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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. 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

Urease Urea + 2 H₂O — ▶ 2 NH₄⁺ + 2 HCO₃⁻

GLDH

2-Oxoglutarate + NH4⁺ + NADH -----► L-Glutamate + NAD⁺ + H₂O

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 $2-8^{\circ}$ 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.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- 4. 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.
- 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/plas	sma [4]:	
7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	–20°C
Stability in urine [4]: 2 days 7 days 4 weeks	at at at	20 – 25°C 4 – 8°C –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 laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.		Kit si	ze
TruCal U	5 9100 99 10 063	20	х	3 mL
	5 9100 99 10 064	6	х	3 mL
TruLab N	5 9000 99 10 062	20	х	5 mL
	5 9000 99 10 061	6	х	5 mL
TruLab P	5 9050 99 10 062	20	х	5 mL
	5 9050 99 10 061	6	х	5 mL
TruLab Urine Level 1	5 9170 99 10 062	20	х	5 mL
	5 9170 99 10 061	6	х	5 mL
TruLab Urine Level 2	5 9180 99 10 062	20	х	5 mL
	5 9180 99 10 061	6	х	5 mL

Performance Characteristics

Measuring range up to 300 mg/ Measuring range up to 7300 mg In case of higher concentration manual dilution with NaCl solution	dL in serum. //dL in urine. ons re-measure samples after on (9 g/L) or use rerun function.
Limit of detection**	3 mg/dL
Onboard stability	4 weeks
Calibration stability	7 days

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Interfering substance		Interferences (serum) ≤ 10% up to		Analyte concentration [mg/dL]	
Ascorbic acid		30 mg/dL			89.7
Bilirubin (conjugated)		65 m	g/dL		9.03
		70 m	g/dL		39.9
Bilirubin (unconjugated)		70 m	g/dL		9.28
		65 m	g/dL		42.2
Hemoglobin		500 m	ng/dL		9.60
		550 m	ng/dL		38.6
Lipemia (triglycerides)		1000 r	ng/dL		10.5
		1900 r	ng/dL		41.0
Ammonium ions interfer heparin as anticoagulant	e; t for	herefore d	o not use of plasma	e am a.	monium
For further information on inte	erfei	ring substar	nces refer	to Yo	ung DS [5,6].
Precision (Serum)	_				
Within run (n=20)	S	ample 1	Sample	2	Sample 3
Mean [mg/dL]		18.8	38.8		154
CV [%]		2.96	2.48		2.11
Between day (n=20)	s	ample 1	Sample	2	Sample 3
Mean [mg/dL]		23.2	38.4		149
CV [%]		2.71	3.58		2.28
Method comparison (Serum; 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			
Precision (Urine)					
Within run (n=20)	S	ample 1	Sample	2	Sample 3
Mean [mg/dL]		782	1726	6	3953
CV [%]		5.01	1.91		3.23
Between day (n=20)	S	ample 1	Sample	2	Sample 3
Mean [mg/dL]		791	1780)	4033
CV [%]		4.44	2.94		3.74
Method comparison (Ur	ine	: n=94)			
Test x		DiaSys l (BioMaje	Jrea FS sty [®] JCA	-BM	6010/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 [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
United (One official second in the		

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

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respons® 910

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.

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Agent [u] 0 (no hemolysis)	
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Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=17.0 <=43.0
URINE	>=2000.0 <=3307.0
PLASMA	>=17.0 <=43.0
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	Х
Degree	1

* Enter calibrator value