URIC ACID T FL

AU F100 CH	5 x 20 ml
AU F250 CH	5 x 50 ml
AU F402 CH	4 x 100 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 ADPS 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 to 546 (510 - 560) nm.

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 T R1 **F100: 4 x 20 ml (liquid) blue cap**
F250: 4 x 50 ml (liquid) blue cap
F402: 4 x 80 ml (liquid) blue cap

UA T R2 **F100: 1 x 20 ml (liquid) red cap**
F250: 1 x 50 ml (liquid) red cap
F402: 1 x 80 ml (liquid) red cap

Composition in the test: phosphate buffer pH 7.0, ADPS ≥ 0.2 mM, 4-aminoantypyrine 0.3 mM, uricase ≥ 450 U/l, POD > 2500 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

Code F100: add 5 ml of reagent R2 to a bottle of reagent R1.
Code F250: add 12.5 ml of reagent R2 to a bottle of reagent R1.
Code F402: add 20 ml of reagent R2 to a bottle of reagent R1.
If reagents are mixed in reduced quantities, mix 4 parts of reagent R1 with 1 part of reagent R2.
Stability of working reagent: use preferably within 15 days at 2-8°C, away from light sources.
Stability of unmixed reagents: up to expiration date on labels at 2-8°C;
Stability since first opening of vials of unmixed reagents: use preferably within 60 days at 2-8°C.

PRECAUTIONS

UA T R1: Danger. Causes serious eye damage (H318). 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). Immediately call a doctor (P310). If eye irritation persists: get medical advice (P337+P313).

UA T 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: 546 nm (allowed 510 ÷ 560 nm)
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	25 µl	-	-
standard	-	25 µl	-
sample	-	-	25 µl

Mix, incubate at 37°C for 5 minutes.
Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

Serum/plasma sample:

uric acid mg/dl = Ax/As x 5 (standard value)

Random urine sample:

uric acid mg/dl = Ax/As x 5 x 10
(standard value and dilution)

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

uric acid mg/24h = Ax/As x 5 x 10 x diuresis (dl)
(standard value, dilution and 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 30 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 0.04 mg/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 50 mg/dl
bilirubin	≤ 33 mg/dl
lipids	≤ 1200 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	5.03	0.02	0.46
sample 2	10.49	0.05	0.49

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	5.02	0.05	0.97
sample 2	10.50	0.11	1.08

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

Uric acid T FL Chema = x
Uric acid competitor = y
n = 85

y = 0.9832x - 0.0883 mg/dl r^2 = 0.999

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) Barham D., Trinder P. - Analyst, 97 142 (1972)
4) Fossati P., Prencipe L., Berti G. - Clin. Chem. 26, 277 (1980).
5) Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
6) Milena Jelikic-Stankov, Predrag Djurdjevic and Dejan Stankov - J. Serb. Chem. Soc, 68 (8-9), 691-698 (2003).

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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

CE