BioMed- Urea/BUN-(UV)

Urease-UV fixed rate (enzymatic method).

REF: URE220050 (2 x 50 ml)

INTENDED FOR USE

Biomed urea reagent is intended for the in-vitro quantitative, diagnostic determination of urea in human serum or urine on both automated and manual applications.

PRINCIPLE :

Urea is the major product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver and excreted through the kidneys. The circulating levels of urea depend upon protein intake, protein catabolism and kidney function. Elevated urea levels can occur due to renal impairment or in some diseases such as diabetes, infection, congestive heart failure and during different liver diseases. Determination of blood urea nitrogen is the most widely used screening test for renal function together with serum creatinine.

Assay Principle

The series of reactions involved in the assay are as follows :

1. Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide.

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

2. In the presence of glutamate dehydrogenase (GLDH) and reduced nicotinamide adenine dinucleotide (NADH).the ammonia combines with a-ketoglutarate (a-KG) to produce L-glutamate.

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

The rate decrease in the NADH concentration is directly proportional to the urea concentration in the specimen. It is determined by measuring the absorbance at 340 nm.

SPECEMEN COLLECTION :

No special preparation of the patient is required. Use nonhemolyzed serum or plasma only. The only acceptable anticoagulants are heprin, EDTA and fluoride. Do not use ammonium heparin plasma.

Stability: 7 days at 15 -25 °C ; 7 days at 2 - 8 °C;
1 year at -20 °C
Urine samples are prediluted 1 : 50 with ammonium free water prior to assay.
Stability: 2 days at 155-5 °C ; 7 days at 2 - 8 °C;
1 month at -20 °C

REAGENTS COMPOSITION :

Standard urea (ST)	50 mg/dl 8.33 mmol/L
Reagent (R1)	
Tris Buffer (pH 8.5)	50 mmol/L
a-Ketoglutarate	10 mmol/L
GLDH	8.0 KU/L
Urease	5.0 KU/L
Sodium azide	8.0 mmol/L
Reagent (R2)	
NADH	>0.20 mmol/L
Sodium azide	8 mmol/L

The reagent also contains additives required to maintain NADH in its reduced forrm.
For further information, refer to the Urea/Bun reagent material safety data sheet.

PACKAGE : Collection & storage .

Biomed Urea reagent is supplied ready-to-use and stable up to the expiry date labeled on the bottles. Once opened, the opened vial is stable for 3 months at 2 - 8 °C.

PRECAUTIONS & WARNING :

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
Reagent (R) contains sodium azide which may react with copper or lead plumbing.

REAGENT PREPARATION & STABILITY :

Working reagent : R1: 4 volumes + R2: 1 volume
Mix well do not shake
Deterioration
Do not use Biomed Urea reagent if it is turbid or if the absorbance of the working reagent is less than 0.9 at 340 nm. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instruments .

PROCEDURE :

Wave length :		340 nm
Optical Path :		1 cm
Assay type		Fixed Rate
Direction		Decrease
Sample:	Reagent Ratio	1 : 100
e.g.:	Reagent volume	1 ml
	Sample volume	10 µL
First read time		30 seconds
Delay time		60 seconds
Last read time		90 seconds
Temperature :		37 °C
Zero adjustment		Against Air
Reagent Blank Limits		Low 0.9 AU
		High 2.0 AU
Sensitivity		0.9 mg/dL (0.15 mmol/L)
Linearity		300 mg/dL (49.8 mmol/L)

	Standard	Specimen
Working Reagent	1 ml	1 ml
Standard	10 uJ	------
Specimen	------	10 uJ

Mix, and after 30 seconds read the absorbance A1 of the standard or specimen. Exactly 1 minute later, read the absorbance A2 of standard or specimen.

CALCULATION :

Δ A specimen =A1 specimen-A2 specimen
Δ A standard = A1 standard - A2 standard

$$\text{Serum urea concentration (mg/dl)} = \frac{\Delta\,A\ \text{specimen}}{\Delta\,A\ \text{standard}} \times n$$

Where n = 50.0 mg/dL

Urine urea concentration is determined by multiplying the result by the dilution factor (50).

EXPECTED VALUE :

Urea (Serum)
Adults <65 years : 15-50 mg/dL (2.5-8.33 mmol/L)
Adults >65 years : <70 mg/dL (<11.66 mmol/L)

Urine (24) hours
Urea 20-35 g/24hrs (330-580 mmol/24hrs)
BUN 9.3-16.4 g/24 hrs

0.9 – 300 mg/dL (0.15 – 49.8 mmol/L)

WASTE DISPOSAL :

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination. S61: avoid release in environment, refer to special instructions/safety data sheets.

QUALITY CONTROL

Nomali ab0nor^all commercial control serum of known concentrations should be analyzed with each run

PERFORMANCE:

	Level 1	Level 2
n	20	20
Mean (mg/dL)	45	150
SD	0.7	2.7
CV%	1.5	1.95

Run to run (Reproducibility)

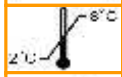
	Level 1	Level 2
n	20	20
Mean (mg/dL)	47	153
SD	0.82	2.81
CV%	1.63	2.15

Methods Comparison
A comparison between BIOMED Urea (UV) reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.992 was obtained.
Sensitivity
When run Is recommended, the minimum detection limit of the assay is 0.9 mg/dL.
Linearity
The reaction is linear up to a urea concentration of 300 mg/dL. Specimens showing higher concentration should be diluted 1+2 with physiological saline and repeat the assay (result x 3).
Interfering Substances Serum, plasma
Haemolytsis
Eraythrocyte contamination doesn't elevate results. Haemolytic specimens may cause high absorbance flagging.
Icterus
No significant interference.
Lipemia
Lipemic specimens may cause high absorbance flagging Diluted sample treatment may be recommended.

Anticoagulants
Ammonium heparin should not be used.
Others
Ammonium ions should be avoided since it may cause erroneously elevated results

REFERENCES:

1. Batton, C. J & Crouch, S.R: Anal. Chem. , 1977, 49:464-469 .
2. Shephard MD, Mezzachi RD: Clin Biochem Revs, 4:61-7, 1983.
3. Tiffany TO, jansen JM, Burtis CA.Overtion JB, SCOTT CD. Enzymatic kinetic rate and end point analyses of substrate, by use of a gemsaec fast analyzer. Clin Chem. 1972;18:829-840.
4. Tietz NW, Ed Clinicl guide to laboratory tests. 2ND. Philadelphia: WB Saunders;1990:566.

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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