A1MG2

cobas®

Tina-quant α1-Microglobulin Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
06750052 190	Tina-quant α1-Microglobulin Gen.2 1 x 100 tests	System-ID 07 6791 3	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
03121305 122	C.f.a.s. PUC (5 x 1 mL)	Code 489	
03121313 122	Precinorm PUC (4 x 3 mL)	Code 240	
03121291 122	Precipath PUC (4 x 3 mL)	Code 241	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

A1MG2: ACN 614

For **cobas c** 502 analyzer:

A1MG2: ACN 8614

Intended use

Immunoturbidimetric test for the quantitative in vitro determination of α1-microglobulin in human urine on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5]

Alpha 1-microglobulin (α1-M) is a low molecular weight, pH stable glycoprotein. It has a molar mass of 30000 daltons and is synthesized by the hepatocytes and lymphocytes. It is almost entirely filtered in the glomeruli with approximately 99.8 % of the re-absorption and catabolism taking place in the proximal tubules.

Increased excretion of α1-microglobulin in tubular proteinuria is indicative of reduced tubular re-absorption under normal glomerular filtration conditions. This form of proteinuria is typical for chronic interstitial nephropathy and for acute and chronic tubular damage caused by endogenous and exogenous tubular toxins. In renal failure, the plasma levels of this microprotein increase from an early stage. The resultant protein hyperfiltration in the residual nephron causes increased renal excretion as re-absorption capacity is exceeded (overflow proteinuria). α1-Microglobulin can be used as a marker for the diagnosis of tubulo-interstitial nephropathy, for example, at an early stage or rule it out with a high degree of certainty; the detection limit is approximately 10-20 mg/L (333-666 nmol/L). Acute and chronic forms of tubular insufficiency (all forms of primary and secondary Fanconi syndrome), heavy metal intoxication, nephrotoxic side-effects of pharmaceuticals, and rejection reactions following kidney transplantation can also be excluded.

Test principle[1]

Immunoturbidimetric assay

Anti-α1-microglobulin antibodies react with antigen in the sample to form an antigen/antibody complex which, after agglutination, can be determined turbidimetrically.

Reagents - working solutions

R1 Acetate buffer: 35 mmol/L, pH 5.3; PEG; detergent; stabilizer; preservatives

R2 Polyclonal anti-human α1-microglobulin antibody (sheep), dependent on titer; acetate buffer: 50 mmol/L, pH 5.3; stabilizer; preservatives

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.

Reagent handling

Ready for use

Storage and stability

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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

Diluent NaCl 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.
Urine.

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.

Centrifuge samples containing precipitates before performing the assay.

Stability:[6]	7 days at 15-25 °C
	4 weeks at 2-8 °C
	6 months at (-15)-(-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 urine

cobas c 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 6-33	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mg/L (nmol/L)	
Reagent pipetting		Diluent (H_2O)
R1	125 µL	–
R2	25 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.5 µL	–	–

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Decreased	3.7 µL	–	–
Increased	7.5 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-35
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mg/L (nmol/L)
Reagent pipetting	Diluent (H_2O)
R1	125 µL –
R2	25 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.5 µL	–	–
Decreased	3.7 µL	–	–
Increased	7.5 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-35
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mg/L (nmol/L)
Reagent pipetting	Diluent (H_2O)
R1	125 µL –
R2	25 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.5 µL	–	–
Decreased	3.7 µL	–	–
Increased	15 µL	–	–

Calibration

Calibrators	S1: H_2O S2-S5: C.f.a.s. PUC Multiply the lot-specific C.f.a.s. PUC calibrator value by the factors below to determine the standard concentrations for the 5-point calibration curve: S2: 0.070 S4: 0.480 S3: 0.250 S5: 1.000
Calibration mode	RCM2
Calibration frequency	Full calibration • after reagent lot change • as required following quality control procedures

Traceability: This method has been standardized against an internal standard traceable to a nephelometric method.

Quality control

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

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

Roche/Hitachi **cobas c** systems automatically calculate the analyte concentration of each sample.

Conversion factor: mg/L x 33.3 = nmol/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at an α1-microglobulin concentration of 20 mg/L (666 nmol/L).

Icterus:[7] No significant interference up to a conjugated bilirubin concentration of 428 µmol/L or 25 mg/dL.

Hemolysis:[7] No significant interference up to a hemoglobin concentration of 155 µmol/L or 250 mg/dL.

High-dose hook effect: No false result occurs up to an α1-microglobulin concentration of 1000 mg/L.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[8]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[9]

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 Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/Multiclean/SCCS or 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 not required.

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

Limits and ranges

Measuring range

5.0-200 mg/L (167-6660 nmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Lower detection limit of the test

5.0 mg/L (167 nmol/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

2nd morning urine:[10]	< 14 mg/g creatinine or < 1.58 g/mol creatinine (< 52.6 mmol/mol creatinine)
24-hour urine:[11]	< 12 mg/L (< 400 nmol/L) < 20 mg/24 h (< 666 nmol/24 h)

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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:

Repeatability	*Mean*	*SD*	*CV*
	mg/L (nmol/L)	*mg/L (nmol/L)*	*%*
Precinorm PUC	29.8 (992)	0.5 (17)	1.7
Precipath PUC	98.5 (3280)	1.9 (63)	2.0
Human urine 1	18.4 (613)	0.7 (23)	3.6
Human urine 2	60.8 (2025)	1.5 (50)	2.5
Intermediate precision	*Mean*	*SD*	*CV*
	mg/L (nmol/L)	*mg/L (nmol/L)*	*%*
Precinorm PUC	30.3 (1009)	1.2 (40)	3.9
Precipath PUC	101 (3363)	3 (100)	3.2
Human urine 3	16.8 (559)	0.9 (30)	5.6
Human urine 4	58.7 (1955)	1.8 (60)	3.0

Method comparison

α1-Microglobulin values for human urine samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 225

Passing/Bablok[12]	Linear regression
y = 0.995x - 1.29 mg/L	y = 0.973x - 0.508 mg/L
τ = 0.942	r = 0.997

The sample concentrations were between 7.50 and 153 mg/L (250 and 5095 nmol/L).

References

1 Kurrle-Weittenhiller A, Engel W. AACC Poster Abstract. Clin Chem 1992;38:1090-1091.

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9 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.

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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.

CONTENT — Contents of kit

→ — Volume after reconstitution or mixing

CE

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