


Urea FS*

Order Information

Cat. No.

1 3101 99 10 920

Kit size

 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of urea in human serum, heparin plasma or urine on automated respons[®]910.

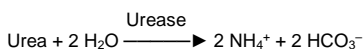
Summary

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].



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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [5].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.

- 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.
- 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.
- 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.

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 2.49 mg/dL up to 300 mg/dL, linearity is given 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**	2.49 mg/dL
Limit of quantitation**	2.49 mg/dL
Onboard stability	4 weeks
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	89.7
Bilirubin (conjugated)	65 mg/dL	9.03
	70 mg/dL	39.9
Bilirubin (unconjugated)	70 mg/dL	9.28
	65 mg/dL	42.2
Hemolysis	500 mg/dL	9.60
	550 mg/dL	38.6
Lipemia (triglycerides)	1000 mg/dL	10.5
	1900 mg/dL	41.0
Ammonium ions interfere; therefore, do not use ammonium heparin as anticoagulant for collection of plasma.		
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]	18.8	38.8	154
CV [%]	2.96	2.48	2.11
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	23.2	38.4	149
CV [%]	2.71	3.58	2.28

Method comparison (n=109)	
Test x	DiaSys Urea FS (Hitachi 911)
Test y	DiaSys Urea FS (respons [®] 910)
Slope	1.02
Intercept	-1.08 mg/dL
Coefficient of correlation	0.999

Urine

Measuring range from 64.7 mg/dL up to 7800 mg/dL, linearity is given 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**	64.7 mg/dL
Limit of quantitation**	64.7 mg/dL
Onboard stability	4 weeks
Calibration stability	7 days

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	782	1726	3953
CV [%]	5.01	1.91	3.23
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	791	1780	4033
CV [%]	4.44	2.94	3.74

Method comparison (n=94)	
Test x	DiaSys Urea FS (BioMajesty [®] JCA-BM6010/C)
Test y	DiaSys Urea FS (respons [®] 910)
Slope	0.973
Intercept	-18.4 mg/dL
Coefficient of correlation	0.993

** according to CLSI document EP17-A, Vol. 24, No. 34

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

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- 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).
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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.



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

Urea FS

Application for serum, plasma or 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	UREA
Shortcut:	
Reagent barcode reference:	054
Host reference:	054

Technic	
Type:	Linear kinetic
First reagent:[μ L]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.0000
1 st reading time [min:sec]	05:48
Last reading time [min:sec]	07:00
Reaction way:	Decreasing
Linear Kinetics	
Substrate depletion: Absorbance limit	0.4500
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	2.4900
Concentration technical limits-Upper	300.0000
SERUM	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [μ L]	2.0
Normal dilution (factor)	26
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	26
PLASMA	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	#
URINE	#
PLASMA	#
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value

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