respons®920

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®920.

Summary

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyperuremia or azotemia. Parallel determination of urea and creatinine is performed to differentiate between pre-renal and post-renal azotemia. Pre-renal azotemia, caused by e.g. dehydration, increased protein catabolism, cortisol treatment or decreased renal perfusion, leads to increased urea levels, while creatinine values remain within the reference range. In post-renal azotemias, for example caused by the obstruction of the urinary tract, both urea and creatinine levels rise, but creatinine in a smaller extent. In renal diseases, urea concentrations are elevated when the glomerular filtration rate is markedly reduced and when the protein intake is higher than 200 g/day. [1,2]

Method

"Urease – GLDH": enzymatic UV test

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

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

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 in-use stability of the reagent is 18 months.

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 [3].
4. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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 [4]:

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

Stability in urine [4]:

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. 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

Measuring range up to 300 mg/dL in serum.
Measuring range up to 15000 mg/dL in urine.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	3 mg/dL
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences (serum) ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	89.7
Bilirubin (conjugated)	60 mg/dL	101
Bilirubin (unconjugated)	60 mg/dL	103
Hemoglobin	1000 mg/dL	23.7
Lipemia (triglycerides)	2000 mg/dL	33.2
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 [5,6].		

Precision (Serum)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	39.2	77.8	152
CV [%]	2.54	2.90	2.34
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	39.8	66.9	150
CV [%]	2.22	3.68	2.24

Method comparison (Serum; n=110)	
Test x	DiaSys Urea FS (Hitachi 917)
Test y	DiaSys Urea FS (respons®920)
Slope	1.01
Intercept	1.12 mg/dL
Coefficient of correlation	0.999

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1462	1831	4288
CV [%]	3.21	3.59	4.16
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1366	1786	3968
CV [%]	3.63	3.41	3.37

Method comparison (Urine; n=114)	
Test x	DiaSys Urea FS (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Urea FS (respons®920)
Slope	1.04
Intercept	–1.15 mg/dL
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 = Urea-N in blood)

Reference Range

Serum/Plasma [1]

	[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 [1]
25 – 40 [(mmol/L)/(mmol/L)]
20 – 35 [(mg/dL)/(mg/dL)]

Urea in urine [2]
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. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
2. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.3.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.4.
4. 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.
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.
6. 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.

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IVD CE

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* Fluid Stable

respons®920

Urea FS

Application for serum and plasma

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	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	UREA R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	UREA R2
M2 Start	:	19	M2 End	:	23			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.5000	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	3.0000	Technical Maximum	:	300.0000			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

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

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	µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	:	High

Sample Types

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

Test Details			Test Volumes	Reference Ranges
Test	:	UREA		
Sample Type	:	Serum/plasma		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	17.00	43.00
Panic	:	0.00	0.00

Sample Types

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

respons®920

Urea FS

Application for 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	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	UREA R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	UREA R2
M2 Start	:	19	M2 End	:	23			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.5000	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	3.0000	Technical Maximum	:	17200.00			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

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

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	50 X	
Increase	:	2.00 µL	Dilution Ratio	:	40 X	
Decrease	:	2.00 µL	Dilution Ratio	:	150 X	
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40 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		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:		
Panic	:	0.00	0.00

Sample Types

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