Urea Assay Kit (UREA)

Method: Enzymatic Method

Cat .No.	Size	Instrument
GB9310S	R1: 4×90 ml R2: 2×60 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS9311S	R1: 6×60 ml R2: 2×60 ml	For Hitachi917 & OlympusAU640/400/600
GH9311S	R1: 2×48 ml R2: 2×16 ml	For Hitachi902
GX9311S	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT9311S	R1: 5×42 ml R2: 2×35 ml	For TOSHIBA 40

INTENDED USE

For the *in vitro* quantitative determination of Urea in serum.

CLINICAL SIGNIFICANCE[1-2]

Urea is the final degradation product of protein and amino acid metabolism. In protein catabolism the proteins are broken down to amino acids and deaminated. The ammonia formed in this process is metabolized to urea in the liver. This is the most important catabolic pathway for eliminating excess nitrogen in the human body.

The test is frequently used for the differential diagnosis of prerenal hyperuremia (cardiac decompensation, water depletion increased protein catabolism), renal hyperuremia (glomerulonephritis, chronic nephritis. polycystic kidney, nephrosclerosis, tubular necrosis) and postrenal hyperuremia (obstructions of the urinary tract).

ASSAY PRINCIPLE[3]

The enzymatic method involves a series of coupled enzymatic reactions.

Urea in the specimen is converted to ammonium and carbon dioxide by urease, and then the product ammonium is assayed by glutamate dehydrogenase (GLDH).

NH_3+ketoglutarate $\xrightarrow[NADPH \quad NADP]{GLDH}$ glutamate + H_2O

UREA + H_2O $\xrightarrow{Urease}$ $2NH_3$+ CO_2

NH_3+ketoglutarate $\xrightarrow[NADPH \quad NADP]{GLDH}$ glutamate + H_2O

SPECIMEN COLLECTION

Serum.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Buffer	
glutamate dehydrogenase（GLDH）	20 U/ml
NADPH	0.3 mmol/L
ketoglutarate	10 mmol/L
Stabilizer	
Reagent 2（R2）	
Buffer	
urease	28 U/ml
ketoglutarate	17 mmol/L
Stabilizer	

STABILITY AND PREPARATION OF REAGEANTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃.

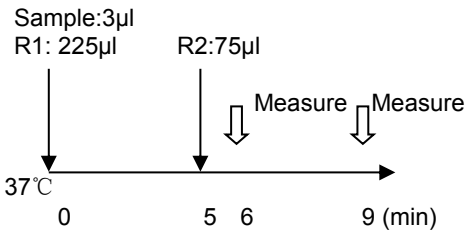
The reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)

Assay Mode: 2 Point Rate 22-28

Wave length (main/sub): 340 nm/405 nm



1. Mix 3μl sample with 225μl R1 and incubate at 37℃ for 5 minutes.
2. Add 75μl R2 into cuvette, mix and incubate for 1 minute at 37℃.
3. Read initial absorbance and start timer simultaneously, read again after 1, 2 and 3 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALCULATION

$$\text{Concentration} = \frac{\triangle A_{sample}/min}{\triangle A_{calibrator}/min} \times \text{calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

1. Check wavelength setting and light source.
2. Ensure that cuvettes are not dirty and that all glassware in use has been cleaned thoroughly.
3. Check water contaminants, ie. bacterial growth may contribute to inaccurate results.
4. Check that assay temperature is accurate.
5. Ensure that reagent pack contents are still within expiry date.

NORMAL RANGE

Serum: 10-50 mg/dl (1.7-8.3 mmol/L)
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

CONVERSION FACTORS

mg/dl ×0.1665= mmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The rang of this assay is approximately 258 mg/dl (43.0 mmol/L). If the concentration exceeds the top standard value, further dilute the sample 1+1 with 0.9% NaCl solution. Multiply the result by 2.

PRECISION

The CV of the test should be CV% ≤5%

Intra assay precision		
N=20	Level 1	Level 2
Mean(mmol/L)	7.69	19.80
SD	0.03	0.06
CV	0.44%	0.31%
Inter assay precision		
N=20	Level 1	Level 2
Mean(mmol/L)	7.83	20.10
SD	0.12	0.23
CV	1.53%	1.15%

SPECIFICITY

A Reagent blank may be performed by replacing sample or standard with double deionized water. The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin	450 mg/dl
Ascorbic Acid	40 mg/dl
Bilirubin	40 mg/dl
Triglyceride	667 mg/dl

CORRELATION

This method (y) was compared with another commercially available method and the following linear regression equation obtained:
y = 0.9608x +0.3342, R^2=0.9982 when 50 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent 2 contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water.In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

REFERENCES

1. Marshall EK Jr: J Biol Chem 1913; 15:487.
2. Talke H; Schubert GE: Klin Wschr 1965; 43:174.
3. Tietz N. W., Textbook of Clinical Chemistry.W.B. Saunders Co, 1987, 1254-1316.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn