DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria, IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at

Liquid Reagents – ready to use

Urea

Urease/colorimetic

3 Reagents

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

REF	Kit Size	Content	
402999	**5 x 100 mL**	2 x 125 mL	Reagent 1
		3 x 83.3 mL	Reagent 2
		1 x 2.5 mL	Reagent 3
		1 x 3 mL	Urea Standard
413925	**6 x 25 mL**	3 x 25 mL	Reagent 1
		3 x 25 mL	Reagent 2
		1 x 0.75 mL	Reagent 3
		1 x 3 mL	Urea Standard

Additionally offered:

D95706	1 x 3 mL	Urea Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Endpoint; Increasing Reaction
Temperature:	20 – 25 °C, 37 °C
Wavelength:	578 nm (560 – 600 nm)
Sample:	Serum, EDTA plasma, heparin plasma (no ammonium heparin!), urine
Linearity:	up to 400 mg/dL (67 mmol/L) in serum/plasma up to 40 g/dL (6.7 mol/L) in urine
Sensitivity:	Limit of detection: 1 mg/dL (0.17 mmol/L)

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 uea and creatinine is performed to differentiate between pre-renl 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.

TEST PRINCIPLE

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

REAGENT COMPOSITION

COMPONENTS	CONCENTRATIONS	
Reagent 1		
Phosphate buffer	120	mmol/L
Sodium salicylate	60	mmol/L
Sodium nitroprusside	40	mmol/L
EDTA	1.3	mmol/L
Reagent 2		
Phosphate buffer	< 50	mmol/L
Sodium hydroxide	150	mmol/L
Sodium hypochlorite	10	mmol/L
Reagent 3		
Urease	≥ 0.5	kU/mL

REAGENT PREPARATION

Reagent 1A: Mix 1 part of R3 with 100 parts of R1.
e.g. 0.5 ml R3 + 50 ml R1
Reagent 2: ready to use.

REAGENT STABILITY AND STORAGE

Conditions:	Sealed and protected from light	
	Avoid contamination	
	Do not freeze the reagents!	
Storage:	at 2 – 8 °C	
Stability:	up to the expiration date	
Stability of Reagent 1A:	Protect from ligtht!	
Stability:	at 15 – 25 °C	2 days
	at 2 – 8 °C	2 weeks

SAMPLE PREPARATION

Urine: Dilute urine 1 + 100 with dist. water (multiply results by 101).

SAMPLE STABILITY AND STORAGE [5]

serum/ plasma:	at 20 – 25 °C	7 days
	at 4 – 8 °C	7 days
	at -20 °C	1 year
urine:	at 20 – 25 °C	2 days
	at 4 – 8 °C	7 days
	at -20 °C	1 month

Discard contaminated specimens. Freeze only once.

STANDARD

Concentration	50 mg/dL (8.33 mmol/L)
Storage:	2 – 25 °C
Stability:	up to the expiration date

Close immediately after use! Protect from light.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Sample	-	-	10 µL
Std./Cal.	-	10 µL	-
Reagent 1A	1000 µL	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	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 within 30 minutes against the reagent blank. In case of 37 °C, read within 5 minutes.			

CALCULATION

Serum/Plasma:

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

Urine:

$$\text{Urea [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]} \times 101$$

UNIT CONVERSION

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)

Rev. 06, 2019-05-23

DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria, IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at

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
Woman > 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
Woman > 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 years	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 [1]:

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

Urea in Urine [2]:

[g/24h]	[mol/24h]
26 – 43	0.43 – 0.72

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, 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.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 1 mg/dL (0.17 mmol/L).

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

SPECIFICITY/INTERFERENCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	200 mg/dL
Triglycerides	800 mg/dL

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].

METHOD COMPARISON

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

CALIBRATION

The assay requires the use of an Urea Standard or Calibrator.
We recommend the Dialab **Urea Standard** and the Dialab multi calibration serum **Diacal Auto**.
The assigned values of the calibrator have been made traceable to NIST SRM®-909 Level 1.

QUALITY CONTROL

All control sera with urea values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

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 container.
   P280: Wear protective gloves/protective clothing/eye protection/face 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.
   P304+P340: If inhaled: Remove person to fresh air and keep comfortable for breathing.
   P342+P311: If experiencing respiratory symptoms: Call a poison center or doctor/physician.
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.
6. 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

Please refer to local legal requirements.

REFERENCES

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. Fawcett JK, Scott JE. A rapid and precise method fort he determination of urea. Clin Path 1960; 13:156-9.
4. Patton CJ, Crouch SR. Spectrophotometric and kinetics investigation oft he Berthelot reaction fort he 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

CE 2°C 8°C IVD