

# URIC ACID SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

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

## INTENDED USE

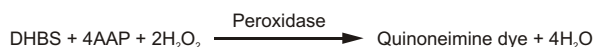
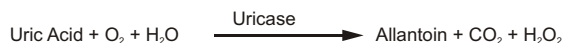
Diagnostic reagent for quantitative *in vitro* determination of Uric Acid in human serum, plasma and urine.

## 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:



1. Uric acid is oxidised to allantoin by uricase with the production of  $\text{H}_2\text{O}_2$ .
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 (2–10°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
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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.
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# BEACON

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:** 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:

$y = 1.003x + 0.094 \text{ mg/dl}$

$r = 0.999$

## 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 Unicorn 480, Bonavera Chem 480 &  
Bonavera 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 µl
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.
SAMPLE VOLUME	5 µl

#### 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		