ALBT2

cobas®

Tina-quant Albumin Gen.2 - Serum/Plasma Application

Specific proteins

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04469658 190	Tina-quant Albumin Gen.2 (100 tests)	System-ID 07 6743 3	COBAS INTEGRA 400 plus COBAS INTEGRA 800
03121305 122	C.f.a.s. PUC (5 × 1 mL)	System-ID 07 6755 7	
10557897 122	Precinorm Protein (3 × 1 mL)	System-ID 07 9105 9	
11333127 122	Precipath Protein (3 × 1 mL)	System-ID 07 9106 7	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7	
20756350 322	NaCl Diluent 9 % (6 × 22 mL)	System-ID 07 5635 0	

English

System information

Test ALBS2, test ID 0-172 on COBAS INTEGRA 400 plus systems;
test ID 0-243 on COBAS INTEGRA 800 systems

Intended use

In vitro test for the quantitative immunological determination of human albumin in serum, plasma, urine and cerebrospinal fluid.

The applications for urine and cerebrospinal fluid are described in the Tina-quant Albumin Gen.2 *Urine Application* and in the Tina-quant Albumin Gen.2 *CSF Application* method sheets.

Summary[1,2]

Albumin is a carbohydrate-free protein, representing 55-65 % of the total plasma proteins. It maintains the plasma colloidal osmotic pressure, transports and stores a wide variety of ligands, and serves as a source of endogenous amino acids. Albumin binds and solubilizes a variety of compounds amongst which are bilirubin, calcium, and long-chain fatty acids. Albumin also binds toxic heavy metal ions and many drugs, which is why a decrease in albumin in the blood can have important pharmacokinetic consequences.

Hyperalbuminemia is of little diagnostic significance except in dehydration.

Hypoalbuminemia is very common in many diseases and stems from various factors: impaired synthesis, either primary as a result of a liver disease or secondary due to diminished protein intake; increased catabolism because of tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria due to nephrotic syndrome; protein loss by way of feces (neoplastic disease). In severe hypoalbuminemia plasma albumin levels are below 25 g/L. The low plasma oncotic pressure allows water to move out of the blood capillaries into the tissues (edema). Albumin measurements also allow monitoring of the patient's response to nutritional support and are a useful test of liver function.

Test principle[3,4]

Immunoturbidimetric assay

Human albumin forms a precipitate with a specific antiserum which is determined turbidimetrically at 340 nm.

Reagents - working solutions

R1 TRIS[a)] buffer: 50 mmol/L, pH 8.0; PEG: 4.2 %; EDTA: 2 mmol/L; preservative

R2 Polyclonal anti-human albumin antibodies (sheep): dependent on titer; TRIS[a)] buffer: 100 mmol/L, pH 7.2; preservative

SR Reagent for antigen excess check
Albumin in diluted serum (human); phosphate buffer: 50 mmol/L, pH 7.0; preservative

a) TRIS = Tris(hydroxymethyl)-aminomethane

R1 is in position A, R2 is in position B, and SR is in position C.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[5,6]

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
COBAS INTEGRA 400 plus system	
On-board in use at 10-15 °C	12 weeks
COBAS INTEGRA 800 system	
On-board in use at 8 °C	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.
Serum
Plasma: Li-heparin, K_2- or K_3-EDTA

Collect serum and plasma using standard sampling tubes.

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.

Samples and controls are automatically prediluted 1:250 (1+249) with NaCl solution by the instrument.

Centrifuge samples containing precipitates before performing the assay.

Stability:[7]	10 weeks at 15-25 °C
	5 months at 2-8 °C
	4 months at (-15)-(-25) °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

NaCl Diluent 9 %, Cat. No. 20756350 322, system-ID 07 5635 0 for automatic postdilution and standard serial dilutions. NaCl Diluent 9 % is placed in its predefined rack position and is stable for 4 weeks on-board COBAS INTEGRA 400 plus/800 analyzers.

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.

Application for serum/plasma

COBAS INTEGRA 400 plus test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-R2-SR
Reaction direction	Increase
Reaction start with	R2
Wavelength A/B	340/659 nm
Calc. first/last	33/49
Antigen excess check	No
Predilution factor	250
Unit	g/L

Pipetting parameters

		Diluent (H_2O)
R1	100 µL	—
Sample	3 µL	10 µL
R2	20 µL	—
SR	6 µL	10 µL
Total volume	149 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1/R2-S
Reaction direction	Increase
Reaction start with	Sample
Wavelength A/B	340/659 nm
Calc. first/last	T_0/44
Antigen excess check	No
Predilution factor	250
Unit	g/L

Pipetting parameters

		Diluent (H_2O)
R1	100 µL	—
R2	20 µL	—
Sample	3 µL	10 µL
Total volume	133 µL	

Calibration

Calibrator	C.f.a.s. PUC
Calibration dilution ratio	Undiluted and 1:2, 1:4, 1:8, 1:16, 1:32 performed automatically by the instrument
Calibration mode	Logit/log 4
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Enter the assigned lot-specific albumin value of the undiluted calibrator, indicated in the package insert of C.f.a.s. PUC.

Traceability: This method has been standardized against an internal method traceable to the certified reference material in human serum of the IRMM (Institute for Reference Materials and Measurements) ERM-DA470k/IFCC.

Quality control

Reference range	Precinorm Protein or PreciControl ClinChem Multi 1
Pathological range	Precipath Protein or PreciControl ClinChem Multi 2
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

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

COBAS INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

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

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Serum/plasma

Icterus:[8] 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).[b)]

Hemolysis:[8] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).[b)]

Lipemia (Intralipid):[8] No significant interference up to an L index of 1500.[b)] 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.[9,10]

Rheumatoid factors < 1200 IU/mL do not interfere.[b)]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[11]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

b) measured at analyte concentrations up to approximately 3.5 g/dL

ACTION REQUIRED

Special wash programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the Method Manual, Introduction, Extra Wash Cycles 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

3-108 g/L (46-1642 µmol/L or 0.3-10.8 g/dL) (typical measuring range)

The upper and lower limits of the measuring range depend on the actual calibrator value.

Lower limits of measurement

Lower detection limit of the test:
3 g/L (46 µmol/L or 0.3 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 a zero sample (zero sample + 3 SD, repeatability, n = 21).

Expected values

Reference range study[12]

Adults	35.6-46.1 g/L (541-701 µmol/L or 3.56-4.61 g/dL)

Consensus values[13]

Adults	35-52 g/L (532-790 µmol/L or 3.5-5.2 g/dL)

Reference intervals according to Tietz[14]

Newborns 0-4 d	28-44 g/L (426-669 µmol/L or 2.8-4.4 g/dL)
Children 4 d-14 y	38-54 g/L (578-821 µmol/L or 3.8-5.4 g/dL)
Children 14-18 y	32-45 g/L (486-684 µmol/L or 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.

Specific performance data

Representative performance data on the COBAS INTEGRA 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 (1 aliquot per run, 1 run per day, 10 days). The following results were obtained:

Repeatability	*Mean g/L*	*SD g/L*	*CV %*
Serum low	25.5	0.5	1.8
Serum high	64.0	1.7	2.6
Precinorm Protein	40.2	1.0	2.5
Precipath Protein	61.4	1.8	2.9

Intermediate precision	*Mean g/L*	*SD g/L*	*CV %*
Serum low	25.1	0.3	1.4
Serum high	62.2	1.5	2.4
Precinorm Protein	39.1	1.1	2.8
Precipath Protein	63.1	1.8	2.9

Method comparison

Albumin values for human serum samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Tina-quant Albumin Gen.2 reagent (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

cobas c 501 analyzer	Sample size (n) = 80
Passing/Bablok[15]	Linear regression
y = 0.903x + 0.875 g/L	y = 0.875x + 2.336 g/L
r = 0.945	r = 0.995

The sample concentrations were between 6.9 and 97.7 g/L(105 and 1485 µmol/L or 0.69 and 9.77 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 1987:291-345.

2 Marshall WJ, ed. Plasma proteins. In: Illustrated textbook of clinical chemistry. London: Gower Medical Publishing 1988;207-218.

3 Gerbaut L.Immunoturbidimetry of albumin in serum, cerebrospinal fluid, and urine with a unique calibration curve. Clin Chem 1987;33:1260-1261.

4 Croci D, Nespolo A, Bosoni MA, et al. A simple immunoturbidimetric method for IgG and albumin quantitation in cerebrospinal fluid and serum. J Clin Chem Clin Biochem 1989;27:863-868.

5 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

6 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers form risk related to exposure to biological agents at work.

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

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

10 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.

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

12 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.

13 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.

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

15 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.

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

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche