Urea FS*

Diagnostic reagent for quantitative in vitro determination of urea in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order information

Cat. No.	Tests		
1 3101 99 10 963	R1	4 x	570 tests
	R2	3 x	760 tests
1 3101 99 10 962	R1	6 x	380 tests
	R2	6 x	380 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 up to 300 mg/dL (50 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**	2 mg/dL (0.35 mmol/L) urea
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 500 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
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)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	34.2	97.2	166
Mean [mmol/L]	5.69	16.2	27.7
Coefficient of variation [%]	1.64	1.04	1.07
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	33.6	92.4	162
Mean [mmol/L]	5.60	15.4	27.0
Coefficient of variation [%]	1.42	0.94	1.30

Method comparison (Serum/plasma; n=100)	
Test x	Competitor Urea
Test y	DiaSys Urea FS
Slope	1.000
Intercept	–0.30 mg/dL (–0.05 mmol/L)
Coefficient of correlation	0.999

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	737	1715	4194
Mean [mmol/L]	123	286	698
Coefficient of variation [%]	3.22	1.42	1.07
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	750	1735	4217
Mean [mmol/L]	125	289	702
Coefficient of variation [%]	3.23	1.42	1.63

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Method comparison (Urine; n=100)	
Test x	Competitor Urea
Test y	DiaSys Urea FS
Slope	1.011
Intercept	21.4 mg/dL (3.57 mmol/L)
Coefficient of correlation	0.999

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

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

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Urea FS

Chemistry code 10 310

Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	UREA
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	With dil
Undil. sample vol.	0	3
Diluent volume	0	150
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	23
M-DET.P.n	29
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Dec

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	1.0

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999