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

In vitro diagnostic medical device for quantitative in vitro determination of uric acid in biological fluids (serum) and intended to aid in the diagnosis and to determination of therapy adequacy of gout or kidney diseases. The IVD is to be used on automatic random-access analyzer. The product is intended for professional use in clinical laboratories.

TEST PRINCIPLE

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[2,14-15].

MATERIALS PROVIDED AND COMPOSITION

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

Composition: Buffer pH 7.0, ADPS ≥ 0.2 mM, stabilizers and preservatives.

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: Buffer pH 7.7, 4-aminoantipyrine ≥ 1 mM, uricase ≥ 500 U/l, POD > 5000 U/l, stabilizers and preservatives.

Standard: **uric acid 5 mg/dl - 5 ml**

* Traceability: this method has been standardized against HPLC, according to Original formulation Gindler (1980 - U.S. Patent 4207203) - Weighed in purified material.

MATERIALS REQUIRED BUT NOT SUPPLIED

General laboratory equipment.
Analyser: Ilab or Hitachi or Cobas Mira S.
Saline solution.
For calibrators and controls see the paragraph "Quality control and calibration".

REAGENT PREPARATION

Working reagent: mix 4 parts of reagent R1 with 1 part of reagent R2.

STABILITY AND STORAGE

Store all components at 2-8°C.
Stability of single reagents: up to expiration date on labels at 2-8°C.
Stability of single reagents after first opening: 60 days at 2-8°C.
Stability of **working reagent**: 15 days at 2-8°C.

PRECAUTIONS

UA T R1: Danger. Causes serious eye damage (H318). Wear protective gloves. Eye protection (P280). 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).

UA T R2: It is not classified as hazardous.

Standard: It is not classified as hazardous.

SPECIMEN

Serum.
Uric acid is not normally affected by additives such as heparin, ethylenediaminetetraacetic acid (EDTA), separation gels, or procoagulants, so the samples should be collected in the same manner routinely used for any laboratory test[1].
Freshly drawn serum are the preferred specimens.
Uric acid is stable 48 hours a 20-25°C, 14 days at 4°C and 4 months at -20°C[1].

TEST PROCEDURE

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

dispense:	blank	standard	sample
Working 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

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

EXPECTED VALUES

Men[1,3]: 3.5 - 7.2 mg/dl (0.21 - 0.43 mmol/l)
Women[1,3]: 2.6 - 6.0 mg/dl (0.16 - 0.36 mmol/l)

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

QUALITY CONTROL AND CALIBRATION

Calibration is required with each change in reagent lot number. It is suggested to verify calibration with at least one level of an internal quality control. If control results fall outside acceptable ranges, recalibration may be necessary. For this purpose the following human based control sera are available:
QUANTINORM CHEMA - MULTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA - MULTIPATH 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

The uric acid T FL has been validated on Ilab 650 (a) Hitachi 912 (b) and Cobas Mira S (c). However, the use of the reagent can be extended to all automatic random-access analyzers, because they have comparable characteristics[18,19]

Sensitivity / Limit of Detection (LOD)[4, b]
The LOD is 0.04 mg/dl.

Analytical specificity:
Interferences[5, b]
interference does not occurr in the presence of:

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

N-acetylcysteine (NAC), metamizole and acetaminophen may cause interference in the Trinder reaction[11-13].
To avoid interference, the blood withdrawal should be performed before drug administration.

In very rare cases gammopathy may give unreliable results[16,17]

Carry-over effect[6, a]
BIAS% < 9.81

Accuracy:
Trueness[6, a]
Total observed error% < 11.97 (allowable total error)

Precision[7, b]
Repeatability

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

Reproducibility

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	5.03	0.05	0.97
sample 2	10.50	0.11	1.08

Measurement range[8, b]
0.11 - 30.00 mg/dl

Linearity[8, c]
the method is linear up to 30 mg/dl.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Methods comparison[7, b]
a comparison between Chema and a commercially available product gave the following results:

Uric Acid T FL Chema = x
Uric Acid AOX FL Chema = y
n = 85

Linear regression
y = 1.016x + 0.095 mg/dl r = 0.9995

Passing-Bablok[9-10]
y = 1.018x + 0.081 mg/dl

Positive and negative Predictive Value
Positive predictive value (PPV): 88.9%
Negative predictive value (NPV): 100.0%

WASTE DISPOSAL

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

NOTICE TO THE USER

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

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19. Data on file

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SYMBOLS

Chema Diagnostica uses symbols listed in the ISO 15223-1 (see www.chema.com - Section "Products" for definition of symbols used).

Addition, deletions or changes are indicated with a vertical line on the side of the affected paragraph.