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 ≥ 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 ≥ 450 U/l, POD ≥ 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

UA AOX R1: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

UA AOX R2: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

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 yeld 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

Wavelenght: 550 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	50 µl	-	-
calibrator	-	50 µl	-
sample	-	-	50 µl

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 µl	250 µl	250 µl

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 = $(Ax_2-Ax_1)/(Ac_2-Ac_1)$ x 5 (standard value)

Random urine sample:

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

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

uric acid mg/24h = $(Ax_2-Ax_1)/(Ac_2-Ac_1)$ x 5 x 10 x 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	≤ 1000 mg/dl
bilirubin	≤ 29 mg/dl
lipids	≤ 970 mg/dl
ascorbic acid	≤ 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 = 0.882 x + 0.037 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, Dastych M. Euromedlab 2017. ISSN 1437-4431
3) M. Jelikic'-Stankov, P. Djurdjevic', 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

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

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