UREA UV SYSTEM PACK

(UV GLDH METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI33	Urea UV System Pack	4x40 + 4x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Urea in human serum, plasma and urine.

CLINICAL SIGNIFICANCE

Urea is the major end product of protein nitrogen metabolism in humans. It constitutes the largest fraction of the non-protein nitrogen component of the blood. Urea is produced in the liver and excreted through the kidneys in the urine. Consequently, the circulating levels of urea depend upon protein intake, protein catabolism and kidney function. Elevated urea levels can occur with dietary changes, diseases which impair kidney function, liver diseases, congestive heart failure, diabetes and infections.

PRINCIPLE

The enzyme methodology employed in this reagent is based on the reaction first described by Talke and Schubert. To shorten and simplify the assay, the calculations are based on the discovery of Tiffany et al. that urea concentration is proportional to absorbance change over a fixed time interval.

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

$$NH_3 + \alpha\text{-KG} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + \text{NAD}$$

1. Urea is hydrolysed in the presence of water and Urease to produce ammonia and carbon dioxide.
2. In the presence of GLutamate Dehydrogenase (GLDH) and reduced Nicotinamide Ademine Dinucleotide (NADH), ammonia combines with α-ketoglutarte (α-KG) to produce L-Glutamate.
3. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm as NADH is converted to NAD.

REAGENT COMPOSITION

Reagent 1 : Urea Enzyme Reagent

Tris Buffer	>100 mmol/L
ADP	>1 mmol/L
Urease	>20000 U/L
GLDH	>1500 U/L
2-Oxalagularate	>15 mmol/L

Reagent 2 : Urea Substrate Reagent

NADH	>1.05 mmol/

Also contains Non-reactive fillers and stabilizers.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

Reagents are ready to use.
After opening, reagents are stable until expiry date at +2-+8°C if stored at appropriate conditions, closed carefully and without any contamination.

On board stability: Min. 30 days if refrigerated (+8-+14 °C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use serum, EDTA plasma and heparin (no ammonium heparin) plasma, urine. It is recommended to follow NCCLS procedures (or similar standardized conditions). Dilute urine 1 + 100 with dist. water and multiply results by 101.

Stability

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

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

mg/dl x 0.1665 = mmol/l
Urea (mg/dl) x 0.467 = BUN (mg/dl)
BUN (mg/dl) x 2.14 = Urea (mg/dl)

EXPECTED VALUES

In Serum / Plasma

10 - 40 mg/dl

Urea in Urine

26 – 43 g/24 h (0.43 – 0.72 mol/24 h)

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.
Data obtained in your laboratory may differ from these values.

Limit of quantification: 1 mg/dl
Linearity: 300 mg/dl
Measuring range: 1 - 300 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	42.89	1.06	2.48
Sample 2	111.96	1.62	1.45

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	24	1.12	4.60

COMPARISON

A comparision between Urea UV System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 1.055x - 2.825 mg/dl
r = 0.998

INTERFERENCES

Following substances do not interfere:
haemoglobin up to 7.5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contains less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400
(Fully Auto Biochemistry Analyzer)

TEST NAME	UREA UV
FULL NAME	UREA UV
PRI WAVE	340 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	12
END	15
DECIMAL	0
UNIT	mg/dl
LINEARITY RANGE LOW	1
LINEARITY RANGE HIGH	300
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSTRATE DEPLETED	-
LINEARITY	300 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTRATION STD	Refer calibrator value sheet.

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

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   C V Mosby Company St Louis 1984; 1257-61.
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SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics