Spectrum For Diagnostic Industries

Urea/BUN – (UV) (4+1)

IVD

REF.	Pack size
152 05 030	(5 x 30 ml) 150 tests

Intended Use

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

Introduction

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.

Method

Urease-UV fixed rate (enzymatic method).

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.

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

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

$$\begin{matrix} 2NH_4 + 2\alpha\text{-KG} \\ + \\ 2\ \text{NADH} \end{matrix} \xrightarrow{\textit{GLDH}} \begin{matrix} 2\ \text{L-Glutamate} \\ + \\ 2\ NAD^+ + H_2O \end{matrix}$$

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.

Reagents

Reagent 1 (R1 Buffer)	
Tris Buffer (pH 8.5)	50 mmol/L
α-Ketoglutarate	10 mmol/L
GLDH	8.0 K U/L
Urease	5.0 K U/L
Sodium azide	8.0 mmol/L
Reagent 2 (R2 Buffer)	
NADH	>0.20 mmol/L
Sodium azide	8 mmol/L
Standard urea	
BUN	50 mg/dL
Urea	107 mg/dL

Reagents preparation, storage and stability

Prepare the working solution by adding 4 volumes of reagent 1 (R1) and 1volume of reagent 2 (R2) eg. 400 µl R1 +100 µl R2.
Working solution is stable for 1 month at 2 – 8 °C or 8 days at 15 – 25 °C.
All reagents are stable until expiration date stated on label when stored refrigerated at 2 – 8 °C.
Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Do not use liquizyme BUN reagent if it is turbid or if the absorbance of the working reagent is less than 1.0 at 340 nm. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Precautions and Warnings

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 contains sodium azide which may react with copper or lead plumbing.

Specimen collection and preservation

No special preparation of the patient is required. Use non-hemolyzed serum or plasma only. The only acceptable anticoagulants are heparin, 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 15 – 25 °C ; 7 days at 2 – 8 °C;
1 month at -20 °C

Procedure

Wavelength	340 nm
Optical path	1 cm
Assay type	Fixed Rate
Direction	Decrease
Sample : Reagent Ratio	1 : 100
Delay time	30 seconds
Read time	60 seconds
Temperature	37 °C
Zero adjustment	Against Dist. water
Reagent Blank Limits	Low 1.00 AU
	High 2.0 AU

	Standard	Specimen
Working solution	1 ml	1 ml
Standard	10 µl	------
Specimen	------	10 µl

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

$$\text{Serum urea concentration (mg/dL)} = \frac{\Delta A_{specimen}}{\Delta A_{standard}} \times n$$

where n = 107.0 mg/dL

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

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Interference

Haemolysis
Erythrocyte 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.

Expected Values

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)

BUN (Serum)
Adults <65 years : 7-23.5 mg/dL
Adults >65 years : 7-32.9 mg/dL
Children : 5-18 mg/dL

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

Performance characteristics

Method Comparison

A comparison between Urea (UV) reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.992 was obtained.

Precision

Within run (Repeatiblity)

	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

Sensitivity

When run as recommended, the minimum detection limit of the assay is 0.9 mg/dL.

Linearity

The reaction is linear up to a urea concentration of 200 mg/dL. Specimens showing higher concentration should be diluted 1+2 with physiological saline and repeat the assay (result × 3).

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.

References

1. Tietz NW, Ed.Clinical guide to laboratory tests. 2ND. Philadelphia: WB Saunders;1990:566.
2. Tiffany TO, jansen JM, Burtis CA,Overtion JB,SCOTT CD. Enzymatic kinetic rate and endpoint analyses of substrate, by use of a gemsaec fast analyzer. Clin Chem. 1972.
3. Shephard MD, Mezzachi RD: Clin Biochem Revs,1983.

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

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