04858689001V9.0

ALB2

Albumin Gen.2

CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM
Trương Thị Tố Hoa
Trưởng phòng Đăng ký, Đối ngoại và Quản lý Chất lượng

cobas®

Order information

REF	CONTENT		Analyzer(s) on which kit(s) can be used
04657357 190	Albumin Gen.2 (4 × 100 tests)		**cobas c** 111

Materials required (but not provided):

10759350 190	Calibrator f.a.s. (12 × 3 mL)	Code 401	
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	Code 401	
12149435 122	Precinorm U plus (10 × 3 mL)	Code 300	
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	Code 300	
12149443 122	Precipath U plus (10 × 3 mL)	Code 301	
12149443 160	Precipath U plus (10 × 3 mL, for USA)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	Code 392	
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	Code 392	
04774248 190	Cleaner	Code 947	

English

System information

ALB2: ACN 413

Intended use

In vitro test for the quantitative determination of albumin in human serum and plasma on the **cobas c** 111 system.

Summary[1,2]

Albumin is a carbohydrate-free protein, which constitutes 55-65 % of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e.g. bilirubin, calcium and long-chain fatty acids. Furthermore, albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL (380 µmol/L). Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Test principle[3]

Colorimetric assay
At a pH value of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromcresol green (BCG), an anionic dye, to form a blue-green complex.

$$\text{Albumin} + \text{BCG} \xrightarrow{\text{pH 4.1}} \text{Albumin-BCG complex}$$

The color intensity of the blue-green color is directly proportional to the albumin concentration in the sample and is measured photometrically.

Reagents - working solutions

R1 Citrate buffer: 95 mmol/L, pH 4.1; preservatives; stabilizers

SR Citrate buffer: 95 mmol/L, pH 4.1; Bromcresol green: 0.66 mmol/L; preservatives; stabilizers

Precautions and warnings

For 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.

Reagent handling

Ready for use

Storage and stability

Shelf life at 15-25 °C	See expiration date on reagent
On-board in use and refrigerated on the analyzer:	4 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: Heparin (Li-, Na-, NH_4^+-) or EDTA (K_2-, K_3-) plasma.

Separate serum or plasma from clot or cells within 1 hour and analyze immediately.

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.

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

Stability:[4]	2.5 months at 20-25 °C
	5 months at 4-8 °C
	4 months at –20 °C

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the

VV-183460

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.

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 111 **test definition**

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction direction	Increase
Wavelength A/B	583/512 nm
Calc. first/last	16/18
Unit	g/L
Reaction mode	R1-S-SR

Pipetting parameters

		Diluent (H_2O)
R1	100 µL	
Sample	2 µL	20 µL
SR	20 µL	10 µL
Total volume	152 µL	

Calibration

Calibrator	Calibrator f.a.s.
	Deionized water is used automatically by the instrument as the zero calibrator.
Calibration mode	Linear regression
Calibration interval	Each lot and 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 the reference preparation of the IRMM (Institute for Reference Materials and Measurements) BCR470/CRM470 (RPPHS - Reference Preparation for Proteins in Human Serum).[5]

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

The **cobas c** 111 analyzer automatically calculates the analyte concentration of each sample.

Conversion factors:

g/L × 0.1 = g/dL

g/dL × 10 = g/L

g/L × 15.2 = µmol/L[6]

Limitations - interference

Criterion: Recovery within ± 10 % of initial values at an albumin concentration of 35 g/L (532 µmol/L).

Icterus:[7] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[7] No significant interference up to an H index of 420 (approximate hemoglobin concentration: 261 µmol/L or 420 mg/dL).

Lipemia (Intralipid):[7] No significant interference up to an L index of 900. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[8,9]

γ-Globulin: No significant interference.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[10]

Colorimetric methods used for the determination of albumin may lead to falsely elevated test results in patients suffering from renal failure or insufficiency due to interference with other proteins. Immunoturbidimetric assays are less affected.

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 the **cobas c** 111 analyzer. For information about test combinations requiring special wash steps, please refer to the latest version of the carry over evasion list found with the CLEAN Method Sheet and the operator's manual for further instructions.

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

Limits and ranges

Measuring range

2.0-60 g/L (30.4-912 µmol/L or 0.2-6 g/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement

Lower detection limit of the test:
2 g/L (30.4 µmol/L or 0.2 g/dL)

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

Reference range study[11]			
Adults	39.7-49.4 g/L	603-751 µmol/L	3.97-4.94 g/dL
Consensus values[12]			
Adults	35-52 g/L	532-790 µmol/L	3.5-5.2 g/dL
Reference intervals according to Tietz[13]			
Newborns			
0-4 days	28-44 g/L	426-669 µmol/L	2.8-4.4 g/dL
Children			
4 days-14 years	38-54 g/L	578-821 µmol/L	3.8-5.4 g/dL
14-18 years	32-45 g/L	486-684 µmol/L	3.2-4.5 g/dL

Roche has not evaluated reference ranges in a pediatric population.

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 **cobas c** 111 analyzer 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, 10 days). The following results were obtained:

Repeatability	*Mean* *g/L (µmol/L, g/dL)*	*SD* *g/L (µmol/L, g/dL)*	*CV* *%*
Precinorm U	46.7 (710, 4.67)	0.2 (4, 0.02)	0.5
Precipath U	29.9 (455, 2.99)	0.2 (4, 0.02)	0.8
Human serum 1	30.1 (458, 3.01)	0.2 (3, 0.02)	0.6
Human serum 2	54.8 (833, 5.48)	0.3 (5, 0.03)	0.6

Intermediate precision	*Mean* *g/L (µmol/L, g/dL)*	*SD* *g/L (µmol/L, g/dL)*	*CV* *%*
Precinorm U	46.2 (702, 4.62)	0.9 (13, 0.09)	1.9
Precipath U	29.7 (451, 2.97)	0.4 (7, 0.04)	1.5
Human serum 3	29.8 (453, 2.98)	0.6 (8, 0.06)	1.8
Human serum 4	54.0 (821, 5.40)	0.7 (10, 0.07)	1.2

Method comparison

Albumin values for human serum and plasma samples obtained on a **cobas c** 111 analyzer (y) were compared with those determined using the corresponding reagent on a COBAS INTEGRA 400 analyzer (x).

Sample size (n) = 85

Passing/Bablok[14]	Linear regression
y = 1.017x + 0.165 g/L	y = 1.017x + 0.164 g/L
τ = 0.985	r = 1.00

The sample concentrations were between 2.58 and 59.3 g/L (39.2 and 901 µmol/L or 0.258-5.93 g/dL).

References

1 Grant GH, Silverman LM, Christenson RH. Amino acids and proteins. In: Tietz NW, ed. Fundamentals of Clinical Chemistry, 3rd edition Philadelphia, PA: WB Saunders 1987:328-330.

2 Marshall WJ, ed. Illustrated Textbook of Clinical Chemistry, 3rd ed. London: Gower Medical Publishing 1989;207-218.

3 Doumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromcresol green. Clin Chim Acta 1971;31:87-96.

4 Use of Anticoagulants in Diagnostic Laboratory Investigations. WHO Publication WHO/DIL/LAB/99.1 Rev. 2: Jan 2002.

5 Baudner S, Bienvenu J, Blirup-Jensen S, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins CRM470. Report EUR 15243 EN 1993;1-186.

6 Young DS. Effects of Drugs on Clinical Laboratory Tests. 2nd edition, AACC Press 1997.

7 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.

8 Breuer J. Report on the Symposium "Drug effects in Clinical Chemistry Methods". Eur J Clin Chem Clin Biochem 1996;34:385-386.

9 Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem 2001;38:376-385.

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

11 Junge W, Bossert-Reuther S, Klein G, et al. Reference Range Study for Serum Albumin using different methods. Clin Chem Lab Med (June 2007 Poster EUROMEDLAB) 2007;45 Suppl:194.

12 Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996;34:517-520.

13 Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed Philadelphia, PA: WB Saunders 2006;549.

14 Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem 1988 Nov;26(11):783-790.

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):

CONTENT	Contents of kit
REAGENT	Reagent
→	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.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336