respons®940

Urea FS*

Order Information

Cat. No.	Kit size
1 3101 99 10 920	Σ 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®940.

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

Dilute TruLab Urine controls 1 + 50 with dist. water and multiply results by 51.

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

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Performance Characteristics

Serum/Plasma

Measuring range from 5 mg/dL up to 350 mg/dL. Linearity ≤ 10 mg/dL is given with ± 2.4 mg/dL, between 10 mg/dL to 17 mg/dL within ± 10%, at > 17 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**	5 mg/dL
Limit of quantitation**	5 mg/dL
Onboard stability	16 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ammonium	60 µg/dL	10.5
	200 µg/dL	32.5
Ascorbic acid	36 mg/dL	11.3
	36 mg/dL	32.0
Bilirubin (conjugated)	70 mg/dL	12.0
	70 mg/dL	31.8
Bilirubin (unconjugated)	60 mg/dL	12.1
	60 mg/dL	32.1
Hemolysis	670 mg/dL	11.9
	960 mg/dL	29.6
Lipemia (triglycerides)	1300 mg/dL	10.7
	2000 mg/dL	26.8
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]	18.2	42.4	153
CV [%]	2.66	1.19	0.513
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	17.7	41.1	140
CV [%]	3.12	2.06	1.72
Reproducibility (n=75, no. of instruments=3)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	17.4	34.2	148
CV [%]	2.28	4.27	2.44

Method comparison (n=149)	
Test x	Competitor Urea (cobas c 501)
Test y	DiaSys Urea FS (respons®940)
Slope	1.01
Intercept	0.392 mg/dL
Coefficient of correlation	0.999

Urine

Measuring range from 255 mg/dL up to 17850 mg/dL. Linearity ≤ 510 mg/dL is given with ± 122.4 mg/dL, between 510 mg/dL to 867 mg/dL within ± 10%, at > 867 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**	255 mg/dL
Limit of quantitation**	255 mg/dL
Onboard stability	16 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ammonium	252 mg/dL	1608
	252 mg/dL	2958
Ascorbic acid	303 mg/dL	1522
	303 mg/dL	3022
Boric acid	300 mg/dL	1565
	300 mg/dL	3017
Glucose	2400 mg/dL	1605
	2400 mg/dL	3145
Hydrochloric acid	3.6 mL/dL	1612
	3.6 mL/dL	3017
Protein	320 mg/dL	1596
	320 mg/dL	3037
Sodium-Oxalate	70 mg/dL	1510
	70 mg/dL	2943
Uric acid	24 mg/dL	1461
	24 mg/dL	2917
Urobilinogen	48 mg/dL	1485
	48 mg/dL	2864
Vitamin B12	6 mg/L	1503
	6 mg/L	3036
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]	662	2071	3262
CV [%]	3.32	1.33	1.62
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	635	1987	3145
CV [%]	5.09	3.43	2.36
Reproducibility (n=75, no. of instruments=3)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	626	1882	2652
CV [%]	14.0	11.6	12.2

Method comparison (n=64)	
Test x	Competitor Urea (cobas c 501)
Test y	DiaSys Urea FS (respons®940)
Slope	1.08
Intercept	98.5 mg/dL
Coefficient of correlation	0.998

** 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

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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.

IVD CE

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

* Fluid Stable

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Urea FS

Application for serum, plasma and urine

Test Details			Test Volumes			Reference Ranges		
Test	:	UREA				Auto Rerun		☐
Report Name	:	Urea				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	0	Special Diluent		☐
Assay Type	:	RATE-A	Curve Type	:	Linear	Warn after	:	20
M1 Start	:	0	M1 End	:	0	Reagents Used	:	2
M2 Start	:	29	M2 End	:	37	Reagent R1		UREA R1
Sample Replicates	:	1	Standard Replicates	:	2	Reagent R2		UREA R2
Control Replicates	:	1	Control Interval	:	0	**Consumables/Calibrators:**		
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.5000	Blank /Level 0		0
Prozone Limit %	:	0	Prozone Check	:	Upper	Calibrator 1		*
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 2		
Technical Minimum	:	5.0000	Technical Maximum	:	350.0000	Calibrator 3		
Y = aX + b a=	:	1.0000	b=	:	0.0000	Calibrator 4		
Reagent Abs Min	:	0.0000	Reagent Abs Max	:	0.0000	Calibrator 5		

Test Details			Test Volumes	Reference Ranges
Test	:	UREA		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00	µL	Dilution Ratio	:	1 X
Increase	:	4.00	µL	Dilution Ratio	:	1 X
Decrease	:	2.00	µL	Dilution Ratio	:	2 X
Standard Volume	:	2.00	µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160.00	µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40.00	µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	UREA		
Sample Type	:	Urine		

Sample Volumes

Normal	:	2.00	µL	Dilution Ratio	:	51 X
Increase	:	4.00	µL	Dilution Ratio	:	51 X
Decrease	:	2.00	µL	Dilution Ratio	:	102 X
Standard Volume	:	2.00	µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160.00	µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40.00	µL	R2 Stirrer Speed	:	High

Sample Types

- ☐ Serum
- ☑ Urine
- ☐ CSF
- ☐ Plasma
- ☐ Whole Blood
- ☐ Other

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Test Details	Test Volumes	Reference Ranges

Test : UREA

Sample Type : Serum** Urine**

Reference Range : DEFAULT

Category : Male

Reference Range

	Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal :	#	#
Panic :	#	#

Sample Types

- ☑ Serum
- ☑ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

* Enter calibrator value
** Specimen selected by user
# Editable by user