SPECTRUM

The Creative Approach to Bioscience

Urea/BUN - LS
(Modified Urease-Berthlot Method)

REF: 321 001	90 Test
R1 Buffer	1 x 90 ml
R2 Urease	1 x 1.5 ml
R3 Alkaline reagent	1 x 20 ml

REF: 321 002	180 Test
R1 Buffer	2 x 90 ml
R2 Urease	2 x 1.5 ml
R3 Alkaline reagent	1 x 40 ml

REF: 321 003	270 Test
R1 Buffer	3 x 90 ml
R2 Urease	3 x 1.5 ml
R3 Alkaline reagent	1 x 65 ml

REF: 321 004	400 Test
R1 Buffer	4 x 100 ml
R2 Urease	4 x 1.7 ml
R3 Alkaline reagent	2 x 40 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics colorimetric urea reagent is intended for the in-vitro quantitative, diagnostic determination of urea in human serum on both automated and manual systems.

Background

Urea is the major end 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-colorimetric method.

Assay Principle

The reaction involved in the assay system is as follows:
Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide.

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

The free ammonia in an alkaline pH and in the presence of indicator forms coloured complex proportional to the urea concentration in the specimen.

Reagents

Standard urea (ST) Aqueous primary standard

50 mg/dL	8.33 mmol/l

Reagent 1 (R1 Buffer)

Phosphate buffer pH 8.0	100 mmol/l
Sodium salicylate	80 mmol/l
Sodium nitroprusside	6.0 mmol/l
EDTA	30.0 mmol/l

Reagent 2 (R2 Enzyme)

Urease	>350000 U/l

Reagent 3 (R3 Alkaline Reagent)

Sodium hydroxide	400 mmol/l
Sodium hypochlorite	20.0 mmol/l

Irritant (xi) R36/38: Irritating to eyes and skin. **S26:** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. **S37/39:** Wear suitable gloves and eye/face protection.

For further information, refer to the Urea/BUN reagent material safety data sheet.

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 Preparation , Storage and Stability

To prepare the working solution add the content of one vial of urease (R2) to one bottle of buffer reagent (R1).Once opened, the reagent vial and standard are stable for 3 months at the specified temperature if contamination is avoided.
Stability : 1 Month at 2-8 °C.

Deterioration

Do not use the reagent if it is turbid. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Serum

No special preparation of the patient is required. Use nonhaemolyzed 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

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

System Parameters

Wavelength	578 nm (578-623 nm)
Optical path	1 cm
Assay type	End-point
Direction	increase
temperature	15-25 °C or 37 °C
Zero adjustment	Against Reagent blank
Reagent Blank Limits	Low 0.02 AU
	High 0.2 AU
Sensitivity	0.6 md/dL (0.1 mmol/l)
Linearity	200 mg/dL (33.3 mmol/l)

Procedure

	Blank	Standard	Specimen
Working solution	1.0 ml	1.0 ml	1.0 ml
Standard	-----	10 µl	-----
Sample	-----	-----	10 µl

Mix and incubate for at least 3 minutes at 37 °C or 5 minutes at 20-25 °C .

R3(Alk)	200 µl	200 µl	200 µl

Mix and incubate for 5 minutes at 37 °C or 10 minutes at 20-25 °C
Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank .

Calculation

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

where n = 50.0 mg/dl (8.33 mmol/l)

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

Urea Nitrogen: To convert the result from urea to urea nitrogen multiply the result by 0.467.

Quality Control

Normal & abnormal control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatiblity)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	60	144
SD	1.87	2.1
CV%	3.12	1.46

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	62	146
SD	1.92	2.5
CV%	3.25	1.65

Methods Comparison

A comparison between Spectrum Diagnostics Urea/BUN reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.97 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 0.6 mg/dL.

Linearity

The reaction is linear up to a urea concentration of (200 mg/dl) 33.3 mmol/L. Specimens showing higher concentrations should be diluted 1+2 with physiological saline and repeat the assay (result×3).

Interfering Substances

Serum, plasma

Haemolysis
Erythrocyte contamination doesn't elevate results.

Icterus
No significant interference.

Lipemia
Lipemic specimens interfere with the method of Berthlot.

Anticoagulants
Ammonium heparin should not be used.

Others
Ammonium ions should be avoided since it may cause erroneously elevated results. Color development in the Berthlot reaction is suppressed by amines, thiols, steroids and ascorbic acid.

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

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

0.6 – 200 mg/dL (0.1 - 33.3 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.

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. Tietz NW, ED. Clinical guide to Laboratory tests. 2ND ED. Philadelphia: WB Saunders; 1990:566.
4. Tiffany to, jansen JM, Burtis CA,Overton JB, Scott CD. Enzymatic Kinetic Rate and end Point analyses of Substrate, By USE of A Gemsaec fast analyzer. Clin Chem.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
321 001	1 x 90 ml
321 002	2 x 90 ml
321 003	3 x 90 ml
321 004	4 x 100 ml

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