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

$$\text{Urea} + 2\,H_2O \xrightarrow{\text{Urease}} 2\,NH_4^+ + 2\,HCO_3^-$$

$$\text{2-Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + NAD^+ + H_2O$$

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

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. 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.
5. 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 prediluted 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®-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]
Adults		
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
Children		
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]
Adults		
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
Children		
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. 1st ed. Darmstadt: GIT Verlag; 2001; p. 48-9, 52-3.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
3. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd 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

IVD CE

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	120	
Sample Type	Serum			R2 UREA	30	
Unit	mg/dL			Diluent	Disable	
Assay Type	Rate			Sample Ppt. Wash	Disable	

Measuring points — Start — End — Stirring Speed R1: Middle — R2: Middle

	Start	End
1	27	33
2	Disable	

Wave Length: Prim. 340 — Sec. 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0 <	1.5 <	0.0		
Rerun (High/Prozone)					
☐ Diluent	0.0 <	1.5 <	0.0		
Rerun (Low)					
☐ Diluent	0.0 <	1.5 <	0.0		

Technical Range
(Conc) 2 – 300
(mAbs/10) * – *

Previous Result Comparison (%) * – * %

Abnormal Range (Conc) * – *

Panic Range (Conc) 2 – 300

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

Limit Checks

✓ Duplicate Limit	100	mAbs/10
✓ Sensitivity Limit	1000	mAbs/10
✓ Linearity Limit	10	%
	370	(mAbs/10)/min
☐ Prozone Limit	Higher	%
SL1-S	–	SL1-F
SL2-S	–	SL2-F
Sensitivity		mAbs/10

✓ Absorbance Limit
Abs. in reaction: Decrease
Limit: 9000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor
a 1.00 — b 0.00

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*
Method Name	UREA
Sample Type	Serum
Replication	Duplicate
Check Interval	42
Test without calibration	Disable
Calibration Type	Linear
Reagent Lot	New / Add
Calibrator Name	TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.
C1	0	Automatic entry	Automatic entry	*
C2	*	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

☐ All

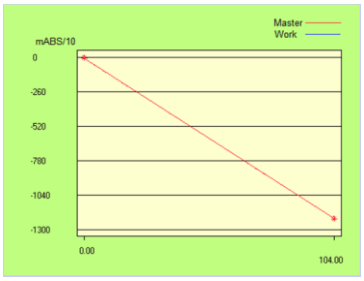
K: Automatic entry

☐ C1 Blank
☐ Reagent Blank for C1

***Entered by user**

Reagent Lot No.

(R1) * Last
(R2) *



The calibration curve is lot dependent

Reagent blank		mAbs/10	Last	
Blank	Automatic entry	mAbs/10	Last	
Calibration Curve			Conc.	
Absorbance		mAbs/10	Recalculation	

Urea FS

Chemistry Code 100 76

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	UREA		Reagent Name	Reagent (µL)	Water (µL)
Print Name	Urea			R1	UREA	160	
Sample	Serum			R2 ✓ Enable	UREA	40	
Unit	mg/dL						
Assay Type	Rate			Diluent ☐ Enable			

Measuring points

		Start		End
	1	40	–	49
☐ Enable	2		–	

Decimal Points: 0

Wave Length: Prim. 340 Sec ☐ Disable 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sampling	Sample (µL)	Diluent (µL)
☐ Dilution	2.0		
Rerun (High/Prozone) ☐ Dilution	2.0		
Rerun (Low) ☐ Dilution	2.0		

Technical Range

(Conc)	2	–	300
(mAbs/10)		–	

SPT Wash ☐ Enable — Reagent Name:

Stirring Speed: R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name UREA Sample Serum

Limit Checks

✓ Duplicate Limit	100	mAbs/10	
✓ Sensitivity Limit	1000	mAbs/10	
✓ Linearity Limit	10	%	(mAbs/10)/min
☐ Prozone Limit		%	Upper
SL1-S		– SL1-F	
SL2-S		– SL2-F	
Sensitivity		mAbs/10	
✓ Absorbance Limit			
Reaction	Decrease		
Limit	9000	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:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor: a 1.00 b 0.00

Urea FS

Chemistry Code 100 76

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: UREA

Sample: Serum

Sampling: Duplicate

Check Interval: 42 days

Auto: Change Lot | Full Calibration

Auto Interval: hours

Type: Linear | Lot: New

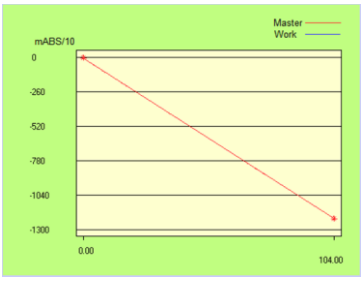
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ 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: Automatic entry mAbs/10 | Last:

Type: | Conc.:

Absorbance: mAbs/10 | Recalculation

Urea FS

Chemistry Code 100 76

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * | Method Name UREA

Print Name Urea | MethodColor

Sample Type Urine

Unit mg/dL

Assay Type Rate

Reagent Name	Reagent (µL)	Water (µL)
R1 UREA	160	
R2 UREA	40	

Diluent: Disable

Sample Ppt. Wash: Disable

Measuring points

	Start	End
1	27	34
2	Disable	

Stirring Speed R1: Middle R2: Middle

Wave Length: Prim. 340 Sec. 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)		Diluent (µL)
☐	Diluent	0.0 <	2.0 <	0.0	2.0		200
	Rerun (High/Prozone)						
☐	Diluent	0.0 <	2.0 <	0.0	2.0		200
	Rerun (Low)						
☐	Diluent	0.0 <	2.0 <	0.0	2.0		200

Technical Range
(Conc) 200 – 33000
(mAbs/10) * – *

Previous Result Comparison (%) * * %

Abnormal Range (Conc) * – *

Panic Range (Conc) –

Decimal Point 0 Profile SI Disable

*Entered by user

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * | Method Name UREA | Sample Serum

Limit Checks

- ✓ Duplicate Limit 100 mAbs/10
- ✓ Sensitivity Limit 1000 mAbs/10
- ✓ Linearity Limit 10 %
- 370 (mAbs/10)/min
- ☐ Prozone Limit Higher %
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity mAbs/10
- ✓ Absorbance Limit
  Abs. in reaction Decrease
  Limit 9000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
- ✓ Duplicate Limit 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

Urea FS

Chemistry Code 100 76

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name UREA

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration
Disable

Calibration Type Linear

Reagent Lot New Add

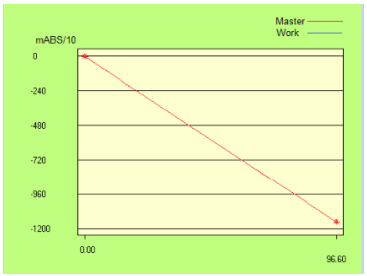
Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0.0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

***Entered by user**

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

Urea FS

Chemistry Code 100 76

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: UREA

Print Name: Urea | Sample: Urine | Unit: mg/dL | Assay Type: Rate

	Reagent Name	Reagent (µL)	Water (µL)
R1	UREA	160	
R2 ✓ Enable	UREA	40	
Diluent ☐ Enable			

Decimal Points: 0

Measuring points

	Start	End
1	40	49
☐ Enable 2		

Wave Length: Prim. 340 | Sec ☐ Disable 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	2.0	2.0	200
Rerun (High/Prozone) ☐ Dilution	2.0	2.0	200
Rerun (Low) ☐ Dilution	2.0	2.0	200

Technical Range: (Conc) 200 – 30000; (mAbs/10) –

SPT Wash ☐ Enable | Reagent Name:

Stirring Speed: R1 Middle | R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * | Name: UREA | Sample: Urine

Limit Checks

- ✓ Duplicate Limit: 100 mAbs/10
- ✓ Sensitivity Limit: 1000 mAbs/10
- ✓ Linearity Limit: 10 % 370 (mAbs/10)/min
- ☐ Prozone Limit: % Upper
  - SL1-S – SL1-F
  - SL2-S – SL2-F
  - Sensitivity: mAbs/10
- ✓ Absorbance Limit
  - Reaction: Decrease
  - Limit: 9000 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:
✓ Duplicate Limit: 10 mAbs/10

Instrument Factor: a 1.00 b 0.00

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method * Name UREA

Sample Urine

Sampling Duplicate

Check Interval 42 days

Auto Change Lot Full Calibration

Auto Interval hours

Type Linear Lot New

Material Name TruCal U

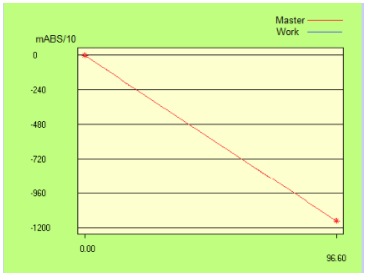
	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0.0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1 * Last

R2 *



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Type Conc.

Absorbance mAbs/10 Recalculation