URIC ACID SYSTEM PACK

(URICASE / POD METHOD)

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

BEACON

Code	Product Name	Pack Size
UNI34	Uric Acid System Pack	4 x 50 ml

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Uric Acid in human serum, plasma and urine.

CLINICAL SIGNIFICANCE
Uric acid is a metabolite of purines, nucleic acids and nucleoproteins, consequently, abnormal levels may be indicative of a disorder in the metabolism of these substances. Hyperuricaemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes and hypothyroidism. Decreased levels are present in patients with Wilson's Disease.

PRINCIPLE
The series of reactions involved in the assay system is as follows:

$$\text{Uric Acid} + O_2 + H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$\text{DHBS} + 4\text{AAP} + 2H_2O_2 \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4H_2O$$

1. Uric acid is oxidised to allantoin by uricase with the production of H_2O_2.
2. The peroxide reacts with 4-aminoantipyrine (4-AAP) and DHBS in the presence of peroxidase to yield a quinoneimine dye. The absorbance of this dye at 505 nm is proportional to uric acid concentration in the sample.

REAGENT COMPOSITION

Reagent 1 : Uric Acid Enzyme Reagent	
HEPES Buffer	>60 mmol/L
4-AAP	>0.2 mmol/L
URICASE	>300 U/L
Peroxidase	>1000 U/L
DHBS	>0.75 mmol/L

REAGENT PREPARATION
Reagents are liquid, ready to use.

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.

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

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (heparin, EDTA) or urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability:

in serum / plasma:	3 days	at +20-+26 °C
	7 days	at +4 - +8°C
	6 months	at -20°C
in urine:	4 days	at +20-+26 °C

Dilute urine 1 + 9 ratio and multiply results by 10

CALIBRATION
Calibration with the Beacon Multicalibrator recommended.

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

UNIT CONVERSION
mg/dl x 60 = µmol/l

EXPECTED VALUES
Serum:
Adults
Male: 4.0 – 7.2 mg/dl
Female: 2.7 – 6.5 mg/dl
Urine, 24 h:
average diet: 250 – 750 mg/24 hrs.

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 contained in your laboratory may differ from these values.

Limit of quantification: 0.6 mg/dl
Linearity: 20 mg/dl
Measuring range: 0.6 - 20 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	**Mean (mg/dl)**	**SD (mg/dl)**	**CV (%)**
Sample 1	6.28	0.14	2.27
Sample 2	8.84	0.26	2.89

Inter-assay precision Run to run (n=20)	**Mean (mg/dl)**	**SD (mg/dl)**	**CV (%)**
Sample 1	8.89	0.15	1.71

COMPARISON
A comparison between Uric Acid System Pack (y) and a commercially available test (x) using 20 samples gave following results:
y = 1.003x + 0.094 mg/dl
r = 0.999

INTERFERENCES
Following substances do not interfere:
haemoglobin up to 10 g/l, bilirubin up to 40 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.

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	URIC ACID
FULL NAME	URIC ACID
PRI WAVE	505 nm
SEC WAVE	630 nm
ASSAY/POINT	1 POINT END
START	-
END	33
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	0.6
LINEARITY RANGE HIGH	20
SAMPLE VOLUME	5 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSTRATE DEPLETED	-
LINEARITY	20 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.

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REFERENCES

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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

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