Urea CT* FS**

Diagnostic reagent for quantitative in vitro determination of urea in serum, plasma or urine on photometric systems

Order Information

Cat. No.	Kit size
1 3115 99 10 021	R1 2 x 25 mL + R2 2 x 25 mL + R3 1 x 0.5 mL + 1 x 3 mL Standard
1 3115 99 10 026	R1 3 x 100 mL + R2 3 x 100 mL + R3 2 x 1.5 mL
1 3115 99 90 305	R1 6 x 25 mL + R2 6 x 25 mL + R3 1 x 1.5 mL
1 3100 99 10 030	6 x 3 mL Standard

Summary [1,2]

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.

Method

Colorimetric test

Principle

Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide. Ammonium ions react with hypochlorite and salicylate to give a green dye. The increase in absorbance at 578 nm is proportional to the urea concentration in the sample.

Reagents

Components and Concentrations

R1:	Phosphate buffer	120 mmol/L
	Sodium salicylate	60 mmol/L
	Sodium nitroprusside	40 mmol/L
	EDTA	1.3 mmol/L
R2:	Phosphate buffer	< 50 mmol/L
	Sodium hydroxide	150 mmol/L
	Sodium hypochlorite	10 mmol/L
R3:	Urease	≥ 0.5 kU/mL
Standard:		50 mg/dL (8.33 mmol/L)

Storage Instructions and Reagent Stability

Reagents and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 2: Warning. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. P234 Keep only in original packaging. P280 Wear protective gloves/protective clothing/eye protection. P332+P313 If skin irritation occurs: Get medical advice/attention. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
2. Reagent 3: Danger. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. P261 Avoid breathing vapours/spray. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
3. Standard and R3 contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. Please refer to the safety data sheets 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.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Mix R1 + R3 in the ratio 100 + 1
e.g. 20 mL R1 + 0.2 mL R3 = R1A
Stability of R1A:
2 weeks at 2 – 8°C
2 days at 15 – 25°C
R1A and R2 must be protected from light!
Reagent 2 and standard are ready for use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, EDTA plasma and heparin plasma (no ammonium heparin!), urine
Dilute urine 1 + 100 with dist. water and multiply results by 101.

Stability in serum or plasma [5]:
7 days at 20 – 25°C
7 days at 4 – 8°C
1 year at –20°C
Stability in urine [5]:
2 days at 20 – 25°C
7 days at 4 – 8°C
1 month at –20°C
Freeze only once! Discard contaminated specimens!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	578 nm, 560 – 600 nm
Optical path	1 cm
Temperature	20 – 25°C, 37°C
Measurement	Against reagent blank Only one reagent blank per series is required.

	Blank	Sample or calibrator
Sample or standard	-	10 µL
Reagent 1A	1000 µL	1000 µL
Mix, incubate 10 min. at 20 – 25°C or 5 min. at 37°C, then add:		
Reagent 2	1000 µL	1000 µL
Mix, incubate 10 min. at 20 – 25°C or 5 min. at 37°C. In case of 20 – 25°C read the absorbance against reagent blank within 30 min.; in case of 37°C within 5 min.		

* colorimetric test
** fluid stable

Calculation

With standard or calibrator

$$\text{Urea [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal.}} \times \text{Conc. Std/Cal. [mg/dL]}$$

Conversion factors

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)

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrators have been made traceable to NIST SRM®-909 Level 1. For internal quality control, commercially available controls should be assayed. 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

Performance Characteristics

Measuring range

The test has been developed to determine urea concentrations within a measuring range from 1 – 400 mg/dL (0.17 – 67 mmol/L) in serum/plasma or 40 g/dL (6.7 mol/L) in urine. When values exceed this range, the samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 200 mg/dL and lipemia up to 800 mg/dL triglycerides.
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 [6].

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL

Precision (at 20 – 25°C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	27.3	0.38	1.38
Sample 2	39.0	0.54	1.39
Sample 3	149	2.50	1.68

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	21.1	0.74	3.51
Sample 2	43.8	1.01	2.31
Sample 3	145	3.50	2.41

Method Comparison

A comparison of DiaSys Urea CT FS (y) with a kinetic test (x) using 64 samples gave following results:
y = 1.03 x – 2.55 mg/dL; r = 0.999

Reference Range

In 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 years	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]
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.
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3. Fawcett JK, Scott JE. A rapid and precise method for the determination of urea. Clin Path 1960;13:156-9.
4. Patton CJ, Crouch SR. Spectrophotometric and kinetics investigation of the Berthelot reaction for the determination of urea. Anal Chem 1977;49:464-9.
5. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001;p. 48-9, 52-3.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240–1243.

Manufacturer

IVD CE

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