

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
08056692190	Albumin Gen.2 (750 tests)	System-ID 2009 001 cobas c 303, cobas c 503
Materials required (but not provided):		
10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001

English

System information

ALB2-G: ACN 20090

Intended use

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

Summary^{1,2}

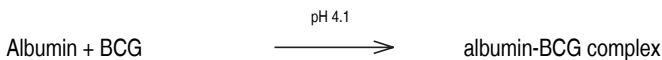
Albumin is a carbohydrate-free protein, which constitutes 55-65 % of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e.g. 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 principle³

Colorimetric assay

At a pH value of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromocresol green (BCG), an anionic dye, to form a blue-green 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
R3 Citrate buffer: 95 mmol/L, pH 4.1; bromocresol green: 0.66 mmol/L; preservatives, stabilizers

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

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.

Reagent handling

Ready for use

Storage and stability

Shelf life at 15-25 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 26 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

Do not use fluoride plasma.

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 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

Test definition

Reporting time 10 min

Wavelength (sub/main)	505/570 nm		
Reagent pipetting		Diluent (H ₂ O)	
R1	80 µL	–	
R3	16 µL	24 µL	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	1.6 µL	–	–
Decreased	1.6 µL	25 µL	50 µL
Increased	1.6 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Calibrators	S1: H ₂ O
	S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	Automatic full calibration
	- after reagent lot change
	Full calibration
	- after 4 weeks on-board
	- 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. It is recommended to perform quality control always after lot calibration and subsequently at least every 26 weeks.

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 in the unit g/L (µmol/L, g/dL).

Conversion factors:	g/L x 15.2 = µmol/L
	g/L x 0.1 = g/dL

Limitations - interference

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

Icterus:⁶ 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:⁶ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):⁶ No significant interference up to an L index of 550. 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.^{7,8}

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.

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 methods are less affected.

ACTION REQUIRED

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

Limits and ranges**Measuring range**

2-60 g/L (30.4-912 µmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank	= 2 g/L (30.4 µmol/L)
Limit of Detection	= 2 g/L (30.4 µmol/L)
Limit of Quantitation	= 3 g/L (45.6 µmol/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 20 %. It has been determined using low concentration albumin samples.

Expected values**g/L**

Reference range study¹⁰

Adults 39.7-49.4 g/L

Consensus values¹¹

Adults 35-52 g/L

Reference intervals according to Tietz¹²

Newborn

0-4 days 28-44 g/L

Children

4 days-14 years 38-54 g/L

14-18 years 32-45 g/L

µmol/L*

* calculated by unit conversion factor

Reference range study¹⁰

Adults 603-751 µmol/L

Consensus values¹¹

Adults 532-790 µmol/L

Reference intervals according to Tietz¹²

Newborn	
0-4 days	426-669 µmol/L
Children	
4 days-14 years	578-821 µmol/L
14-18 years	486-684 µmol/L

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. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c 503** analyzer.

Repeatability	Mean g/L	SD g/L	CV %
PCCC ^{1a)}	33.9	0.270	0.8
PCCC ^{2b)}	47.2	0.223	0.5
Human serum 1	52.3	0.252	0.5
Human serum 2	16.0	0.245	1.5
Human serum 3	32.7	0.280	0.9
Human serum 4	45.6	0.253	0.6
Human serum 5	49.5	0.258	0.5
Intermediate precision	Mean g/L	SD g/L	CV %
PCCC ^{1a)}	33.9	0.865	2.6
PCCC ^{2b)}	48.9	0.878	1.8
Human serum 1	52.3	0.656	1.3
Human serum 2	16.0	1.00	6.2
Human serum 3	32.7	0.878	2.7
Human serum 4	45.6	0.767	1.7
Human serum 5	51.4	0.696	1.4

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

The data obtained on **cobas c 503** analyzer(s) are representative for **cobas c 303** analyzer(s).

Method comparison

Albumin values for human serum and plasma samples obtained on a **cobas c 503** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 142

Passing/Bablok ¹³	Linear regression
$y = 0.987x + 1.75$ g/L	$y = 0.999x + 1.26$ g/L
$\tau = 0.851$	$r = 0.992$

The sample concentrations were between 2.60 and 57.7 g/L.

Albumin values for human serum and plasma samples obtained on a **cobas c 303** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 72

Passing/Bablok ¹³	Linear regression
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$$y = 1.004x + 0.719 \text{ g/L} \quad y = 1.001x + 0.852 \text{ g/L}$$

$$\tau = 0.922 \quad r = 0.998$$

The sample concentrations were between 2.84 and 57.2 g/L.

References




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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

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Additions, deletions or changes are indicated by a change bar in the margin.

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ALB2

Albumin Gen.2

CE 0123



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