Urea FS

Urea Reagent Test Kit

Intended Use

Diagnostic reagent for quantitative determination of Urea in human serum, plasma or Urine on photometric analyzers.

Order Information

Item code.	Pack Size
131019934840	R1:4 x 60 mL; R2: 4 x 15 mL

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, 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

"Urease – GLDH": enzymatic UV test

Principle

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

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

GLDH: Glutamate dehydrogenase

Reagents

Components and Concentrations

R1:	Urease	>10kU/L
	GLDH	>1kU/L
	Tris	12.1g/L
	Sodium Azide	1g/L
	A-keto glutaric acid	3.12g/L
R2:	Tris	12.1g/L
	NADH	1.1 g/L
Preservatives & Stabilizers		q.s.

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. 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 biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use

Stability:	4 weeks	at	2 – 8°C
	5 days	at	15 – 25°C

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment
TruCal U (591009910064)
TruLab N (590009910061)
TruLab P (590509910061)
TruLab Urine level 1(591709910061)
TruLab Urine level 2(591809910061)

Specimen

Serum, plasma (no ammonium heparin!), fresh urine
Dilute urine 1 + 50 with dist. water and multiply results by 51.
TruLab Urine controls must be prediluted the same way as patient samples.

Stability [4]

in serum or plasma:		
7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	–20°C
in urine:		
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	340 nm, 334 nm, 365 nm
Optical path	1 cm
Temperature	25°C/30°C/37°C
Measurement	Against reagent blank 2-point kinetic

	Blank	Sample or Calibrator
Sample or Calibrator	-	10 µL
Reagent 1	1000 µL	800 µL
Mix, incubate 0 – 5 min., then add:		
Reagent 2	250 µL	200 µL
Mix, incubate for approx. 60 sec. at 25°C/30°C or approx. 30 – 40 sec at 37°C, then read absorbance A1. Read absorbance A2 exactly after another 60 seconds.		

A = (A1 – A2) sample or Calibrator

Notes

1. The method is optimized for 2-point kinetic measurement. It is recommended to perform the method only on mechanized equipment because it is difficult to incubate **all** samples and the reagent blank **strictly** for the same time intervals. The assay scheme may be used for adaptation purposes for instruments with no specific adaptation sheet. The volumes may be proportionally smaller.
2. The statement "approx. 60 sec. or approx. 30 - 40 sec" means that the time period chosen does not need to be exactly 60 resp. 30 – 40 sec. A time period once chosen (e.g. 55 sec.) has to be respected **exactly** for all samples, standards and the reagent blanc.

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 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)

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. DiaSys TruLab N, P and TruLab Urine controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring range

The test has been developed to determine urea concentrations within a measuring range from 2 – 300 mg/dL (0.3 – 50 mmol/L) in serum/plasma respectively up to 30 g/dL (5 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 500 mg/dL and lipemia up to 2000 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.

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/dL.

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [.mg/dL]	CV [%]
Sample 1	34.74	1.50	4.33
Sample 2	107.4	2.35	2.19
Sample 3	154.2	3.19	2.07

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	35.4	0.69	1.96
Sample 2	110	3.04	2.77
Sample 3	164	3.97	2.42

Method Comparison

A comparison of DiaSys Urea (y) with a commercially available test (x) using 68 samples gave following results:
y = 0.99 x + 1.06 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 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]
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.

Interpretation of results

High concentration of the Urea 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. Results should be correlated clinically.

Limitation

Result interference can be seen in the samples where triglyceride conc. Exceeds 2000 mg/dL.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
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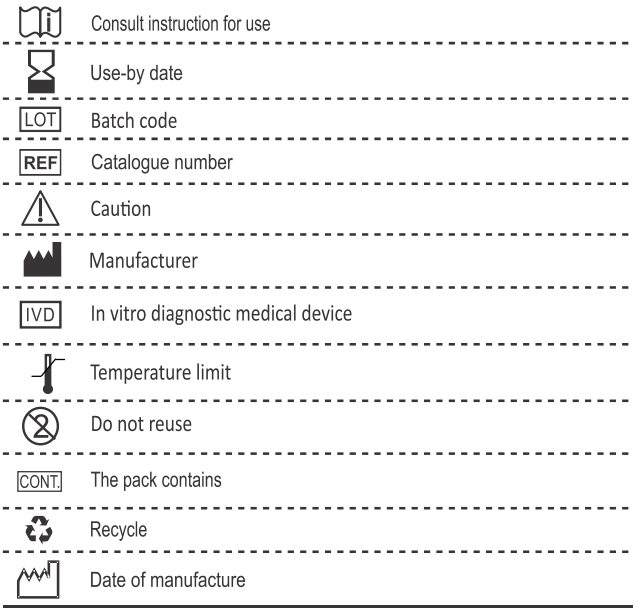
3. Talke H, Schubert GE. Enzymatische Harnstoffbestimmung in Blut und Serum im optischen Test nach Warburg (Enzymatic determination of urea in blood and serum with the optical test according to Warburg). Klin Wschr 1965; 43: 174-5.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 48-9, 52-3.
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240–1243.

Notes on Symbols and Marks



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