


## 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<sup>®</sup>920.

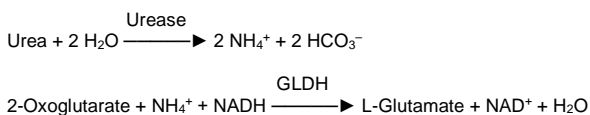
### Summary

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

<b>R1:</b>	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
<b>R2:</b>	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].
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons<sup>®</sup>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.

- 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

Dilute TruLab Urine controls 1 + 49 with dist. water and multiply results by 50.

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 up to 300 mg/dL.  
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

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	30 mg/dL	89.7
<b>Bilirubin</b> (conjugated)	60 mg/dL	101
<b>Bilirubin</b> (unconjugated)	60 mg/dL	103
<b>Hemolysis</b>	1000 mg/dL	23.7
<b>Lipemia</b> (triglycerides)	2000 mg/dL	33.2
<b>Ammonium ions</b> 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]	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 (n=110)	
Test x	DiaSys Urea FS (Hitachi 917)
Test y	DiaSys Urea FS (respons <sup>®</sup> 920)
Slope	1.01
Intercept	1.12 mg/dL
Coefficient of correlation	0.999

### Urine

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

Limit of detection**	150 mg/dL
Onboard stability	6 weeks
Calibration stability	6 weeks

Precision			
Repeatability (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 (n=114)	
Test x	DiaSys Urea FS (BioMajesty <sup>®</sup> JCA-BM6010/C)
Test y	DiaSys Urea FS (respons <sup>®</sup> 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] × 0.1665 = Urea [mmol/L]  
Urea [mg/dL] × 0.467 = BUN [mg/dL]  
BUN [mg/dL] × 2.14 = Urea [mg/dL]

(BUN: Blood urea nitrogen = Urea-N in blood)

### Reference Range

#### Serum/Plasma [3]

	[mg/dL]	[mmol/L]
<b>Adults</b>		
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
<b>Children</b>		
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]
<b>Adults</b>		
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
<b>Children</b>		
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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- 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.
- 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.
- Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.3.

# respons<sup>®</sup>920

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.



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\* Fluid Stable

## Urea FS

Application for serum, plasma or urine

Test Details		Test Volumes		Reference Ranges	
Test	: UREA			Auto Rerun	<input type="checkbox"/>
Report Name	: Urea			Online Calibration	<input type="checkbox"/>
Unit	: mg/dL	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
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	<b>Consumables/Calibrators:</b>	
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				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 2.00 $\mu$ L	Dilution Ratio	: 1 X		
Increase	: 4.00 $\mu$ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 $\mu$ L	Dilution Ratio	: 2 X		
Standard Volume	: 2.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 160 $\mu$ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40 $\mu$ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: UREA				
Sample Type	: Urine				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 2.00 $\mu$ L	Dilution Ratio	: 50 X		
Increase	: 2.00 $\mu$ L	Dilution Ratio	: 40 X		
Decrease	: 2.00 $\mu$ L	Dilution Ratio	: 150 X		
Standard Volume	: 2.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 160 $\mu$ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40 $\mu$ L	R2 Stirrer Speed	: High		

Test Details	Test Volumes	Reference Ranges															
Test : UREA																	
Sample Type : Serum/plasma/urine																	
Reference Range : DEFAULT																	
Category : Male																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Reference Range</th> </tr> <tr> <th style="width: 50%;">Lower Limit (mg/dL)</th> <th style="width: 50%;">Upper Limit (mg/dL)</th> </tr> </thead> <tbody> <tr> <td>Normal : #</td> <td>#</td> </tr> <tr> <td>Panic : #</td> <td>#</td> </tr> </tbody> </table>		Reference Range		Lower Limit (mg/dL)	Upper Limit (mg/dL)	Normal : #	#	Panic : #	#	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Sample Types</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Serum</td> </tr> <tr> <td><input checked="" type="checkbox"/> Urine</td> </tr> <tr> <td><input type="checkbox"/> CSF</td> </tr> <tr> <td><input checked="" type="checkbox"/> Plasma</td> </tr> <tr> <td><input type="checkbox"/> Whole Blood</td> </tr> <tr> <td><input type="checkbox"/> Other</td> </tr> </tbody> </table>	Sample Types	<input checked="" type="checkbox"/> Serum	<input checked="" type="checkbox"/> Urine	<input type="checkbox"/> CSF	<input checked="" type="checkbox"/> Plasma	<input type="checkbox"/> Whole Blood	<input type="checkbox"/> Other
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