UA2

cobas®

Uric Acid ver.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03183807 190	Uric Acid ver.2 (400 tests)	System-ID 07 6615 1	**cobas c** 311, **cobas c** 501/502
10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 401	
10759350 360	Calibrator f.a.s. (12 x 3 mL, for USA)	Code 401	
12149435 122	Precinorm U plus (10 x 3 mL)	Code 300	
12149435 160	Precinorm U plus (10 x 3 mL, for USA)	Code 300	
12149443 122	Precipath U plus (10 x 3 mL)	Code 301	
12149443 160	Precipath U plus (10 x 3 mL, for USA)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311 analyzer:

UA2: ACN 700 (serum/plasma)

UA2-U: ACN 702 (urine)

For **cobas c** 501 analyzer:

UA2: ACN 700 (serum/plasma/urine)

For **cobas c** 502 analyzer:

UA2: ACN 8700 (serum/plasma)

UA2-U: ACN 8702 (urine)

Intended use

In vitro test for the quantitative determination of uric acid in human serum, plasma and urine on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5,6,7,8,9,10,11,12,13,14]

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The oxidation of uric acid provides the basis for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid.

A second approach, described by Praetorius and Poulsen, utilizes the enzyme uricase to oxidize uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV measurement of the consumption of uric acid or in combination with other enzymes to provide a colorimetric assay.

Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this precludes any ascorbic acid interference with the subsequent POD indicator reaction. Upon addition of the starter reagent, oxidation of uric acid by uricase begins.

The Roche assay described here is a slight modification of the colorimetric method described above. In this reaction, the peroxide reacts in the presence of peroxidase (POD), N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline (TOOS), and 4-aminophenazone to form a quinone-diimine dye. The intensity of the red color formed is proportional to the uric acid concentration and is determined photometrically.

Test principle

Enzymatic colorimetric test.

Uricase cleaves uric acid to form allantoin and hydrogen peroxide.

$$\text{Uric acid} + 2\ H_2O + O_2 \xrightarrow{\text{Uricase}} \text{allantoin} + CO_2 + H_2O_2$$

In the presence of peroxidase, 4-aminophenazone is oxidized by hydrogen peroxide to a quinone-diimine dye.

$$2\ H_2O_2 + H^+ + \text{TOOS}^a + \text{4-aminophenazone} \xrightarrow{\text{Peroxidase}} \text{quinone-diimine dye} + 4\ H_2O$$

The color intensity of the quinone-diimine formed is directly proportional to the uric acid concentration and is determined by measuring the increase in absorbance.

a) N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline

Reagents - working solutions

R1 Phosphate buffer: 0.05 mol/L, pH 7.8; TOOS: 7 mmol/L; fatty alcohol polyglycol ether: 4.8 %; ascorbate oxidase (EC 1.10.3.3; zucchini) ≥ 83.5 µkat/L (25 °C); stabilizers; preservative

R3 Phosphate buffer: 0.1 mol/L, pH 7.8; potassium hexacyanoferrate (II): 0.3 mmol/L; 4-aminophenazone ≥ 3 mmol/L; uricase (EC 1.7.3.3; Arthrobacter protophormiae) ≥ 83.4 µkat/L (25 °C); peroxidase (POD) (EC 1.11.1.7; horseradish) ≥ 50 µkat/L (25 °C); stabilizers; preservative

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Danger

H318 Causes serious eye damage.

Prevention:

P280	Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling

Ready for use

Storage and stability

UA2

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	8 weeks

NaCl Diluent 9 %

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and K_2-EDTA plasma.

EDTA plasma values are approximately 7 % lower than serum values.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Urine: Assay urinary uric acid as soon as possible. Do not refrigerate.

To prevent ureate precipitation in urine samples, add sodium hydroxide to keep urine alkaline (pH > 8.0). To achieve stated uric acid stability, add NaOH prior to sample collection. Urine samples are diluted 1 + 10 with distilled/deionized water or 0.9 % NaCl. This dilution is taken into account in the calculation of the results.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Stability in serum/plasma:[15]	7 days at 4-8 °C
	3 days at 20-25 °C
	6 months at -20 °C
Stability in urine[15] (upon NaOH addition):	4 days at 20-25 °C

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

See “Order information” section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 23-27		
Wavelength (sub/main)	700/546 nm		
Reaction direction	Increase		
Units	mg/dL (µmol/L, mg/L)		
Reagent pipetting		Diluent (H_2O)	
R1	72 µL	25 µL	
R3	14 µL	20 µL	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	12 µL	15 µL	135 µL
Increased	3 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 34-42		
Wavelength (sub/main)	700/546 nm		
Reaction direction	Increase		
Units	mg/dL (µmol/L, mg/L)		
Reagent pipetting		Diluent (H_2O)	
R1	72 µL	25 µL	
R3	14 µL	20 µL	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	12 µL	15 µL	135 µL
Increased	3 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 34-42		
Wavelength (sub/main)	700/546 nm		
Reaction direction	Increase		
Units	mg/dL (µmol/L, mg/L)		
Reagent pipetting		Diluent (H_2O)	
R1	72 µL	25 µL	
R3	14 µL	20 µL	
Sample volumes	*Sample*	*Sample dilution*	

		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	12 µL	15 µL	135 µL
Increased	6 µL	–	–

Application for urine

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 23-27
Wavelength (sub/main)	700/546 nm
Reaction direction	Increase
Units	mg/dL (µmol/L, mg/L)

Reagent pipetting		Diluent (H_2O)
R1	72 µL	25 µL
R3	14 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	15 µL	150 µL
Decreased	3 µL	6 µL	160 µL
Increased	3 µL	15 µL	150 µL

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 34-42
Wavelength (sub/main)	700/546 nm
Reaction direction	Increase
Units	mg/dL (µmol/L, mg/L)

Reagent pipetting		Diluent (H_2O)
R1	72 µL	25 µL
R3	14 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	15 µL	150 µL
Decreased	3 µL	6 µL	160 µL
Increased	3 µL	15 µL	150 µL

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 34-42
Wavelength (sub/main)	700/546 nm
Reaction direction	Increase
Units	mg/dL (µmol/L, mg/L)

Reagent pipetting		Diluent (H_2O)
R1	72 µL	25 µL
R3	14 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	15 µL	150 µL
Decreased	3 µL	6 µL	160 µL
Increased	6 µL	15 µL	150 µL

Calibration

Calibrators	S1: H_2O
	S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point calibration
	- after reagent lot change
	- as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against ID/MS.[16]

Quality control

Serum/plasma

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

Urine

Quantitative urine controls are recommended for routine quality control.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

cobas c systems automatically calculate the analyte concentration of each sample.

Conversion factors:	mg/dL x 59.5 = µmol/L
	mg/dL x 10 = mg/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at a uric acid concentration of 7 mg/dL (417 µmol/L) in serum/plasma and at a uric acid concentration of 92 mg/dL (5474 µmol/L) in urine. Recovery within ± 10 % for drug interference.

Serum/plasma

Icterus:[17] No significant interference up to an I index of 40 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 684 µmol/L or 40 mg/dL).

Hemolysis:[17] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[17] No significant interference up to an L index of 1500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 0.17 mmol/L (3 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[18,19] Exceptions: Calcium dobesilate causes artificially low uric acid results.

Uricase reacts specifically with uric acid. Other purine derivatives can inhibit the uric acid reaction.

Dicynone (Etamsylate) at therapeutic concentrations may lead to false-low results.[20]

Acetaminophen intoxications are frequently treated with N-Acetylcysteine. N-Acetylcysteine at the therapeutic concentration when used as an antidote and the Acetaminophen metabolite N-acetyl-p-benzoquinone imine (NAPQI) independently may cause falsely low results.

Venipuncture should be performed prior to the administration of Metamizole. Venipuncture immediately after or during the administration of Metamizole may lead to falsely low results.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[21]

Urine

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19] Exceptions: Calcium dobesilate, Levodopa and methyldopa can all cause artificially low uric acid results.

High homogentisic acid concentrations in urine samples lead to false results.

Dicynone (Etamsylate) at therapeutic concentrations may lead to false-low results.

Acetaminophen, Acetylcysteine and Metamizole are metabolized quickly. Therefore, interference from these substances is unlikely but cannot be excluded.

Urea: No significant interference from urea up to a concentration of 2100 mmol/L (12612 mg/dL).

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Serum/plasma

0.2-25.0 mg/dL (11.9-1487 µmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.5.

Urine

2.2-275 mg/dL (131-16362 µmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.5.

Lower limits of measurement

Lower detection limit of the test

Serum/plasma

0.2 mg/dL (11.9 µmol/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Urine

2.2 mg/dL (131 µmol/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Expected values

Serum/plasma[22]

Males:	3.4-7.0 mg/dL	(202.3-416.5 µmol/L)
Females:	2.4-5.7 mg/dL	(142.8-339.2 µmol/L)

Urine (reference range according to Krieg and Colombo)

1st morning urine[23]	37-92 mg/dL	(2200-5475 µmol/L)
24-hour urine[24]	200-1000 mg/day	(1200-5900 µmol/day)
corresponding to	13-67 mg/dL	(773-3986 µmol/L)

(calculated from a urine volume of 1.5 L/24 h)

Urine (reference range according to Tietz)[25]

Average diet		250-750 mg/24 hours
Low purine diet		
	Females	< 400 mg/24 hours
	Males	< 480 mg/24 hours
High purine diet		< 1000 mg/24 hours

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

Serum/plasma

Repeatability	*Mean*	*SD*	*CV*
	mg/dL (µmol/L)	*mg/dL (µmol/L)*	*%*
Precinorm U	4.54 (270)	0.04 (2)	0.9
Precipath U	11.1 (660)	0.1 (6)	0.7
Human serum 1	4.03 (240)	0.04 (2)	1.0
Human serum 2	7.23 (430)	0.06 (4)	0.8
Intermediate precision	*Mean*	*SD*	*CV*
	mg/dL (µmol/L)	*mg/dL (µmol/L)*	*%*
Precinorm U	4.47 (266)	0.07 (4)	1.5
Precipath U	11.1 (660)	0.2 (12)	1.6
Human serum 3	3.96 (236)	0.05 (3)	1.3
Human serum 4	7.17 (427)	0.10 (6)	1.3

Urine

Repeatability	*Mean*	*SD*	*CV*
	mg/dL (µmol/L)	*mg/dL (µmol/L)*	*%*
Control level 1	11.7 (696)	0.1 (6)	1.2
Control level 2	21.7 (1291)	0.3 (18)	1.3
Urine 1	28.8 (1714)	0.6 (36)	2.1
Urine 2	32.5 (1934)	0.5 (30)	1.5
Intermediate precision	*Mean*	*SD*	*CV*
	mg/dL (µmol/L)	*mg/dL (µmol/L)*	*%*
Control level 1	11.4 (678)	0.2 (12)	1.9
Control level 2	21.3 (1267)	0.3 (18)	1.6
Urine 3	29.3 (1743)	0.9 (54)	3.0
Urine 4	32.1 (1910)	0.8 (48)	2.3

Method comparison

Uric acid values for human serum, plasma and urine obtained on a **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Serum/plasma

Sample size (n) = 89

Passing/Bablok[26]	Linear regression
y = 0.993x + 0.158 mg/dL	y = 0.986x + 0.224 mg/dL
τ = 0.969	r = 1.000

The sample concentrations were between 2.70 and 23.4 mg/dL (161 and 1392 µmol/L).

Urine

Sample size (n) = 86

Passing/Bablok[26]	Linear regression
y = 0.997x + 0.456 mg/dL	y = 0.998x + 0.522 mg/dL
τ = 0.952	r = 0.999

The sample concentrations were between 6.35 and 269 mg/dL (378 and 16006 µmol/L).

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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