

URIC ACID AOX FL

AX F100 CH	5 x 20 ml
AX F250 CH	5 x 50 ml
AX F600 CH	5 x 120 ml
AX 100F CH	5 x 200 ml

INTENDED USE

Reagent for quantitative in vitro determination of uric acid in biological fluids.

SUMMARY OF TEST

In humans, uric acid is the major product of the catabolism of the purine nucleosides, adenosine and guanosine. The daily synthesis rate of uric acid is approximately 400 mg; dietary sources contribute another 300 mg. In men consuming a purine-free diet, the total body pool of exchangeable urate is estimated at 1200 mg; this same value is estimated to be 600 mg in women.

PRINCIPLE OF THE METHOD

Uric acid in sample is oxidized to allantoin in presence of the enzyme uricase and H_2O_2 is generated. The H_2O_2 reacts with TOOS and 4-aminoantipyrine in the presence of peroxidase to form a violet dye. The intensity of color formed is proportional to the uric acid concentration and can be measured photometrically between 510 and 560 nm. Product contains ascorbate oxidase to eliminate ascorbic acid interference.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

UA AOX R1 F100: 4 x 20 ml (liquid) blue cap
F250: 4 x 50 ml (liquid) blue cap
F600: 4 x 120 ml (liquid) blue cap
100F: 4 x 200 ml (liquid) blue cap

Composition: phosphate buffer pH 7.0 100 mM, TOOS 0.38 mM, ascorbate oxidase \geq 1000 U/l, surfactant.

UA AOX R2 F100: 1 x 20 ml (liquid) red cap
F250: 1 x 50 ml (liquid) red cap
F600: 1 x 120 ml (liquid) red cap
100F: 1 x 200 ml (liquid) red cap

Composition: Good buffer pH 7.7 50 mM, 4-aminoantipyrine 1.5 mM, uricase \geq 450 U/l, POD \geq 1000 U/l, surfactant.

Standard: uric acid 5 mg/dl - 5 ml

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Use separate reagents ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C

Note: if it is necessary, you can use mixed reagent -add 1 part of reagent R2 to 4 parts of reagent R1 - but ascorbate oxidase will be of less efficacy.

Stability of working reagent: 90 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

N-acetylcysteine (NAC), metamizole and acetaminophen may cause interference in the Trinder reaction.^(1,2)

To avoid interference, the blood withdrawal should be performed before drug administration.

SPECIMEN

Serum, plasma heparinate. Oxalate, citrate and fluoride could yield a small decrease of uric acid. Urine.

Uric acid is stable 5 days at 4-25°C.

Dilute urine sample 1:10 with deionized water.

TEST PROCEDURE

Wavelength:	550 nm		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	50 μ l	-	-
calibrator	-	50 μ l	-
sample	-	-	50 μ l
Mix, incubate at 37°C for 5 minutes. Read absorbances of calibrator (Ac_1) and samples (Ax_1) against reagent blank.			
dispense:	blank	calibrator	sample
reagent R2	250 μ l	250 μ l	250 μ l
Mix, incubate at 37°C for 5 minutes. Read absorbances of calibrator (Ac_2) and samples (Ax_2) against reagent blank.			

RESULTS CALCULATION

Serum/plasma sample:

uric acid mg/dl = $(Ax_2 - Ax_1) / (Ac_2 - Ac_1) \times 5$ (standard value)

Random urine sample:

uric acid mg/dl = $(Ax_2 - Ax_1) / (Ac_2 - Ac_1) \times 5 \times 10$
(standard value and dilution)

24 hours urine sample (uric acid mg/24h):

uric acid mg/24h = $(Ax_2 - Ax_1) / (Ac_2 - Ac_1) \times 5 \times 10 \times \text{diuresis (dl)}$
(standard value, dilution, diuresis in dl)

EXPECTED VALUES

Serum/plasma samples:

Men: 3.5 - 7.2 mg/dl (0.21 - 0.42 mmol/l)

Women: 2.6 - 6.0 mg/dl (0.15 - 0.35 mmol/l)

24h urine:

250 - 750 mg/24h (1.50 - 4.50 mmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QUANTINORM CHEMA

with normal or close to normal control values

QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 35 mg/dl.

If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)

the limit of detection is 0.06 mg/dl.

Interferences

no interference was observed by the presence of:

hemoglobin \leq 1000 mg/dl

bilirubin \leq 29 mg/dl

lipids \leq 970 mg/dl

ascorbic acid \leq 50 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	4.49	0.02	0.47
sample 2	12.04	0.06	0.49

inter-assay (n=21)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	4.53	0.08	1.67
sample 2	12.01	0.24	2.00

Methods comparison

a comparison between Chema and a commercially available product gave the following results:

Uric acid AOX FL Chema = x

Uric acid competitor = y

n = 120

$y = 0.882x + 0.037 \text{ mg/dl}$ $r^2 = 0.99$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

- 1) N-acetylcysteine interference of Trinder-based assays. Genzen JR, Hunsaker JJ, Nelson LS, Faine BA, Krasowski MD. Clin Biochem. 2016 Jan;49(1-2):100-4
- 2) Drug interference in Trinder reaction. Wiewiorka O, Čermáková Z, Dastyh M. Euromedlab 2017. ISSN 1437-4431
- 3) M. Jelikić-Stankov, P. Djurdjević, D. Stankov - J. Serb. Chem. Soc. 68 (8-9), 691 - 698 (2003)
- 4) P. Fossati, L. Prencipe, G. Berti - Clin. Chem. 26/2, 227 - 231 (1980)

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SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use