ALBP

Albumin BCP

cobas®

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
05599261 190	Albumin BCP (225 tests)	System-ID 07 7471 5	Roche/Hitachi **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	
10557897 122	Precinorm Protein (3 x 1 mL)	Code 302	
10557897 160	Precinorm Protein (3 x 1 mL, for USA)	Code 302	
11333127 122	Precipath Protein (3 x 1 mL)	Code 303	
11333127 160	Precipath Protein (3 x 1 mL, for USA)	Code 303	
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** 311/501 analyzers:

ALBP: ACN 760

For **cobas c** 502 analyzer:

ALBP: ACN 8760

Intended use

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

Summary

Albumin constitutes about 60 % of the total serum protein in normal, healthy individuals. Unlike most other serum proteins, albumin serves a number of functions, which include transport of large insoluble organic anions (e.g., long chain fatty acids and bilirubin), binding of toxic heavy metal ions, transport of excess quantities of poorly soluble hormones (eg, cortisol, aldosterone, and thyroxine), maintenance of serum osmotic pressure, and provision of a reserve store of protein.

In 1953, Bracken and Klotz described the first useful dye-binding technique for measuring albumin in serum; albumin added to a solution of methyl orange buffered at pH 3.5 was found to bind and effectively remove some of the pink anion, resulting in a decrease in absorbance at 550 nm.[1] Other dyes successfully used to bind and quantitate serum albumin include 2-(4-hydroxy-azobenzene) benzoic acid (HABA), bromcresol green (Doumas procedure)[2], and bromcresol purple. Of these, bromcresol purple offers increased sensitivity. Although bromcresol purple is structurally similar to bromcresol green, its pH color change interval is higher (5.2-6.8 for BCP as opposed to 3.8-5.4 for BCG), thus reducing the number of weak electrostatic dye/protein interactions. The Albumin/BCP procedure eliminates many nonspecific reactions with other serum proteins as a result of the increased reagent pH. In addition, use of a sample blank removes background spectral interferences not completely removed by bichromatic analysis.

Test principle

Colorimetric test
At the reaction pH, BCP binds selectively with albumin, causing a color change that is measured photometrically.

Reagents - working solutions

R1 Buffer; preservatives; surfactants

R2 BCP: 526 µmol/L; buffer; preservatives; surfactant

R1 is in position B and R2 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.

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

ALB BCP

Shelf life at 15-25 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	4 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

If possible, the patient should be recumbent for at least 1 hour preceding specimen collection. Erect posture causes a redistribution of body fluids, increasing the serum albumin concentration.[3]

For specimen collection and preparation only use suitable tubes or collection containers.

ALBP

Albumin BCP

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and K_2-EDTA plasma.

Do not use citrate or oxalate.

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.

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:[4]	2.5 months at 20-25 °C
	5 months at 4-8 °C
	4 months at -20 °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 serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 6-26		
Wavelength (sub/main)	700/600 nm		
Reaction direction	Increase		
Units	g/L (µmol/L, g/dL)		
Reagent pipetting		Diluent (H_2O)	
R1	115 µL	–	
R2	70 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 10-28		
Wavelength (sub/main)	700/600 nm		
Reaction direction	Increase		
Units	g/L (µmol/L, g/dL)		
Reagent pipetting		Diluent (H_2O)	
R1	115 µL	–	
R2	70 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 10-28		
Wavelength (sub/main)	700/600 nm		
Reaction direction	Increase		
Units	g/L (µmol/L, g/dL)		
Reagent pipetting		Diluent (H_2O)	
R1	115 µL	–	
R2	70 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	135 µL
Increased	4 µL	–	–

Calibration

Calibrators	S1: H_2O
	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 the ERM DA470k reference preparation.

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 factors:	g/L x 15.2 = µmol/L
	µmol/L x 0.0658 = g/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:[5] 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:[5] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[5] No significant interference up to an L index of 1000. 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.[6,7]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[8]

The absorptivity of the dye-albumin complex differs for albumin obtained from different species. Materials used for the standardization and control of test results must be of human origin or must have albumin values assigned using an albumin BCP procedure.

Negative bias of approximately 10 % has been observed on samples from patients undergoing hemodialysis. Samples from patients with elevated serum creatinine levels, or undergoing treatment with peritoneal dialysis, were unaffected.[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 Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with 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 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

2-100 g/L (30.4-1520 µmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Lower limits of measurement

Lower detection limit of the test

2 g/L (30.4 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[10,11]

Adults		35-52 g/L	532-790 µmol/L	3.5-5.2 g/dL
Newborn	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

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Roche has not evaluated reference ranges in a pediatric population.

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 g/L (µmol/L)*	*SD g/L (µmol/L)*	*CV %*
Precinorm U	31.7 (482)	0.2 (3)	0.7
Precipath U	29.1 (442)	0.4 (6)	1.3
Human serum 1	36.6 (556)	0.3 (5)	0.8
Human serum 2	44.6 (678)	0.3 (5)	0.7

Intermediate precision	*Mean g/L (µmol/L)*	*SD g/L (µmol/L)*	*CV %*
Precinorm U	31.0 (471)	0.3 (5)	1.1
Precipath U	28.6 (435)	0.3 (5)	1.0
Human serum 1	36.2 (550)	0.4 (6)	1.1
Human serum 2	44.0 (669)	0.6 (9)	1.3

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

Method comparison

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

Sample size (n) = 75

Passing/Bablok[12]	Linear regression
y = 0.978x + 1.03 g/L	y = 0.977x + 1.11 g/L
τ = 0.967	r = 0.999

The sample concentrations were between 8.6 and 91.8 g/L (131 and 1395 µmol/L).

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

References

1 Bracken JS, Klotz IM. A simple method for the rapid determination of serum albumin. Am J Clin Pathol 1953;23(10):1055-1058.

2 Doumas BT, Biggs HG. Standard Methods of Clinical Chemistry. Cooper GA (ed). New York, NY: Academic Press, Inc 1972;7:175-188.

3 Winsten S. Standard Methods of Clinical Chemistry 1965;5:1.

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

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

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

7 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.

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

9 Beyer C, Boekhout M, van Iperen H. Bromcresol Purple Dye-binding and Immunoturbidimetry for Albumin Measurement in Plasma or Serum of Patients with Renal Failure. Clin Chem 1994;40(5):844-845.

10 Burtis CA, Ashwood ER, eds. Tietz Fundamentals of Clinical Chemistry, 5th ed. Pa: WB Saunders Co 2001;962.

11 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.

12 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
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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