

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
Materials required (but not provided):		
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.

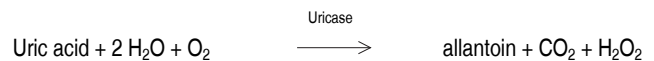
Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this 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-dimine dye. The intensity of the red color formed is proportional to the uric acid concentration and is determined photometrically.

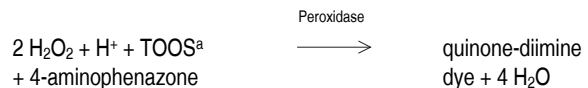
Test principle

Enzymatic colorimetric test.

Uricase cleaves uric acid to form allantoin and hydrogen peroxide.



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



The color intensity of the quinone-dimine 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

In vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

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:

**Warning**

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Prevention:

P264 Wash skin thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear eye protection/ face protection.

Response:

P337 + P313 If eye irritation persists: Get medical advice/attention.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

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 K₂-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
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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 ₂ O)	
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 ₂ O)	
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 ₂ O)	
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 ₂ O)	
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 ₂ O)	
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 ₂ O)	
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 ₂ O 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.

Dicyclic (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 methylodopa can all cause artificially low uric acid results.

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

Dicyclic (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 NaOH-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/plasma²²

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 urine²³ 37-92 mg/dL (2200-5475 µmol/L)

24-hour urine²⁴ 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
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Precipath U	11.1 (660)	0.1 (6)	0.7
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Human serum 1	4.03 (240)	0.04 (2)	1.0
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Human serum 2	7.23 (430)	0.06 (4)	0.8
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Intermediate precision	Mean	SD	CV
	mg/dL (µmol/L)	mg/dL (µmol/L)	%

Precinorm U	4.47 (266)	0.07 (4)	1.5
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Precipath U	11.1 (660)	0.2 (12)	1.6
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Human serum 3	3.96 (236)	0.05 (3)	1.3
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Human serum 4	7.17 (427)	0.10 (6)	1.3
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Urine

Repeatability	Mean	SD	CV
	mg/dL (µmol/L)	mg/dL (µmol/L)	%

Control level 1	11.7 (696)	0.1 (6)	1.2
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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
<i>Intermediate precision</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	<i>mg/dL (μmol/L)</i>	<i>mg/dL (μmol/L)</i>	<i>%</i>
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

The data obtained on **cobas c 501** analyzer(s) are representative for **cobas c 311** analyzer(s).

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
$y = 0.993x + 0.158 \text{ mg/dL}$	$y = 0.986x + 0.224 \text{ mg/dL}$
$\tau = 0.969$	$r = 1.000$

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
$y = 0.997x + 0.456 \text{ mg/dL}$	$y = 0.998x + 0.522 \text{ mg/dL}$
$\tau = 0.952$	$r = 0.999$

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

The data obtained on **cobas c 501** analyzer(s) are representative for **cobas c 311** analyzer(s).

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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.

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.

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):

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

UA2

Uric Acid ver.2



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