		≥ 1 kU/L
R2:	NADH		1.3 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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

### Waste Management

Please refer to local legal requirements.

### Reagent Preparation

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

## Specimen

Serum, plasma (no ammonium heparin!), fresh urine

Stability [1]

in serum or plasma:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	-20°C

in urine:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
1 month	at	-20°C

Discard contaminated specimens. Freeze only once.

TruLab Urine controls must be pre-diluted the same way as patient samples.

## Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. The assigned values of the calibrators have been made traceable to the reference material NIST SRM<sup>®</sup>-909 Level 1. 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 in serum up to 300 mg/dL (50.0 mmol/L) urea (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	1 mg/dL (0.167 mmol/L) urea
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 30 mg/dL	33.0 mg/dL (5.50 mmol/L)
Hemoglobin	up to 500 mg/dL	32.9 mg/dL (5.47 mmol/L)
Bilirubin, conjugated	up to 60 mg/dL	32.9 mg/dL (5.47 mmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	33.5 mg/dL (5.58 mmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	44.3 mg/dL (7.37 mmol/L)
Ammonium ions interfere; therefore do not use ammonium heparin as anticoagulant for collection of plasma!		
For further information on interfering substances refer to Young DS [5].		

Precision (Serum/plasma) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	19.0	53.5	150
Mean [mmol/L]	3.16	8.90	24.9
Coefficient of variation [%]	1.38	0.786	0.683
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	19.0	53.0	145
Mean [mmol/L]	3.16	8.83	24.2
Coefficient of variation [%]	1.70	1.50	1.20

Method comparison serum (n=108)	
Test x	Urea FS (BioMajesty 6010C)
Test y	Urea FS (BX-4000)
Slope	0.973
Intercept	1.02 mg/dL (0.170 mmol/L)
Coefficient of correlation	0.9998

Measuring range in urine up to 30000 mg/dL (5000 µmol/L) urea (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Precision (Urine) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	883	1841	2574
Mean [mmol/L]	147	307	429
Coefficient of variation [%]	3.76	2.73	3.04
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	886	1936	2594
Mean [mmol/L]	147	322	432
Coefficient of variation [%]	4.27	1.83	2.30

Method comparison urine (n=74)	
Test x	Urea FS (BX-4000)
Test y	Urea FS (BX-3010)
Slope	0.957
Intercept	3.57 mg/dL (0.595 mmol/L)
Coefficient of correlation	0.999

#### Conversion factor

Urea [mg/dL] x 0.1665 = Urea [mmol/L]

Urea [mg/dL] x 0.467 = BUN [mg/dL]

BUN [mg/dL] x 2.14 = Urea [mg/dL]

(BUN: Blood urea nitrogen)

#### Reference Range

##### Serum/Plasma [2]

	[mg/dL]	[mmol/L]
<b>Adults</b>		
Global	17 – 43	2.8 – 7.2
Women < 50 years	15 – 40	2.6 – 6.7
Women > 50 years	21 – 43	3.5 – 7.2
Men < 50 years	19 – 44	3.2 – 7.3
Men > 50 years	18 – 55	3.0 – 9.2
<b>Children</b>		
1 – 3 year(s)	11 – 36	1.8 – 6.0
4 – 13 years	15 – 36	2.5 – 6.0
14 – 19 years	18 – 45	2.9 – 7.5

##### BUN in Serum/plasma [mg/dL] [mmol/L]

<b>Adults</b>		
Global	7.94 – 20.1	2.8 – 7.2
Women < 50 years	7.01 – 18.7	2.6 – 6.7
Women > 50 years	9.81 – 20.1	3.5 – 7.2
Men < 50 years	8.87 – 20.5	3.2 – 7.3
Men > 50 years	8.41 – 25.7	3.0 – 9.2
<b>Children</b>		
1 – 3 year(s)	5.14 – 16.8	1.8 – 6.0
4 – 13 years	7.01 – 16.8	2.5 – 6.0
14 – 19 years	8.41 – 21.0	2.9 – 7.5

##### Urea/Creatinine ratio [2]

25 – 40 [(mmol/L)/(mmol/L)]

20 – 35 [(mg/dL)/(mg/dL)]

##### Urea in Urine [3]

26 – 43 g/24h (0.43 – 0.72 mol/24h)

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

#### Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 48-9, 52-3.
2. Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
3. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.
4. Talke H, Schubert GE. Enzymatische Harnstoffbestimmung in Blut und Serum im optischen Test nach Warburg (Enzymatic determination of urea in blood and serum with the optical test according to Warburg). Klin Wschr 1965; 43: 174-5.
5. 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.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

#### Manufacturer

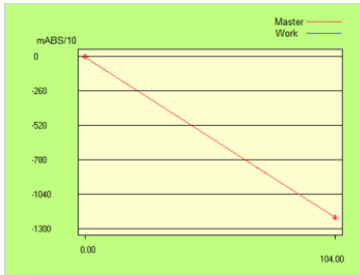


DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																										
Method No.	*	Method Name	UREA	Reagent Name	Reagent (µL)	Water (µL)																								
Print Name	Urea	MethodColor		R1	UREA	160																								
Sample Type	Serum			R2	UREA	40																								
Unit	mg/dL			Diluent	Disable																									
Assay Type	Rate			Sample Ppt. Wash	Disable																									
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle																								
		1	27 - 33																											
		2	Disable -																											
Wave Length	Prim. 340	Sec. 415		<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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2	Male-G2	*	*																											
3	Male-G3	*	*																											
4	Female-G1	*	*																											
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																										
	Low Normal High			(Conc)	2	300																								
<input type="checkbox"/> Diluent	0.0 < 2.0 < 0.0			(mAbs/10)	*	*																								
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	*	* %																								
<input type="checkbox"/> Diluent	0.0 < 2.0 < 0.0			Abnormal Range	*	*																								
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc) 2	300																								
<input type="checkbox"/> Diluent	0.0 < 2.0 < 0.0			Decimal Point	1	Profile SI Disable																								

\*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	UREA	Sample	Serum	
<b>Limit Checks</b> <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="100"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="1000"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text" value="10"/> % <input type="text" value="370"/> (mAbs/10)/min <input type="checkbox"/> Prozone Limit <input type="text" value="Higher"/> % <input type="text" value=""/> % 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				<b>Blank measurement</b> 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		
<input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction <input type="text" value="Decrease"/> Limit <input type="text" value="9000"/> mAbs/10				<b>Instrument Factor</b> a <input type="text" value="1.00"/> b <input type="text" value="0.00"/>		

<u>Calibration Registration</u>		<b>Sysmex BX-3010 Chemistry Analyzer Analytical Parameters</b>																																											
Method No.	<input type="text" value="*"/>	(R1) <input type="text" value="*"/>	Reagent Lot No. <input type="text"/>																																										
Method Name	<input type="text" value="UREA"/>	(R2) <input type="text" value="*"/>	Last <input type="text"/>																																										
Sample Type	<input type="text" value="Serum"/>	 <p>The calibration curve is lot dependent</p>																																											
Replication	<input type="text" value="Duplicate"/>																																												
Check Interval	<input type="text" value="42"/>																																												
Test without calibration	<input type="text" value="Disable"/>																																												
Calibration Type	<input type="text" value="Linear"/>																																												
Reagent Lot	<input type="text" value="New"/> <input type="button" value="Add"/>	Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/> Blank <input type="text" value="Automatic entry"/> mAbs/10 Last <input type="text"/> Calibration Curve <input type="text"/> Conc. <input type="text"/> Absorbance <input type="text"/> mAbs/10 <input type="button" value="Recalculation"/>																																											
Calibrator Name	<input type="text" value="TruCal U"/>																																												
	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <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%;">Calibr. Lot No.</th> <th style="width: 10%;"></th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> <td rowspan="7" style="vertical-align: top; padding-left: 5px;"><input type="checkbox"/> All</td> </tr> <tr> <td>C2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td>*</td> </tr> <tr> <td>C3</td> <td>*</td> <td></td> <td></td> <td></td> </tr> <tr> <td>C4</td> <td>*</td> <td></td> <td></td> <td></td> </tr> <tr> <td>C5</td> <td>*</td> <td></td> <td></td> <td></td> </tr> <tr> <td>C6</td> <td>*</td> <td></td> <td></td> <td></td> </tr> <tr> <td>C7</td> <td>*</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Conc.	WORK	MASTER	Calibr. Lot No.		C1	0	Automatic entry	Automatic entry	*	<input type="checkbox"/> All	C2	*	Automatic entry	Automatic entry	*	C3	*				C4	*				C5	*				C6	*				C7	*				K <input type="text" value="Automatic entry"/> <input type="checkbox"/> C1 Blank <input type="checkbox"/> Reagent Blank for C1	
	Conc.	WORK	MASTER	Calibr. Lot No.																																									
C1	0	Automatic entry	Automatic entry	*	<input type="checkbox"/> All																																								
C2	*	Automatic entry	Automatic entry	*																																									
C3	*																																												
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C6	*																																												
C7	*																																												
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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="UREA"/>																						
Print Name	<input type="text" value="Urea"/>	R1	<input type="text" value="UREA"/>	<input type="text" value="160"/>	<input type="text"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="UREA"/>	<input type="text" value="40"/>																				
Unit	<input type="text" value="mg/dL"/>	Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																				
Assay Type	<input type="text" value="Rate"/>	Measuring points	Start	End	Decimal Points																				
		1	<input type="text" value="40"/>	- <input type="text" value="49"/>	<input type="text" value="0"/>																				
		<input type="checkbox"/> Enable	2	<input type="text"/>	- <input type="text"/>																				
Wave Length	Prim. <input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="415"/>																					
<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	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>	(Conc)	<input type="text" value="2"/> - <input type="text" value="300"/>																				
	Rerun (High/Prozone)			(mAbs/10)	<input type="text"/> - <input type="text"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>																						
	Rerun (Low)																								
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>																						
			SPT Wash	<input type="checkbox"/> Enable	<input type="text"/>																				
			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="UREA"/>	Sample	<input type="text" value="Serum"/>
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="100"/>	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="1000"/>	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%	<input type="text"/>	(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="Decrease"/>			
	Limit	<input type="text" value="9000"/>	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"/>	

**Registration Calibration**

**Sysmex BX-4000 Chemistry Analyzer  
Analytical Parameters**

Method  Name

Sample

Sampling

Check Interval  days

Auto

Auto Interval  hours

Type  Lot

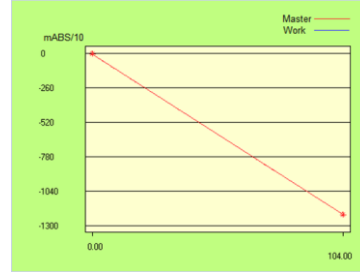
Material Name

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	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

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

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="UREA"/>	Reagent Name	Reagent (μL)	Water (μL)	
Print Name	<input type="text" value="Urea"/>	MethodColor		R1	<input type="text" value="UREA"/>	<input type="text" value="160"/>	
Sample Type	<input type="text" value="Urine"/>			R2	<input type="text" value="UREA"/>	<input type="text" value="40"/>	
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="27"/>	- <input type="text" value="34"/>				
	2	<input type="text" value="Disable"/>	- <input type="text" value=""/>				
Wave Length				Normal Range			
Prim.	<input type="text" value="340"/>	Sec.	<input type="text" value="415"/>	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	Normal	High	(Conc)	<input type="text" value="200"/>	-	<input type="text" value="33000"/>
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/>	< <input type="text" value="2.0"/>	< <input type="text" value="0.0"/>	(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="2.0"/>	< <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=""/>	- <input type="text" value=""/>
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/>	< <input type="text" value="2.0"/>	< <input type="text" value="0.0"/>	Decimal Point	<input type="text" value="0"/>	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="UREA"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks	Blank measurement					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="100"/>	mAbs/10		Blank measurement:		
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="1000"/>	mAbs/10		<input type="text" value="Disable reagent blank and C1 blank"/>		
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%		Measurement of Reagent Blank during Run:		
	<input type="text" value="370"/>	(mAbs/10)/min		<input type="text" value="None"/>		
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%		Reagent blank measurement at calibration:		
	<input type="text" value=""/>			<input type="text" value="Reagent blank (No sample)"/>		
SL1-S <input type="text" value=""/>	-	SL1-F <input type="text" value=""/>	The number of measurement:			
SL2-S <input type="text" value=""/>	-	SL2-F <input type="text" value=""/>	<input type="text" value="Duplicate"/>			
Sensitivity <input type="text" value=""/>	mAbs/10		Reagent blank limit checks:			
<input checked="" type="checkbox"/> Absorbance Limit	Abs. in reaction <input type="text" value="Decrease"/>		<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="10"/> mAbs/10			
Limit <input type="text" value="9000"/>	mAbs/10		Instrument Factor			
	a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>		

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer  
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

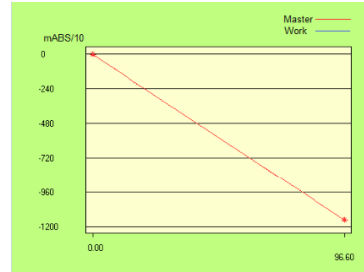
Calibration Type

Reagent Lot

Calibrator Name

Reagent Lot No. (R1)  Last

(R2)



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0.0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K   C1 Blank  Reagent Blank for C1

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="UREA"/>																						
Print Name	<input type="text" value="Urea"/>		R1	<input type="text" value="UREA"/>	<input type="text" value="160"/>																				
Sample	<input type="text" value="Urine"/>		R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="UREA"/>																				
Unit	<input type="text" value="mg/dL"/>																								
Assay Type	<input type="text" value="Rate"/>		Diluent	<input type="checkbox"/> Enable	<input type="text"/>																				
Measuring points	Start	End	Decimal Points	<input type="text" value="0"/>																					
	1	<input type="text" value="40"/>	-	<input type="text" value="49"/>																					
<input type="checkbox"/> Enable	2	<input type="text"/>	-	<input type="text"/>																					
Wave Length	Prim.	<input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="415"/>																				
<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	<input type="text" value="2.0"/>	<input type="text" value="2.0"/>	<input type="text" value="200"/>	(Conc)	<input type="text" value="200"/>																				
				(mAbs/10)	<input type="text" value="30000"/>																				
					<input type="text"/>																				
<input type="checkbox"/> Rerun (High/Prozone)																									
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text" value="2.0"/>	<input type="text" value="200"/>																						
<input type="checkbox"/> Rerun (Low)																									
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text" value="2.0"/>	<input type="text" value="200"/>																						
			SPT Wash	<input type="checkbox"/> Enable	<input type="text"/>																				
			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" value="*"/>	Name	<input type="text" value="UREA"/>
Sample	<input type="text" value="Urine"/>		
Limit Checks	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="100"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="1000"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text" value="10"/> % <input type="text" value="370"/> (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="Decrease"/>	
	Limit	<input type="text" value="9000"/> 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"/>

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer Analytical Parameters

Method \*  Name

Sample

Sampling

Check Interval  days

Auto

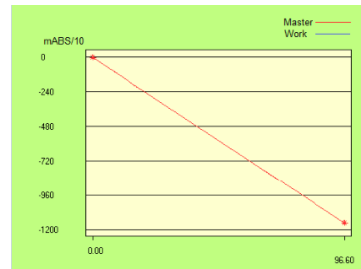
Auto Interval  hour s

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	0.0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K   S1 Blank  Reagent Blank for S1

\*Entered by user