URIC ACID

Enzymatic colorimetric determination of uric acid in biological liquids.

TEST SUMMARY
Uric Acid, in presence of Uricase, is transformed in Allantoin and Oxygenated Water, which reacts with a phenolic derivative and Aminophenaction forming a blue-violet compound.

SAMPLES
Serum, plasma heparinate or EDTA and urine in 24h.
The use of Oxalate, citrate or fluoride could give law results.
Dilute urine sample 1:10 with distilled water.
Stability serum/plasma samples 7 days at 2-8°C or 6 months at -20°C.
Stability urine samples 4 days at 20-25°C.

REAGENTS
Single Reagent: Borate buffer pH 7.0 180 mmol/l, Uricase > 50 U/l, 4-aminophenazone 0.25 mmol/l, TOPS 0.3 mmol/l, peroxidase > 100 U/l, stabilizers and preservatives.

Standard: Uric Acid 6 mg/dl; stabilizers and preservatives.

MATERIAL REQUIRED BUT NOT SUPPLIED
Normal laboratory equipment. Spectrophotometer UV/VIS with thermostatation. Automatic Micropipette. Cuvette in optical glass or monouse in optical polystyrene. Distilled water.

PRECAUTIONS
Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

REAGENTS PREPARATION
Reagents are ready to use and are stable until expiration date on label, away from direct light source, stored at 2-8°C.
Warning: do not contaminate reagents after the vials opening.
Bring the reagents at work temperature before use.

PROCEDURE
Kind of analysis:	End Point
Reading time:	10 minutes
Wavelength:	550 nm
Temperature:	37°C
Lightpath:	1 cm
Zero:	Blank Reagent

Reagents	Blank Reagent	Standard	Sample
Distilled Water	25 µl	--	--
Standard	--	25 µl	--
Sample	--	--	25 µl
Sole Reagent	1 ml	1 ml	1 ml

Mix, incubate for 10 minutes at 37°C, read absorbances of the sample and standard against blank reagent.

CALCULATION
Serum/Plasma Uric Acid (mg/dl)

(A sample/A standard) x 6

Spontaneous Urine Uric Acid (mg/dl)

(A sample/A standard) x 6 x 10

24 hours Urine Uric Acid (mg/24h)

(A sample/A standard) x 6 x 10 x diuresis (dl)

EXPECTED VALUES

SERUM PLASMA	Female mg/dl (µmol/l)	Male mg/dl (µmol/l)
Adults	2.3 - 6.1 (137 - 363)	3.6 - 8.2 (214 - 488)
Children		
0-5 days	1.9 - 7.9 (113 - 470)	
1-4 ages	1.7 - 5.1 (101 - 303)	2.2 - 5.7 (131 - 340)
5-11 ages	3.0 - 6.4 (178 - 381)	
12-14 ages	3.2 - 6.1 (190 - 363)	3.2 - 7.4 (190 - 440)
15-17 ages	3.2 - 6.4 (190 - 381)	4.5 - 8.1 (268 - 482)

Every laboratory should establish own reference intervals in accordance with own population.

NOTES
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL
It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE
Precision

Intra-assay (n = 30)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	4.01	0.0547	1.37
Sample 2	10.22	0.0761	0.74

Inter-assay (n = 30)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	3.96	0.0897	2.27
Sample 2	10.24	0.1033	1.01

Sensivity/limit of detection
The method is able to discriminate until 0.3 mg/dl.

Linearity
The method is linear up to 20 mg/dl for the serum samples and up to 2200 mg/l for urine samples.
If the values is exceeded, it is suggested to dilute the sample 1+1 with saline solution for the serum samples and distilled water for the urine samples, to repeat the test, multiplying the results by 2.

Methods comparison
A comparison with a commercial available product gave the following results in a comparison on 31 samples of serum:

Uric Acid LTA = x
Uric Acid competitor = y
n = 31

y = 1,02736x - 0,14213 r = 0,99832

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 50 mg/dl
bilirubin	≤ 20 mg/dl
triglycerides	≤ 2000 mg/dl
ascorbic acid	≤ 30 mg/dl

A comparison with a commercial available product gave the following results in a comparison on 21 samples of urine:

Uric Acid LTA = x
Uric Acid competitor = y
n = 21

y = 0,99541x + 1,17927 r = 0,99872

WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING
CODE CC00100	(400 TESTS)	
Single Reagent	4 x 100 ml	(liquid)
Standard	1 x 5 ml	(liquid)

REFERENCES

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SYMBOLS
IVD Only for IVD use
LOT Lot of manufacturing
REF Code number
Storage temperature interval
Expiration date
Warning, read enclosed documents
Read the directions
Biological risk

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