CE IVD

Liquid Reagents – ready to use

URIC ACID AOX

Enzymatic, Colorimetric with ATCS*
2 Reagents

Diagnostic reagent for quantitative in vitro determination of uric acid in human serum, plasma or urine on photometric systems

REF	Cont.		
D98714	**5 x 50 ml**	4 x 50 ml	Reagent 1
		1 x 50 ml	Reagent 2
D94708	1 x 3 ml	Uric Acid Standard	
D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, Enzymatic
Wavelength:	Hg 546 nm, 550 nm
Temperature:	20 - 25°C, 37°C
Sample:	Serum, , heparinized or EDTA-plasma
	urine
Linearity:	up to 20 mg/dl
Sensitivity:	The lower limit of detection is 0.3 mg/dl.

* **A**dvanced **T**urbidity **C**learing **S**ystem; minimzes turbidity caused by lipemia

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION	
Reagent 1:		
Phosphate Buffer, pH 7.0	100	mmol/L
TOOS	1	mmol/L
Ascorbate Oxidase	1	kU/L
Reagent 2:		
Phosphate Buffer, pH 7.0	100	mmol/L
4-Aminoantipyrine	0.3	mmol/L
K4 [$FE(CN)_6$]	10	µmol
POD	>1	kU/L
Uricase	>50	U/L

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.

Sample Start:
Not possible (Elimination of Ascorbic Acid by Ascorbic Acid Oxidase in first incubation step with Reagent 1).

REAGENT STABILITY AND STORAGE

Conditions:	protect from light
	close immediately after use
Storage:	at 2 – 8°C
Stability	up to the expiration date

Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of a mixture of 4 parts R1 and 1 part R2 is < 0.3 at 546 nm.

SAMPLE PREPARATION

Urine: Dilute urine 1 + 10 with dist. water.

SAMPLE STABILITY AND STORAGE

serum / plasma:	at 20 - 25°C	3 days
	at 4 - 8°C	7 days
	at -20°C	6 months
urine:	at 20 - 25°C	4 days

Discard contaminated specimens.

STANDARD

(has to be ordered separately)

Concentration	6 mg/dl
Storage:	2 – 8°C
Stability:	up to the expiration date

CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:

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

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate start

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample or Std./Cal.	-	20 µl	20 µl
Distilled water	20 µl	-	-
Mix. Incubate for 5 min. at 20-25°C/37°C. Then add:			
Reagent 2	250 µl	250 µl	250 µl
Mix. Incubate for 10 min. at 20–25°C or for 5 min. at 37°C. Measure absorbance of sample and std./cal. against reagent blank within 30 minutes.			

CALCULATION (light path 1 cm)

serum/plasma:

$$\text{Uric Acid (mg/dl)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal (mg/dl)}$$

urine:

$$\text{Uric Acid (mg/dl)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal (mg/dl)} \times 11$$

UNIT CONVERSION

mg/dl x 59.48 = µmol/L

REFERENCE RANGE *(mg/dl)

serum / plasma:	Females	Males
Adults	2.3–6.1	3.6-8.2
Children		
0 – 5 days	1.9-7.9	1.9-7.9
1 – 4 years	1.7-5.1	2.2-5-7
5 – 11 years	3.0-6.4	3.0-6.4
12 – 14 years	3.2-6.1	3.2-7.4
15 – 17 years	3.2-6.4	4.5-8.1

urine:

assuming normal diet	≤ 800 mg/24h
assuming low purine diet	≤ 600 mg/24h

* It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

$$\text{Uric Acid} + H_2O + O_2 \xrightarrow{\text{URICASE}} \text{Allantoine} + CO_2 + H_2O_2$$

$$\text{TOOS} + \text{4-AAP} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Indamine} + 3\,H_2O$$

The reaction is a coupled uricase method, the intensity of the color of the dye is proportional to the concentration of uric acid in the sample.

ABBREVIATIONS:

4-AAP = 4-Aminoantipyrine
POD = Peroxidase
TOOS = N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m toluidine
AOX = Ascorbate Oxidase

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to 20 mg/dl. Above this concentration, dilute the sample with destilled water or NaCl (9 g/L sodium chloride in water) and reassay multiplying the result by the dilution factor.

PRECISION (at 37°C)

Intra-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	4.03	0.08	1.99
Sample 2	5.41	0.05	0.92
Sample 3	10.9	0.12	1.06

Inter-assay n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	3.12	0.08	2.56
Sample 2	4.75	0.05	1.05
Sample 3	10	0.08	0.80

METHOD COMPARISON

A comparison between Dialab Uric acid AOX (y) and a commercially available test (x) using 68 samples gave following results: y = 1.02 x + 0.26 mg/dl; r= 0.999.

QUALITY CONTROL

All control sera with Uric Acid values determined by this method can be used.
We recommend:

REF Cont.

D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The assay requires the use of an Uric Acid Standard or Calibrator.
We recommend:

REF Cont.

D94708	1 x 3 ml	**URIC ACID STANDARD**	
D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 208-14.
2. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-70.

2°C 8°C IVD

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