

#### Order information:

Catalogue number	Size
9551C	10 x 65 + 10 x 33 ml
9552C	4 x 65 + 4 x 33 ml

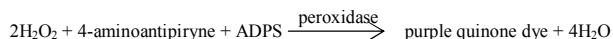
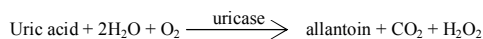
#### Reagent kit for quantitative in vitro determination of uric acid in serum and plasma.

#### Summary

In the human body uric acid is the end-product of purine metabolism. It is excreted by the kidney. Increases of uric acid in the serum plasma or urine can be due to the overproduction of purine containing molecules or to insufficient excretion. The concentration is increased in various renal diseases, with increased cell lysis in the presence of tumors, leukemia, toxemia of pregnancy. Prolonged elevation of the concentration leads to gout.

#### Method

Uricase/peroxidase method with ascorbate oxidase at 546 nm



#### Reagents

##### Composition and concentrations

##### Reagent 1

Pipes buffer, pH:7,00	50 mmol/l
4-aminoantipyrine	0,95 mmol/l
Peroxidase	≥4500 U/l
Ascorbate-oxidase	≥4800 U/l

##### Reagent 2

Ferrocyanide	50 μmol/l
ADPS	3,3 mmol/l
Uricase	≥350 U/l

#### Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!

Onboard stability after opening and the frequency of calibration is 72 days.

#### Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

#### Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

#### Preparation

The reagent is ready for use.

#### Sample

Serum, heparin, citrate or EDTA plasma. CSF

Stability in serum: 3-5 days at 4°C  
6 months at -20°C

Urine. Dilute it 1:9 before measurement. Do not refrigerate. Add NaOH to keep urine alkaline.

#### Expected values and reference range

Serum: 181 – 352 μmol/l  
Urine: 1,53 – 4,6 mmol/l/24h  
CSF: 5 – 55 μmol/l

It is recommended that each laboratory should assign its own normal range.

#### Assay procedure

Wavelength: 546 nm / 700 nm (primary/secondary)  
Optical path: 1 cm  
Temperature: 37°C  
Measurement: against reagent blank  
Reaction: endpoint, increasing

	blank	sample or standard
reagent 1	200 μl	200 μl
dist. water (diluent)	400 μl	400 μl
dist. water (blank)	45 μl	-
sample or standard	-	45 μl
Mix and incubate for 1 minute		
reagent 2	100 μl	100 μl
dist. water (diluent)	200 μl	200 μl
Mix and incubate for 5 minutes and read the absorbance against reagent blank.		

#### Calculation

Uric acid[μmol/l]=ΔA sample/ΔA standard × standard concentration[μmol/l]

#### Conversion factor

[μmol/l]=[mg/dl]×59,44

#### Calibration and quality control

S1: Distilled water

S2: Uric acid standard Cat.: 50511 or

Roche C.F.A.S. (Calibrator for automated system) or

Randox Calibration Serum Level I or

Randox Calibration Serum Level II

Calibration is recommended:

- after opening new reagent batch
- after system maintenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

#### Performance characteristics

##### Measuring range

The method is linear in the range 60 – 2250 μmol/l

##### Interferences

No significant interference was observed by bilirubin up to 1000 μmol/l bilirubin, triglycerides up to 11 mmol/l, hemoglobin up to 1 g/l and ascorbate up to 1,5 g/l. Significant interference: >10%.

##### Limit of detection

The limit of detection is 0,234 μmol/l

##### Precision

Repeatability n = 20	mean	SD	CV
	[μmol/l]	[μmol/l]	[%]
normal sample	351	2,03	0,58
pathological sample	574	4,31	0,75
Reproduceability n = 10	mean	SD	CV
	[μmol/l]	[μmol/l]	[%]
normal sample	349	1,98	0,57
pathological sample	572	4,58	0,8

#### Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 2400

number of samples: 151

range: 66 – 1138 μmol/l










correlation coefficient: 0,997

regression line equation: y = 1,022x – 0,676

(x= normal reagent, y= concentrated reagent)

#### For in vitro diagnostic use only!

#### The following symbols can be used on the labels

	In vitro diagnostic device
	Manufacturer
	CE-marking
	Temperature limitations
	Use by (year/month)
	Batch code
	Catalogue number
	This way up
	Biological risk

#### Literature

Trivedi R.C., Rebar R., Berka E., Strong L.: Clin. Chem., 1978, 24:1908  
Tietz Clinical Guide To Laboratory Tests, 4<sup>th</sup> edition, Elsevier, 2006