08056722500V10.0

ALBT2

cobas®

Tina-quant Albumin Gen.2

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08056722190	08056722500	Tina-quant Albumin Gen.2 (500 tests)	System-ID 2006 001	**cobas c** 303, **cobas c** 503, **cobas c** 703
08056722214*	08056722500	Tina-quant Albumin Gen.2 (500 tests)	System-ID 2006 001	**cobas c** 303, **cobas c** 503, **cobas c** 703

Materials required (but not provided):

03121305122	C.f.a.s. PUC (5 x 1 mL)	Code 20489	
03121313122	Precinorm PUC (4 x 3 mL)	Code 20240	
03121291122	Precipath PUC (4 x 3 mL)	Code 20241	
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	
08059322190	Antigen Excess Reagent (START) (1000 tests)	System-ID 2008 001	

* Some kits shown may not be available in all countries.

English

System information

ALBT2: ACN 20060 (Albumin in serum/plasma)

ALBT2U: ACN 20061 (Albumin in urine)

ALBT2C: ACN 20062 (Albumin in CSF)

Specific applications for Reiber diagnostic*

ALBT2C: ACN 20062 (Albumin in CSF)

ALBT2R: ACN 20067 (Albumin in CSF, application in serum/plasma)

*not available in all countries

Intended use

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

Intended use of the specific applications for Reiber diagnostic*

*not available in all countries

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

Summary

Albumin measurement in human serum and plasma with this device can be used to aid in the assessment of hyperalbuminemia (seen only in case of dehydration) or hypoalbuminemia (seen in a multitude of clinical conditions such as inflammation, liver diseases, Inflammatory disease of the intestinal tract, tissue damage like burns, nephrotic disease or neoplastic disease).

Albumin measurements in urine can be used to aid in the assessment of glomerular, tubular, glomerulotubular and postrenal proteinuria. Microalbuminuria (slightly elevated albumin excretion in urine) is of particular importance in the early diagnosis of diabetic nephropathy.

Albumin measurement in human cerebrospinal fluid (CSF) can be used to aid in the assessment of increased permeability of the blood-brain barrier, indicative of a blood brain barrier disorder. Albumin measurements in CSF aid in the determination of intrathecal IgG production associated with demyelinating disorders.

Albumin is a carbohydrate-free protein, which constitutes 55-65 % of total plasma protein. It maintains plasma oncotic pressure, is involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids.[1]

In serum and plasma, hyperalbuminemia is of little diagnostic significance except in dehydration. Hypoalbuminemia instead is very common in many diseases and is caused by several 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 or increased gastrointestinal loss (inflammatory bowel disease such as Crohn's disease and ulcerative colitis); proteinuria due to nephrotic syndrome; negative protein and energy balance due to neoplastic disease(s).[2,3,4]

In severe cases of hypoalbuminemia, plasma albumin levels are below 25 g/L (380 µmol/L).[3] 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.[1,5,6]

The kidney normally prevents loss of serum albumin into the urine. However, albumin is still found in normal urine in small amounts. Because size (69 kD), anionic charge, and tubular reabsorption all play a role in albumin's renal handling, excretion increases with altered glomerular size and charge selectivity as well as with tubular impairment.[1]

In glomerular disease far higher amounts of albumin may be secreted than in tubular disease. Urinary albumin is therefore considered the most important marker for glomerular dysfunction.[7] Nearly 40 % of insulin dependent diabetes patients develop diabetic nephropathy which presents in its earliest stage with microalbuminuria. Microalbuminuria is defined as excretion above normal but lower than the detection limit of traditional dipstick tests, i.e. between 20 and 200 µg/min.[8]

About 80 % of the protein content in CSF originates from plasma as a result of ultrafiltration. Low molecular weight proteins predominate, albumin, prealbumin, and transferrin in particular. Albumin is neither synthesized nor metabolized within the central nervous system. Therefore, it is suitable to indicate increased permeability of the blood-brain barrier in case of pathological, traumatic, or inflammatory events.[1]

Impairment of the blood-brain barrier can be evaluated using the CSF/serum ratio (Q_{Alb}) which provides method independent values.[9,]

$Q_{Alb} = Albumin_{CSF}/Albumin_{serum} \times 1000$

Normal Q_{Alb} values are < 6.5 for the population between 15 and 40 years old, < 8.0 for the population between 41 and 60 and < 9.0 for the population over 60 years old. Q_{Alb} values greater than or equal to the reported thresholds indicate impairment of blood brain barrier.[9,10]

The measurement of albumin in CSF is of further interest in the determination of intrathecal IgG production which is associated with demyelinating disorders and inflammatory diseases of the central nervous system (CNS) (e.g. multiple sclerosis, neurosyphilis, acute inflammatory polyradiculoneuropathy, subacute sclerosing panencephalitis).[1]

An increased IgG concentration in CSF may be caused by increased permeability or increased intrathecal production. To determine the intrathecal IgG production, several formulae have been proposed and evaluated. The linear IgG index has been broadly used in the past because of its simplicity, but it has been replaced by non linear formulae, such as Reiber's hyperbolic formula that better reflects human neurophysiology.[11,12] Increase of the IgG index (Q_{IgG}) is a reflection of increased IgG intrathecal production. The most informative method indicating intrathecal synthesis of

IgG is the qualitative demonstration of 2 or more CSF-specific oligoclonal bands.[13,14]

Test principle

Immunoturbidimetric assay

Anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, are measured turbidimetrically.[15]

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

R1 is in position B and R2 is in position C.

Antigen Excess Reagent (Cat. No. 08059322190; for ACNs 20061 and 20062):

R3 Albumin in diluted serum (human); NaCl: 150 mmol/L; phosphate buffer: 50 mmol/L, pH 7.0; preservative

R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for laboratory 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.

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 use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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.[16,17]

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °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 K_2-EDTA plasma
Urine
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.

Serum, plasma

Stability:[18]	10 weeks at 15-25 °C
	5 months at 2-8 °C
	4 months at -20 °C (±5 °C)

Freeze only once.

Urine

Spontaneous, 24-hour urine or 2nd morning urine

Stability:[18]	7 days at 15-25 °C
	1 month at 2-8 °C
	6 months at -20 °C (±5 °C)

Freeze only once.

CSF

Stability:[19]	up to 3 days at 2-8 °C
	6 months at -20 °C (±5 °C)
	indefinitely at (-60)-(-80) °C

Freeze only once.

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)	700/340 nm	
Reagent pipetting		Diluent (H_2O)
R1	80 µL	–
R2	16 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	1.6 µL	1.5 µL	125 µL
Decreased	1.6 µL	1.0 µL	106 µL
Increased	1.6 µL	1.5 µL	125 µL

Application for urine

Test definition

Reporting time	10 min	
Wavelength (sub/main)	700/340 nm	
Reagent pipetting		Diluent (H_2O)
R1	80 µL	–
R2	16 µL	–
R3	5 µL	16 µL

Sample volumes	*Sample*	*Sample dilution*

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		Sample	*Diluent (NaCl)*
Normal	4.8 µL	–	–
Decreased	4.8 µL	10 µL	100 µL
Increased	4.8 µL	–	–

Application for CSF

Test definition

Reporting time	10 min	
Wavelength (sub/main)	700/340 nm	
Reagent pipetting		Diluent (H_2O)
R1	80 µL	–
R2	16 µL	–
R3	5 µL	16 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	4.8 µL	10 µL	110 µL
Decreased	2.4 µL	2.5 µL	90 µL
Increased	4.8 µL	10 µL	110 µL

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

Calibration

Application for serum/plasma (ACN 20060)

Calibrators	S1: H_2O S2-6: C.f.a.s. PUC
Calibration mode	Non-linear
Calibration frequency	Full calibration - after reagent lot change - every 12 weeks on-board - as required following quality control procedures

Application for urine (ACN 20061)

Calibrators	S1: H_2O S2-6: C.f.a.s. PUC
Calibration mode	Non-linear
Calibration frequency	Full calibration - after reagent lot change - every 12 weeks on-board - as required following quality control procedures

Application for CSF (ACN 20062)

Calibrators	S1: H_2O S2-6: C.f.a.s. PUC
Calibration mode	Non-linear
Calibration frequency	Full calibration - after reagent lot change - every 12 weeks on-board - as required following quality control procedures

Calibration of the specific applications for Reiber diagnostic

Application for serum/plasma (ACN 20067)

Transfer of calibration from CSF application (ACN 20062)

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 Materials 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.

Serum/plasma:	PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2
Urine:	Precinorm PUC, Precipath PUC
CSF	undiluted Precipath PUC

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

Serum /plasma

cobas c systems automatically calculate the analyte concentration of each sample in the unit g/L (µmol/L, mg/dL, g/dL).

Conversion factors:	g/L × 15.2 = µmol/L
	g/L × 100 = mg/dL
	g/L × 0.1 = g/dL

Urine and CSF

cobas c systems automatically calculate the analyte concentration of each sample in the unit mg/L (µmol/L, mg/dL, g/L).

Conversion factors:	mg/L × 0.0152 = µmol/L
	mg/L × 0.1 = mg/dL
	mg/L × 0.001 = g/L

Calculation of the specific applications for Reiber diagnostic

cobas c systems automatically calculate the analyte concentration of each sample in the unit mg/L (mg/dL, g/L).

Conversion factors:	mg/L × 0.1 = mg/dL
	mg/L × 0.001 = g/L

Reiber Quotient Graph

With the aid of commercially available software, Reiber Quotient Diagrams can be automatically generated.

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)[20] are plotted. (Example for IgG, CSF/serum quotient diagrams for IgA and IgM are also possible.)

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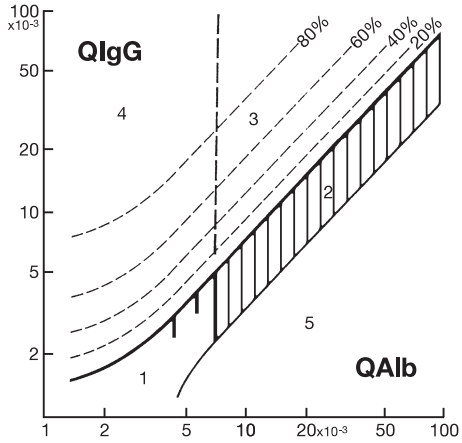

1. Reference range. 2. Blood brain barrier functional disorder without local IgG synthesis. 3. Blood brain barrier functional disorder with concomitant IgG synthesis in the CNS. 4. IgG synthesis in the CNS without blood brain barrier functional disorder. 5. As confirmed empirically, there are no values 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

Serum/plasma

Criterion: Recovery within ± 3.5 g/L of initial values of samples ≤ 35 g/L and within ± 10 % for samples > 35 g/L.

Icterus:[21] 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:[21] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[21] 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.[22,23]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[24]

Urine

Criterion: Recovery within ± 2 mg/L of initial values of samples ≤ 20 mg/L and within ± 10 % for samples > 20 mg/L.

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

Hemolysis: No significant interference up to an H index of 400 (approximate hemoglobin concentration: 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.[22]

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.

CSF

Criterion: Recovery within ± 24 mg/L of initial values of samples ≤ 240 mg/L and within ± 10 % for samples > 240 mg/L.

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

Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 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.

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 **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 further instructions, refer to the operator's manual.

Limits and ranges

Measuring range

Serum, plasma

3-101 g/L (46-1540 µmol/L)

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.

Urine

3-400 mg/L (0.05-6.08 µmol/L)

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.

CSF

36-4800 mg/L (0.55-73.0 µmol/L)

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, Limit of Detection and Limit of Quantitation

Serum, plasma

Limit of Blank	= 1 g/L (15 µmol/L)
Limit of Detection	= 3 g/L (46 µmol/L)
Limit of Quantitation	= 3 g/L (46 µmol/L)

Urine

Limit of Blank	= 2 mg/L (0.03 µmol/L)
Limit of Detection	= 3 mg/L (0.05 µmol/L)
Limit of Quantitation	= 12 mg/L (0.18 µmol/L)

CSF

Limit of Blank	= 20 mg/L (0.3 µmol/L)
Limit of Detection	= 36 mg/L (0.5 µmol/L)
Limit of Quantitation	= 50 mg/L (0.8 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 %).

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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

Serum/plasma

g/L

Consensus values:[25]

Adults	35-52 g/L

Reference intervals according to Tietz:[26]

Newborns (0-4 days):	28-44 g/L
Children (4 days-14 years):	38-54 g/L

µmol/L*

Consensus values:[25]

Adults	532-790 µmol/L

Reference intervals according to Tietz:[26]

Newborns (0-4 days):	426-669 µmol/L
Children (4 days-14 years):	578-821 µmol/L

*calculated by unit conversion factor

Urine

mg/L

2nd morning urine:[27]

Adults:	< 20 mg albumin/g creatinine or
	< 2.26 g albumin/mol creatinine
Children (3-5 years):[28]	< 20 mg/L albumin
	< 30 mg albumin/g creatinine
24-hour urine:[29]	< 20 mg/L
	< 30 mg/24 h

µmol/L

2nd morning urine:[27,*]

Adults:	< 0.304 µmol albumin/g creatinine
	< 34.35 µmol albumin/mol creatinine
Children (3-5 years):[28]	< 0.304 µmol/L albumin
	< 0.456 µmol albumin/g creatinine
24-hour urine:[29,*]	< 0.304 µmol/L
	< 0.456 µmol/24 h

*calculated by unit conversion factor

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

Adults[9]	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. 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.

Serum/plasma

Repeatability	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	30.9	0.290	0.9
PCCC2[b)]	44.2	0.371	0.8
Serum 1	5.10	0.0552	1.1
Serum 2	24.5	0.309	1.3
Serum 3	39.1	0.327	0.8
Serum 4	49.3	0.397	0.8
Serum 5	80.4	1.02	1.3

Intermediate precision	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	30.4	0.376	1.2
PCCC2[b)]	44.2	0.573	1.3
Serum 1	5.10	0.0595	1.2
Serum 2	24.5	0.385	1.6
Serum 3	39.1	0.458	1.2
Serum 4	49.3	0.467	0.9
Serum 5	80.4	1.07	1.3

a) PreciControl ClinChem Multi 1
b) PreciControl ClinChem Multi 2

Urine

Repeatability	*Mean mg/L*	*SD mg/L*	*CV %*
Precinorm PUC	30.4	0.187	0.6
Precipath PUC	119	0.748	0.6
Urine 1	15.3	0.145	0.9
Urine 2	17.9	0.194	1.1
Urine 3	55.7	0.442	0.8
Urine 4	180	1.27	0.7
Urine 5	349	3.85	1.1

Intermediate precision	*Mean mg/L*	*SD mg/L*	*CV %*
Precinorm PUC	29.4	0.346	1.2
Precipath PUC	119	1.11	0.9
Urine 1	15.3	0.329	2.1
Urine 2	17.9	1.03	5.7
Urine 3	56.2	0.926	1.6
Urine 4	183	1.79	1.0
Urine 5	354	7.58	2.1

CSF

Repeatability	*Mean mg/L*	*SD mg/L*	*CV %*
Precipath PUC	117	2.32	2.0
CSF 1	108	2.78	2.6

CSF 2	226	2.93	1.3
CSF 3	338	2.81	0.8
CSF 4	2256	18.1	0.8
CSF 5	3911	42.8	1.1

Intermediate precision	*Mean mg/L*	*SD mg/L*	*CV %*
Precipath PUC	121	2.78	2.3
CSF 1	108	3.28	3.0
CSF 2	232	5.95	2.6
CSF 3	340	6.07	1.8
CSF 4	2226	33.9	1.5
CSF 5	3911	96.7	2.5

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

Method comparison

Albumin values for human serum, plasma, urine and CSF 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).

Serum/plasma

Sample size (n) = 1306

Passing/Bablok[30]	Linear regression
y = 0.995x + 1.06 g/L	y = 0.995x + 1.18 g/L
τ = 0.912	r = 0.995

The sample concentrations were between 4.20 and 101 g/L.

Urine

Sample size (n) = 72

Passing/Bablok[30]	Linear regression
y = 0.984x + 0.314 mg/L	y = 0.980x + 0.362 mg/L
τ = 0.987	r = 0.999

The sample concentrations were between 3.51 and 375 mg/L.

CSF

Sample size (n) = 75

Passing/Bablok[30]	Linear regression
y = 0.970x + 11.3 mg/L	y = 0.937x + 25.0 mg/L
τ = 0.988	r = 1.000

The sample concentrations were between 43.4 and 4634 mg/L.

Albumin values for human serum, plasma, urine and CSF 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).

Serum/plasma

Sample size (n) = 74

Passing/Bablok[30]	Linear regression
y = 0.984x + 1.30 g/L	y = 0.963x + 1.97 g/L
τ = 0.950	r = 0.999

The sample concentrations were between 3.96 and 100 g/L.

Urine

Sample size (n) = 73

Passing/Bablok[30]	Linear regression
y = 1.025x + 0.0660 mg/L	y = 1.000x + 2.45 mg/L
τ = 0.990	r = 0.999

The sample concentrations were between 8.30 and 387 mg/L.

CSF

Sample size (n) = 75

Passing/Bablok[30]	Linear regression
y = 1.019x + 1.61 mg/L	y = 0.991x + 15.2 mg/L
τ = 0.986	r = 1.000

The sample concentrations were between 42.0 and 4545 mg/L.

Albumin values for human serum, plasma, urine and CSF samples obtained on a **cobas c** 703 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Serum/plasma

Sample size (n) = 75

Passing/Bablok[30]	Linear regression
y = 1.031x + 0.677 g/L	y = 1.010x + 1.42 g/L
τ = 0.960	r = 0.999

The sample concentrations were between 3.45 and 100 g/L.

Urine

Sample size (n) = 71

Passing/Bablok[30]	Linear regression
y = 0.980x - 0.129 mg/L	y = 0.955x + 0.627 mg/L
τ = 0.988	r = 1.000

The sample concentrations were between 3.52 and 388 mg/L.

CSF

Sample size (n) = 69

Passing/Bablok[30]	Linear regression
y = 1.015x + 0.546 mg/L	y = 0.991x + 10.8 mg/L
τ = 0.988	r = 1.000

The sample concentrations were between 91.4 and 4657 mg/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:

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

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