A1MG2

Tina-quant ⓐ α1-Microglobulin Gen.2

cobas®

• Indicates **cobas c** systems on which reagents can be used

Roche/Hitachi **cobas c** systems	
cobas c 311	**cobas c** 501/502
•	•

Order information

Tina-quant ⓐ α1-Microglobulin Gen.2		
2 x 75 tests	Cat. No. **03576116** 190	System-ID 07 6791 3
Calibrator f.a.s. Proteins, Urine/CSF (5 x 1 mL)	Cat. No. **03121305** 122	Code 489
Precinorm PUC (4 x 3 mL)	Cat. No. **03121313** 122	Code 240
Precipath PUC (4 x 3 mL)	Cat. No. **03121291** 122	Code 241
Diluent NaCl 9 % (50 mL)	Cat. No. **04489357** 190	System-ID 07 6869 3
cobas c pack MULTI	Cat. No. **04593138** 190	
Open/Close tool	On request	

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.

Various methods for assaying α1-microglobulin are available such as radial immunodiffusion, nephelometry and turbidimetry. The α1-microglobulin assay from Roche is based on the principle of immunological agglutination.

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; preservative

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

Precautions and warnings

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

Reagent preparation and cobas c pack MULTI assembly

Reagent handling
Ready for use.

*Labeling the **cobas c** pack MULTI*
Turn the barcode labeled side of a new **cobas c** pack MULTI toward you. Affix the supplied A1MG2 barcode label directly over the existing barcode label.

*Filling the **cobas c** pack MULTI*

1. Turn the **cobas c** pack MULTI toward you as shown above.
2. Position A of the **cobas c** pack is now in the center, position B on the left side, position C on the right side of the **cobas c** pack.
3. Unscrew the screw cap of the bottle in position A in the center of the **cobas c** pack MULTI using the Open/Close tool.
4. Pour the content of bottle 1 (20 mL) into the opened bottle of the **cobas c** pack (position A).
5. Close the bottle tightly using the Open/Close tool.
6. Unscrew the screw cap of the bottle in position C on the right side of the **cobas c** pack MULTI using the Open/Close tool.
7. Pour the content of bottle 2 (5 mL) into the opened bottle of the **cobas c** pack (position C).
8. Close the bottle tightly using the Open/Close tool.
9. Leave position B empty.

The A1MG2 **cobas c** pack is now ready for use.

Note

*Use only the **cobas c** pack MULTI. Always use a new **cobas c** pack MULTI when preparing fresh reagent. Never reuse accessories designed for single use, as this may result in reagent contamination and could affect test results. If the **cobas c** pack MULTI bottles are not filled correctly, this may result in faulty reagent pipetting and could cause erroneous results.*

Storage and stability

A1MG2	
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 %	
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On-board in use and refrigerated on the analyzer:	12 weeks

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Specimen collection and preparation

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	–	–
Decreased	3.7 µL	–	–
Increased	15 µL	–	–

cobas c 501/502 **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 - and as required following quality control procedures

Traceability: This method has been standardized against an internal standard traceable to a nephelometric method.[7]

Quality control

For quality control, use control materials as listed in the "Order information" section.
Other suitable control material can be used in addition.
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 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:[8] No significant interference up to a conjugated bilirubin concentration of 428 µmol/L (25 mg/dL).

Hemolysis:[8] No significant interference up to a hemoglobin concentration of 155 µmol/L (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.[9]

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

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 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

5-200 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 by the rerun function are automatically multiplied by a factor of 2.

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Lower limits of measurement

Lower detection limit of the test

5 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 three 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)

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. Repeatability* (n = 21), intermediate precision** (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

*Repeatability**	*Mean* *mg/L (nmol/L)*	*SD* *mg/L (nmol/L)*	*CV* *%*
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* *mg/L (nmol/L)*	*SD* *mg/L (nmol/L)*	*CV* *%*
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

* repeatability = within-run precision

** intermediate precision = total precision / between run precision / between day precision

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 same reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 225

Passing/Bablok[11]	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

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