URIC ACID SYSTEM PACK

(URICASE / POD METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120, Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA234	Uric Acid System Pack	5x40 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:

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

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

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

in urine: 4 days at +20 - +26°C

Dilute urine 1 +9 ratio and multiply results by 10

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 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 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	5.81	0.09	1.57
Sample 2	9.44	0.03	0.31

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Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	2.80	0.05	1.77

COMPARISON

A comparison between Uric Acid System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 0.994x - 0.002 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.

MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120,, Bonavera Chem200,Beaconic chem 200,Beaconic B200,Beaconic analyzer 120 & Bonavera chem 100 (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	17
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/Abs.limit	-
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

NOTE

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

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

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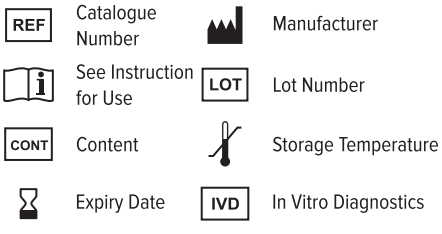
Symbols Used On Labels



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