BioMajesty®

Urea FS*

Order Information

Cat. No.	Kit size
1 3101 99 10 963	Σ 2280 (R1: 4 x 570, R2: 3 x 760)
1 3101 99 10 962	Σ 2280 (R1: 6 x 380, R2: 6 x 380)

Intended Use

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

Summary

Urea is the nitrogen-containing end product of protein catabolism and is primarily secreted by the liver. It plays a crucial role in removing excess nitrogen from the body, as most of the nitrogen from protein intake is not used for metabolic processes but converted into urea [1]. Urea is mainly eliminated from the body through glomerular filtration in the kidneys and to some extent through sweat. Measuring urea levels is clinically significant because it serves as an indicator of kidney function and overall kidney health [2]. Elevated urea levels, known as azotemia, can indicate various clinically relevant conditions. By determining the urea-to-creatinine ratio, differentiation between pre-renal, renal, and post-renal azotemia is possible, thereby identifying the underlying cause of kidney dysfunction [3]. Increased urea levels with creatinine values within the reference range characterize pre-renal azotemia, which can be caused by factors such as dehydration, increased protein catabolism, cortisol treatment, or decreased renal perfusion [4]. In contrast, elevated levels of both urea and creatinine define post-renal azotemia, often resulting from obstruction of the urinary tract. In addition, high urea levels often suggest impaired glomerular filtration rate (GFR), which is a critical parameter in monitoring kidney disease [2]. Thus, urea determination aids to evaluate kidney function, diagnose kidney disease, monitor kidney disease progression, as well as assess overall metabolic health.

Method

"Urease – GLDH": enzymatic UV test

Enzymatic photometric test in which, in the first step, the substrate urea is hydrolyzed by urease to ammonium and bicarbonate ions. In the presence of 2-Oxoglutarate and NADH, the ammonium ions are catalyzed by glutamate dehydrogenase (GLDH). The amount of reduced NADH, measured by the change of absorption at 340 nm, is proportional to the amount of urea present in the sample [3].

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

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

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 (bovine)		≥ 1 kU/L
R2:	NADH		1.3 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [5].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma (no ammonium heparin) or fresh urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [6]:

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

Stability in urine [6]:

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

Only freeze once. Discard contaminated specimens.

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Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to NIST- SRM 909b Level 1. Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Serum/Plasma

Measuring range from 4 mg/dL up to 300 mg/dL. Linearity ≤ 10 mg/dL is given within ± 10%, at > 10 mg/dL within ± 5%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	4 mg/dL
Limit of quantitation**	4 mg/dL
Onboard stability	16 weeks
Calibration stability	16 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ammonium	300 µg/dL	11.2
	300 µg/dL	30.7
Ascorbic acid	60 mg/dL	11.3
	60 mg/dL	29.2
Bilirubin (conjugated)	60 mg/dL	11.3
	60 mg/dL	30.8
Bilirubin (unconjugated)	60 mg/dL	11.5
	60 mg/dL	31.0
Hemolysis	900 mg/dL	11.4
	900 mg/dL	29.4
Lipemia (triglycerides)	2000 mg/dL	9.01
	1900 mg/dL	26.0

For further information on interfering substances, refer to the literature [7,8].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	18.5	42.4	144
CV [%]	1.52	1.07	0.489
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	18.4	43.1	147
CV [%]	2.18	1.37	0.968

Method comparison (n=149)	
Test x	Competitor Urea (cobas c 501)
Test y	DiaSys Urea FS (BioMajesty® JCA-BM6010C)
Slope	1.05
Intercept	0.469 mg/dL
Coefficient of correlation	0.999

Urine

Measuring range from 204 mg/dL up to 15300 mg/dL. Linearity ≤ 510 mg/dL is given within ± 10%, at > 510 mg/dL within ± 5%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	204 mg/dL
Limit of quantitation**	204 mg/dL
Onboard stability	16 weeks
Calibration stability	16 weeks

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	478	988	2114
CV [%]	3.76	1.81	1.28
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	469	932	2001
CV [%]	4.48	2.12	1.50

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ammonium	230 µg/dL	1510
	230 µg/dL	3224
Ascorbic acid	290 mg/dL	1484
	290 mg/dL	2995
Bilirubin (conjugated)	60 mg/dL	1510
	60 mg/dL	2978
Boric acid	590 mg/dL	1413
	590 mg/dL	2818
Glucose	2000 mg/dL	1579
	2000 mg/dL	3397
Hemolysis	1000 mg/dL	1556
	1000 mg/dL	2905
Hydrochloric acid	3.5 mL/dL	1580
	3.5 mL/dL	3381
Protein	300 mg/dL	1524
	300 mg/dL	2948
Sodium-Oxalate	70 mg/dL	1467
	70 mg/dL	2925
Uric acid	22 mg/dL	1473
	22 mg/dL	3003
Urobilinogen	45 mg/dL	1491
	45 mg/dL	2976
Vitamin B12	5.5 mg/L	1562
	5.5 mg/L	2782

For further information on interfering substances, refer to the literature [7,8].

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Method comparison (n=53)	
Test x	Competitor Urea (cobas c 501)
Test y	DiaSys Urea FS (BioMajesty® JCA-BM6010C)
Slope	1.04
Intercept	0.321 mg/dL
Coefficient of correlation	0.995

** according to CLSI document EP17-A2, Vol. 32, No. 8

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 = Urea-N in blood)

Reference Range

Serum/Plasma [3]

	[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

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 in serum [3]
25 – 40 [(mmol/L)/(mmol/L)]
20 – 35 [(mg/dL)/(mg/dL)]

Urea in urine [9]
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. Matsumoto, S., Häberle, J., Kido, J. et al. Urea cycle disorders—update. J Hum Genet 64, 833–847 (2019).
2. Brookes, E.M., Power, D.A. Elevated serum urea-to-creatinine ratio is associated with adverse inpatient clinical outcomes in non-end stage chronic kidney disease. Sci Rep 12, 20827 (2022).
3. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 Jun 24]. https://www.clinical-laboratory-diagnostics.com/
4. Zhang GM, Guo XX, Zhang GM. Limiting the testing of urea: Urea along with every plasma creatinine test? J Clin Lab Anal. 2017 Sep;31(5):e22103
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.4.
6. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples. 3rd ed. Darmstadt: GIT Verlag; 2010. p. 62-3; 68-9.
7. 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.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in May 2022. Published by AACC Press and John Wiley and Sons, Inc.
9. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.3.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

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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)	2
Sample vol (U)	2
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 / Urine control**
Reac. sample vol.	2	2
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)	0.800

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