ALBT2

cobas®

Tina-quant Albumin Gen.2

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	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
03121305 122	C.f.a.s. PUC (5 x 1 mL)	Code 489	
03121313 122	Precinorm PUC (4 x 3 mL)	Code 240	
03121291 122	Precipath PUC (4 x 3 mL)	Code 241	
10557897 122	Precinorm Protein (3 x 1 mL)	Code 302	
11333127 122	Precipath Protein (3 x 1 mL)	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	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

ALBU2: ACN 253 (Albumin in urine)

ALBS2: ACN 128 (Albumin in serum)

ALBC2: ACN 412 (Albumin in CSF)

For **cobas c** 502 analyzer:

ALBU2: ACN 8253 (Albumin in urine)

ALBS2: ACN 8128 (Albumin in serum)

ALBC2: ACN 8412 (Albumin in CSF)

Intended use

In vitro test for the quantitative determination of albumin in human urine, serum, plasma and CSF (albumin CSF/serum ratio) on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5,6,7,8,9,10]

Albumin is a non-glycosylated protein with a molecular weight of 66000 daltons. It is synthesized in liver parenchymal cells at a rate of 14 g/day. Quantitatively, albumin is normally the most important protein component (> 50 %) in plasma, CSF and urine. A small, but abnormal albumin excretion in urine is known as microalbuminuria. Causes of microalbuminuria can be glomerular (e.g. due to diabetic microangiopathy, hypertension, minor glomerular lesion), tubular (inhibition of reabsorption) or postrenal. Albumin is also a marker protein for various forms of proteinuria.

In selective glomerular proteinuria, 100-3000 mg albumin/g creatinine are excreted in the urine. Non-selective glomerular proteinuria is characterized by elevated excretion of high-molecular weight proteins (IgG more than 10 % of the albumin value). Prerenal proteinuria is recognized by a discrepancy between albumin and total protein (albumin accounting for less than 30 %, with concurrent elevation of total protein). Simultaneous elevation of albumin and microproteins is found in glomerulotubular proteinuria occurring due to overloading of tubular reabsorption in glomerulopathy (e.g. nephrotic syndrome), combined glomerular tubulointerstitial nephropathy or in renal failure following diabetic nephropathy or other causes (overflow proteinuria). Albumin has two main functions in plasma: maintaining the oncotic pressure (80 % due to albumin in plasma) and transport. It is the most important transport protein for substances having low water solubility (such as free fatty acids, bilirubin, metal ions, hormones and pharmaceuticals).

Depressed albumin levels are caused by hyperhydration, hepatocellular synthesis insufficiency, secretion disorders in the intravascular space, abnormal distribution between the intravascular and extravascular space, catabolism and loss of albumin, acute phase reactions and congenital analbuminemia.

Blood brain barrier disorders can be reliably quantified with the aid of the albumin CSF/serum ratio. Elevated albumin ratios are indicative of a blood brain barrier disorder.

By simultaneously determining IgG in CSF and serum while taking into account the individual albumin ratios, it is possible to differentiate between IgG originating from the blood and CNS-synthesized immunoglobulin. IgG predominates in multiple sclerosis, chronic HIV encephalitis, neurosyphilis and herpes simplex encephalitis.

A variety of methods, such as radial immunodiffusion, nephelometry and turbidimetry, are available for the determination of albumin.

Test principle[1]

Immunoturbidimetric assay.
Anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, are measured turbidimetrically.

Reagents - working solutions

R1 TRIS buffer: 50 mmol/L, pH 8.0; PEG: ≥ 4.2 %; EDTA: 2.0 mmol/L; preservative

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

R3 Reagent for antigen excess check.

Albumin in diluted serum (human); NaCl: 150 mmol/L; phosphate buffer: 50 mmol/L, pH 7.0; preservative

R1 is in position A, R2 is in position B and R3 is in position C.

Precautions and warnings

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

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 used assays approved by the FDA 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.[11,12]

Reagent handling

Ready for use

Storage and stability

ALBT2

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

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.
Urine
Serum
Plasma: Li-heparin and K_2-EDTA plasma
CSF

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.

CSF

Stability:[13]	up to 3 days	at 2-8 °C
	6 months	at (-15)-(-25) °C
	indefinitely	at (-60)-(-80) °C

Serum, plasma

Stability:[14]	10 weeks	at 15-25 °C
	5 months	at 2-8 °C
	4 months	at (-15)-(-25) °C

Urine

Spontaneous, 24-hour urine or 2nd morning urine.

Stability:[14]	7 days	at 15-25 °C
	1 month	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 / 6-15
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mg/L (µmol/L, mg/dL)

Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	–	–
Decreased	6.0 µL	15 µL	150 µL
Increased	6.0 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-34
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mg/L (µmol/L, mg/dL)

Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	–	–
Decreased	6.0 µL	15 µL	150 µL
Increased	6.0 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-34
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mg/L (µmol/L, mg/dL)

Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	–	–
Decreased	6.0 µL	15 µL	150 µL
Increased	12 µL	–	–

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End

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Reaction time / Assay points	10 / 6-18	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	1.5 µL	1.5 µL	180 µL
Decreased	1.5 µL	1.5 µL	180 µL
Increased	1.5 µL	1.5 µL	180 µL

cobas c 501 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.0 µL	2.1 µL	175 µL
Decreased	2.0 µL	1.7 µL	180 µL
Increased	2.0 µL	2.1 µL	175 µL

cobas c 502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.0 µL	2.1 µL	175 µL
Decreased	2.0 µL	1.7 µL	180 µL
Increased	4.0 µL	2.1 µL	175 µL

Application for CSF

cobas c 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 6-15	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mg/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	10 µL	110 µL
Decreased	3 µL	5 µL	180 µL
Increased	6.0 µL	10 µL	110 µL

cobas c 501 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mg/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	10 µL	110 µL
Decreased	3 µL	5 µL	180 µL
Increased	6.0 µL	10 µL	110 µL

cobas c 502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mg/L (µmol/L, mg/dL)	
Reagent pipetting		Diluent (H_2O)
R1	100 µL	–
R2	20 µL	–
R3	6 µL	20 µL

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Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6.0 µL	10 µL	110 µL
Decreased	3 µL	5 µL	180 µL
Increased	12.0 µL	10 µL	110 µL

Calibration

Calibrators S1: H_2O

S2-6: 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 6-point calibration curve:

cobas c 501/502	S2:	0.0138	S5:	0.467
	S3:	0.0228	S6:	1.00
	S4:	0.0455		
cobas c 311	S2:	0.0276	S5:	0.467
	S3:	0.0456	S6:	1.00
	S4:	0.0909		

Calibration mode RCM

Calibration frequency
- Full calibration
- after reagent lot change
- 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 certified reference material in human serum of the IRMM (Institute for Reference Material and Measurements) ERM-DA470k/IFCC.

Quality control

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

ALBU2: Precinorm PUC, Precipath PUC

ALBS2: Precinorm Protein, Precipath Protein, PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2

ALBC2: undiluted Precipath PUC

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.

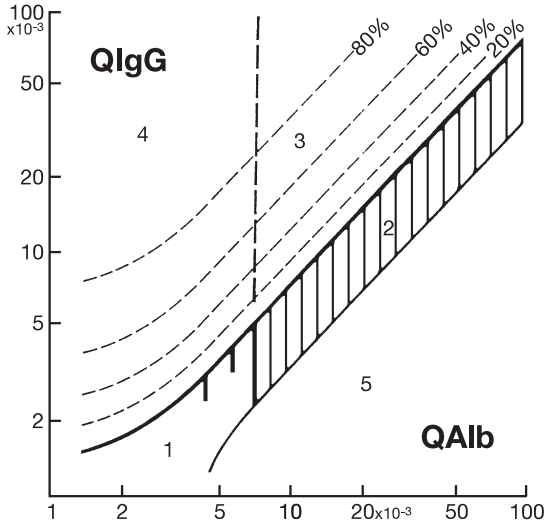
Follow the applicable government regulations and local guidelines for quality control.

Calculation

Roche/Hitachi **cobas c** systems automatically calculate the analyte concentration of each sample.

Conversion factors:
- g/L x 100 = mg/dL
- g/L x 15.2 = µmol/L
- mg/L x 0.1 = mg/dL
- mg/L x 0.0152 = µmol/L

The calculation employs a ratio diagram including hyperbolic functions as differential lines according to Reiber and Felgenhauer. Results from the determination of IgG and albumin in CSF and serum (IgG and albumin ratios)[15] are plotted.



1. Reference range. 2. Blood brain barrier functional disorder without local IgG synthesis. 3. Blood brain barrier functional disorder with concomitant IgG-synthesis in the CNS. 4. IgG synthesis in the CNS without blood brain barrier functional disorder. 5. As confirmed empirically, there are no values in this region (i.e. values here are due to errors introduced by blood sampling or analytical errors). Generally speaking, cases not associated with local IgG synthesis in the CNS lie below the bold line (hyperbolic function). The percentage values indicate what percentage of the total IgG in CSF (minimum) originates in the CNS relative to the statistically-defined 0 % differential lines.

Limitations - interference

Urine

Criterion: Recovery within ± 10 % of initial value at an albumin concentration of 20 mg/L (0.304 µmol/L, 2.0 mg/dL).

Icterus: No significant interference up to a conjugated bilirubin concentration of 855 µmol/L or 50 mg/dL.

Hemolysis: No significant interference up to a hemoglobin concentration of 248 µmol/L or 400 mg/dL.

No significant interference from acetone ≤ 60 mmol/L, ammonia chloride ≤ 0.11 mol/L, calcium ≤ 40 mmol/L, creatinine ≤ 0.18 mol/L, γ-globulin ≤ 500 mg/L, glucose ≤ 0.19 mol/L, phosphate ≤ 70 mmol/L, urea ≤ 0.8 mol/L, uric acid ≤ 5.95 mmol/L and urobilinogen ≤ 378 µmol/L.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16]

High dose hook-effect: Using the prozone check automatically performed by the analyzer, no false result without a flag was observed up to an albumin concentration of 40000 mg/L (608 µmol/L, 4000 mg/dL).

Serum/plasma

Criterion: Recovery within ± 10 % of initial value at an albumin concentration of 35 g/L (532 µmol/L, 3500 mg/dL).

Icterus:[17] 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:[17] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[17] No significant interference up to an L index of 1500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 1200 IU/mL.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[18,16]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[19]

CSF

Criterion: Recovery within ± 10 % of initial value at an albumin concentration of 240 mg/L (3.65 µmol/L, 24 mg/dL).

Hemolysis: No significant interference up to a hemoglobin concentration of 620 µmol/L or 1000 mg/dL.

High dose hook-effect: Using the prozone check automatically performed by the analyzer, no false result without a flag was observed up to an albumin concentration of 30000 mg/L (456 µmol/L, 3000 mg/dL).

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-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

Urine

cobas c 501/502: 3-400 mg/L (0.05-6.08 µmol/L, 0.3-40 mg/dL)

cobas c 311: 3-200 mg/L (0.05-3.04 µmol/L, 0.3-20 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:11 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 11.

Serum, plasma

cobas c 501/502: 3-101 g/L (46-1540 µmol/L, 300-10100 mg/dL)

cobas c 311: 3-96 g/L (46-1459 µmol/L, 300-9600 mg/dL)

cobas c 501/502: Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:1.27 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 1.27.

cobas c 311: Determine samples having higher concentrations by a manual predilution of 1:2. Calculate the final results by multiplying the measured value with a factor of 2.

CSF

cobas c 501/502: 36-4800 mg/L (0.55-73.0 µmol/L, 3.6-480 mg/dL)

cobas c 311: 36-2400 mg/L (0.55-36.5 µmol/L, 3.6-240 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:6.2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 6.2.

Lower limits of measurement

Limit of Blank and Limit of Detection

Urine

Limit of Blank	= 2 mg/L
Limit of Detection	= 3 mg/L

Serum, plasma

Limit of Blank	= 1 g/L
Limit of Detection	= 3 g/L

CSF

Limit of Blank	= 20 mg/L
Limit of Detection	= 36 mg/L

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A 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 %).

Values below the Limit of Detection (≤ 3 mg/L (urine); ≤ 3 g/L (serum, plasma); ≤ 36 mg/L (CSF)) will not be flagged by the instrument.

Expected values

Urine

2nd morning urine:[5]

Adults:	< 20 mg albumin/g creatinine or
	< 2.26 g (34.35 µmol) albumin/mol creatinine
Children (3-5 years):[20]	< 20 mg/L (0.304 µmol/L, 2 mg/dL) albumin
	< 37 mg albumin/g creatinine
24-hour urine:[21]	< 20 mg/L (0.304 µmol/L, 2 mg/dL)
	< 30 mg/24 h (0.456 µmol/24 h)

Serum/plasma

Consensus values:[22]

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

Reference intervals according to Tietz:[23]

Newborns 0-4 d:	2.8-4.4 g/dL (28-44 g/L; 426-669 µmol/L)
Children 4 d-14 yr:	3.8-5.4 g/dL (38-54 g/L; 578-821 µmol/L)

Albumin CSF/serum ratio ($Q_{ALB} \times 10^3$)

Adults:[6]	up to 15 years	5.0
	up to 40 years	6.5
	up to 60 years	8.0

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

Urine

Repeatability	*Mean*	*SD*	*CV*
	mg/L (µmol/L, mg/dL)	*mg/L (µmol/L, mg/dL)*	*%*
Precinorm PUC	30.7 (0.467, 3.07)	0.2 (0.003, 0.02)	0.8
Precipath PUC	108 (1.64, 10.8)	1 (0.01, 0.1)	0.7
Human urine 1	14.3 (0.217, 1.43)	0.2 (0.003, 0.02)	1.6
Human urine 2	252 (3.83, 25.2)	4 (0.06, 0.4)	1.6
Intermediate precision	*Mean*	*SD*	*CV*
	mg/L (µmol/L, mg/dL)	*mg/L (µmol/L, mg/dL)*	*%*
Precinorm PUC	31.2 (0.474, 3.12)	0.5 (0.008, 0.05)	1.7
Precipath PUC	105 (1.60, 10.5)	1 (0.02, 0.1)	1.2
Human urine 3	13.6 (0.207, 1.36)	0.4 (0.006, 0.04)	2.8
Human urine 4	60.6 (0.921, 6.06)	1.4 (0.021, 0.14)	2.3

Serum/plasma

Repeatability	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	39.9 (606, 3990)	0.5 (8, 50)	1.2
Precipath Protein	66.6 (1012, 6660)	1.4 (21, 140)	2.1
Human serum 1	27.6 (420, 2760)	0.3 (5, 40)	1.3
Human serum 2	62.5 (950, 6250)	0.9 (14, 90)	1.5
Intermediate precision	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	42.3 (643, 4230)	0.9 (14, 90)	2.0
Precipath Protein	70.5 (1072, 7050)	1.6 (24, 160)	2.2
Human serum 3	7.78 (118, 778)	0.74 (11, 74)	9.5
Human serum 4	36.2 (550, 3620)	0.7 (11, 70)	2.1

CSF

Repeatability	*Mean*	*SD*	*CV*
	mg/L (µmol/L, mg/dL)	*mg/L (µmol/L, mg/dL)*	*%*
Precipath PUC	99.2 (1.51, 9.92)	1.4 (0.02, 0.14)	1.4
Human CSF 1	174 (2.64, 17.4)	3 (0.05, 0.3)	1.7
Human CSF 2	383 (5.82, 38.3)	4 (0.06, 0.4)	1.0
C.f.a.s. PUC	454 (6.90, 45.4)	4 (0.06, 0.4)	0.8
Intermediate precision	*Mean*	*SD*	*CV*
	mg/L (µmol/L, mg/dL)	*mg/L (µmol/L, mg/dL)*	*%*
Precipath PUC	91.0 (1.38, 9.1)	2.9 (0.04, 0.29)	3.2
Control level 2	389 (5.91, 38.9)	7 (0.11, 0.7)	1.7
Human CSF 3	166 (2.53, 16.6)	4 (0.06, 0.4)	2.3
Human CSF 4	366 (5.56, 36.6)	5 (0.07, 0.5)	1.3

Method comparison

Urine

Albumin values for human urine samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 129

Passing/Bablok[24]	Linear regression
y = 1.021x - 2.91 mg/L	y = 1.026x - 3.66 mg/L
τ = 0.984	r = 0.999

The sample concentrations were between 4.60 and 386 mg/L (0.070 and 5.87 µmol/L, 0.460 and 38.6 mg/dL).

Serum/plasma

Albumin values for human serum and plasma samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined with a nephelometric albumin test (x).

Sample size (n) = 80

Passing/Bablok[24]	Linear regression
y = 0.950x + 0.195 g/L	y = 0.941x + 0.581 g/L
τ = 0.923	r = 0.993

The sample concentrations were between 5.70 and 107 g/L (86.6 and 1626 µmol/L, 570 and 10700 mg/dL).

CSF

Albumin values for human CSF samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined with a nephelometric albumin test (x).

Sample size (n) = 85

Passing/Bablok[24]	Linear regression
y = 1.000x - 8.75 mg/L	y = 0.991x + 0.301 mg/L
τ = 0.936	r = 0.992

The sample concentrations were between 115 and 2640 mg/L (1.75 and 40.1 µmol/L, 11.5 and 264 mg/dL).

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

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