DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Liquid reagents – ready to use

Uric Acid AOX

Enzymatic, colorimetric

2 Reagents with ATCS*

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

REF	Kit Size	Content
D94710	**5 x 100 ml**	4 x 100 mL R1 + 1 x 100 mL R2
D98714	**5 x 50 ml**	4 x 50 mL R1 + 1 x 50 mL R2
D00719	**5 x 25 ml**	4 x 25 mL R1 + 1 x 25 mL R2
D00720	**5 x 10 ml**	4 x 10 mL R1 + 1 x 10 mL R2
D84911	**10 x 50 ml**	10 x 40 mL R1 + 4 x 25 mL R2
D0440917	**5 x 62.5 ml**	4 x 62.5 mL R1 + 1 x 62.5mL R2
DA0846	**5 x 50 ml**	5 x 40 mL R1 + 5 x 10 mL R2
DT1046	**4 x 62.5 ml**	4 x 50 mL R1 + 4 x 12.5mL R2
DK0743	**5 x 50 ml**	4 x 50 mL R1 + 1 x 50 mL R2
DE1846	**8 x 62.5 ml**	8 x 50 mL R1 + 8 x 12.5mL R2

Additionally offered:

D94708	1 x 3 mL	Uric Acid Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P
D08581	12 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08581SV	1 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08582	12 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2
D08582SV	1 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2

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

TEST PARAMETERS

Method:	Colorimetric, enzymatic, endpoint, increasing reaction,
Wavelength:	550 nm, Hg 546 nm
Temperature:	20 – 25 °C, 37 °C
Sample:	Serum, heparin plasma or EDTA-plasma, urine
Linearity:	up to 20 mg/dL (1190 µmol/L)
Sensitivity:	The lower limit of detection is 0.3 mg/dL (18 µmol/L).

SUMMARY [1,2]

Uric acid and its salts are end products of the purine metabolism. In gout, the most common complication of hyperuricemia, increased serum levels of uric acid lead to formation of monosodium urate crystals around the joints. Further causes of elevated blood concentrations of uric acid are renal diseases with decreased excretion of waste products, starvation, drug abuse and increased alcohol consume as well as use of certain medicaments. High uric acid levels also constitute an indirect risk factor for coronary heart disease. Hypouricemia is seldom observed and associated with rare hereditary metabolic disorders.

TEST PRINCIPLE

Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine and N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidine (TOOS) to a blue violet dye. Ascorbate oxidase avoids interference by ascorbic acid and other reducing substances.

$$\text{Uric Acid} + H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

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

ABBREVIATIONS

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

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Phosphate buffer, pH 7.0	100 mmol/L
TOOS	1.25 mmol/L
Ascorbate Oxidase (AOX)	≥ 1.2 kU/L
Reagent 2:	
Phosphate Buffer, pH 7.0	100 mmol/L
4-Aminoantipyrine	1.5 mmol/L
$K_4[Fe(CN)_6]$	50 µmol/L
POD	≥ 5 kU/L
Uricase	≥ 250 U/L

REAGENT PREPARATION

Substrate Start:
The reagents are ready to use.
Sample Start:
Not possible (elimination of ascorbic acid by ascorbate oxidase during incubation with Reagent 1).

REAGENT STABILITY AND STORAGE

Conditions:	Protect from light
	Close immediately after use
	Avoid contamination
	Do not freeze the reagents!
Storage:	at 2 – 8 °C
Stability	up to the indicated expiration date

Note: The measurement is not influenced by occasionally occurring colour 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 [3]

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.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kits – has to be ordered separately)

Concentration	6 mg/dL (357 µmol/L)
Storage:	2 – 8 °C
Stability:	up to the expiration date

Close immediately after use! Avoid contamination!

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	-	-	20 µL
Standard/Calibrator	-	20 µL	-
Distilled water	20 µL	-	-
Mix. Incubate 5 min. at 20 – 25 °C / 37 °C and read absorbance A1 of sample and std./cal. against reagent blank. Then add:			
Reagent 2	250 µL	250 µL	250 µL
Mix. Incubate 10 min. at 20 – 25 °C or 5 min. at 37 °C. Measure absorbance A2 of sample and std./cal. against reagent blank within 30 minutes. Pay attention to apply exactly the same incubation time for std./cal., blank and sample.			

ΔA = (A2 – A1) sample or std/cal.

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CALCULATION

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 *

Serum/Plasma:

	Females		Males	
	mg/dL	µmol/L	mg/dL	µmol/L
Adults [4]	2.6 – 6.0	155 – 357	3.5 – 7.2	208 – 428

	Females		Males	
Children [5]	mg/dL	µmol/L	mg/dL	µmol/L
0 – 30 days	1.0 – 4.6	59 – 271	1.2 – 3.9	71 – 230
31 – 365 days	1.1 – 5.4	65 - 319	1.2 – 5.6	71 - 330
1 – 3 years	1.8 – 5.0	106 – 295	2.1 – 5.6	124 – 330
4 – 6 years	2.0 – 5.1	118 - 301	1.8 – 5.5	106 - 325
7 – 9 years	1.8 – 5.5	106 – 325	1.8 – 5.4	106 – 319
10 – 12 years	2.5 – 5.9	148 - 348	2.2 – 5.8	130 - 342
13 – 15 years	2.2 – 6.4	130 – 378	3.1 – 7.0	183 – 413
16 – 18 years	2.4 – 6.6	142 – 389	2.1 – 7.6	124 – 448

Urine [1]

assuming normal diet	≤ 800 mg/24h (4.76 mmol/24h)
assuming low purine diet	≤ 600 mg/24h (3.57 mmol/24h)

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY / MEASURING RANGE

The assay has been developed to determine uric acid concentrations within a measuring range from 0.3 – 20 mg/dL (18 – 1190 µmol/L). If values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the results multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.3 mg/dL (18 µmol/L).

PRECISION (at 37°C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	3.09	0.05	1.74
Sample 2	6.39	0.03	0.52
Sample 3	10.9	0.04	0.41

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	3.26	0.04	1.31
Sample 2	6.44	0.04	0.56
Sample 3	10.7	0.04	0.39

SPECIFICITY/INTERFERENCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	20 mg/dL
Hemoglobin	400 mg/dL
Triglycerides	2000 mg/dL

For further information on interfering substances refer to Young DS [6].

METHOD COMPARISON

A comparison between Dialab Uric acid AOX (y) and a commercially available test (x) using 107 samples gave following results: y = 1.04 x + 0.09 mg/dL; r= 0.999.

CALIBRATION

The assay requires the use of a uric acid standard or calibrator. We recommend the Dialab **Uric Acid Standard** and the Dialab multi calibration serum **Diacal Auto**.
Calibrator values have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

QUALITY CONTROL

All controls with Uric Acid values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range) as well as the Dialab urine controls **Diacon Urine Level 1** (control urine normal) and **Level 2** (control urine abnormal).
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

Applications for automated systems are available upon 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. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

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