

Order information

REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
05167043190	5167043500	Tina-quant Albumin Gen.2 (750 tests)	System-ID 05 6743 3	cobas c 701/702

Materials required (but not provided):

03121305122	C.f.a.s. PUC (5 x 1 mL)	Code 489	
03121313122	Precinorm PUC (4 x 3 mL)	Code 240	
03121291122	Precipath PUC (4 x 3 mL)	Code 241	
10557897122	Precinorm Protein (3 x 1 mL)	Code 302	
11333127122	Precipath Protein (3 x 1 mL)	Code 303	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
05172152190	Diluent NaCl 9 % (119 mL)	System-ID 08 6869 3	
05168376190	Antigen Excess Reagent (START)* (11 mL)	System-ID 03 7454 5	

*The value encoded in the instrument settings is 6 mL to account for the dead volume of the bottles. This corresponds to 1000 tests.

English

System information

ALBS2: ACN 8128 (Albumin in serum)

ALBU2: ACN 8253 (Albumin in urine)

ALBC2: ACN 8412 (Albumin in CSF)

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.

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

$$Q_{Alb} = \text{Albumin}_{CSF} / \text{Albumin}_{serum} \times 1000$$

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 two 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

Tina-quant Albumin Gen.2:

ALBT2

Tina-quant Albumin Gen.2

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

R2 Polyclonal anti-human albumin antibodies (sheep):
(R3 Serum application) dependent on titer; TRIS buffer: 100 mmol/L, pH 7.2;
preservative

R1 is in position B and R2 (R3 Serum application) is in position C.
Antigen Excess Reagent (Cat. No. 05168376190; for ACN 8253 and ACN 8412):

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 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.

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 by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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:	4 weeks
On-board on the Reagent Manager:	24 hours

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

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 (-15)-(-25) °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 (-15)-(-25) °C

Freeze only once.

CSF

Stability: ¹⁹	up to 3 days	at 2-8 °C
	6 months	at (-15)-(-25) °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

cobas c 701/702 test definition

Assay type	2-Point End		
Reaction time / Assay points	10 / 18-26		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	g/L (μmol/L, mg/dL)		
Reagent pipetting	Diluent (H ₂ O)		
R1	100 μL	–	
R3	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 urine

cobas c 701/702 test definition

Assay type	2-Point End		
Reaction time / Assay points	10 / 6-14		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	mg/L (μmol/L, mg/dL)		
Reagent pipetting	Diluent (H ₂ O)		
R1	100 μL	–	
R2	20 μL	–	
R3 (Special Reagent)	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 CSF**cobas c 701/702 test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 6-14		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	mg/L (µmol/L, mg/dL)		
Reagent pipetting		Diluent (H ₂ O)	
R1	100 µL	–	–
R2	20 µL	–	–
R3 (Special Reagent)	6 µL	20 µL	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	6.0 µL	10.0 µL	110 µL
Decreased	3.0 µL	5.0 µL	180 µL
Increased	12.0 µL	10.0 µL	110 µL

Calibration

Calibrators	S1: H ₂ O 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 six-point calibration curve:		
	S2: 0.0138	S5: 0.467	
	S3: 0.0228	S6: 1.00	
	S4: 0.0455		
Calibration mode	RCM		
Calibration frequency	Full 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 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.

ALBS2:	Precinorm Protein, Precipath Protein, PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2
ALBU2:	Precinorm PUC, Precipath PUC
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.

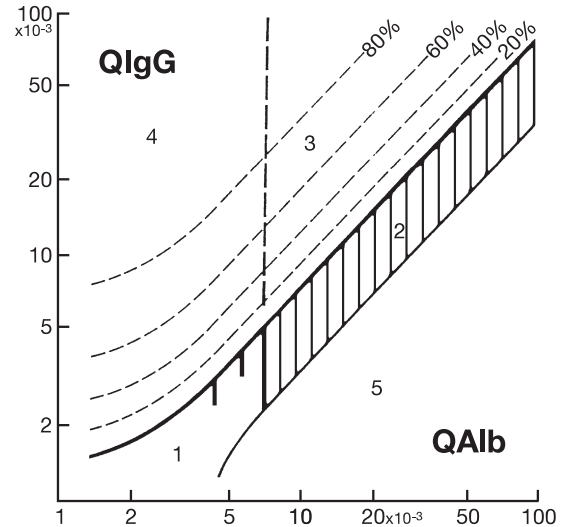
Follow the applicable government regulations and local guidelines for quality control.

Calculation

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)²⁰ 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**Serum/plasma**

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

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: 620 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 $\pm 10\%$ of initial value at an albumin concentration of 20 mg/L (0.30 µmol/L, 2 mg/dL).

Icterus:²¹ No significant interference up to a conjugated bilirubin concentration of 855 µmol/L or 50 mg/dL.

Hemolysis:²¹ 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 μ mol/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 (608 μ mol/L).

CSF

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

Hemolysis:²¹ No significant interference up to a hemoglobin concentration of 620 μ mol/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 μ mol/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 **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SmpCln1+2/SCCS Method Sheet and for further instructions refer to the operator's manual.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges**Measuring range***Serum, plasma*

3-101 g/L (46-1535 μ mol/L, 300-10100 mg/dL)

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 μ mol/L, 0.3-40 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.

CSF

36-4800 mg/L (0.55-73.0 μ mol/L, 3.6-480 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**Serum, plasma*

Limit of Blank = 1 g/L (15.2 μ mol/L, 100 mg/dL)

Limit of Detection = 3 g/L (45.6 μ mol/L, 300 mg/dL)

Urine

Limit of Blank = 2 mg/L (0.03 μ mol/L, 0.2 mg/dL)

Limit of Detection = 3 mg/L (0.05 μ mol/L, 0.3 mg/dL)

CSF

Limit of Blank = 20 mg/L (0.30 μ mol/L, 2.0 mg/dL)

Limit of Detection = 36 mg/L (0.55 μ mol/L, 3.6 mg/dL)

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 $n \geq 60$ 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*Serum/plasma*

Consensus values:²⁵

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

Reference intervals according to Tietz:²⁶

Newborns 0-4 d: 2.8-4.4 g/dL (28-44 g/L; 426-669 μ mol/L)

Children 4 d-14 yr: 3.8-5.4 g/dL (38-54 g/L; 578-821 μ mol/L)

Urine

2nd morning urine:²⁷

Adults: < 20 mg albumin/g creatinine or < 2.26 g (34.35 μ mol) albumin/mol creatinine

Children (3-5 years):²⁸ < 20 mg/L (0.304 μ mol/L, 2 mg/dL) albumin
 < 30 mg albumin/g creatinine

24-hour urine:²⁹ < 20 mg/L (0.304 μ mol/L, 2 mg/dL)
 < 30 mg/24 h (0.456 μ mol/24 h)

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

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. 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:

Serum/plasma

<i>Repeatability</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	<i>g/L</i> (μ mol/L, mg/dL)	<i>g/L</i> (μ mol/L, mg/dL)	<i>%</i>
Precinorm Protein	41.9 (637, 4190)	0.4 (6, 40)	1.0
Precipath Protein	71.0 (1079, 7100)	0.9 (14, 90)	1.2
Human serum A	31.6 (480, 3160)	0.4 (6, 40)	1.3
Human serum B	48.9 (743, 4890)	0.7(11, 70)	1.4
Human serum C	89.3 (1357, 8930)	2.3 (35, 230)	2.5

<i>Intermediate precision</i>	<i>Mean</i> g/L ($\mu\text{mol/L}$, mg/dL)	<i>SD</i> g/L ($\mu\text{mol/L}$, mg/dL)	<i>CV</i> %
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

Urine

<i>Repeatability</i>	<i>Mean</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>SD</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>CV</i> %
Precinorm PUC	30.4 (0.462, 3.04)	0.3 (0.005, 0.03)	0.9
Precipath PUC	95.5 (1.45, 9.55)	0.5 (0.01, 0.5)	0.5
Human urine A	18.4 (0.280, 1.84)	0.3 (0.005, 0.03)	1.9
Human urine B	170 (2.60, 17.0)	1 (0.02, 0.1)	0.7
Human urine C	352 (5.35, 35.2)	5 (0.08, 0.5)	1.4

<i>Intermediate precision</i>	<i>Mean</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>SD</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>CV</i> %
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

CSF

<i>Repeatability</i>	<i>Mean</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>SD</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>CV</i> %
Precipath PUC	78.7 (1.20, 7.87)	1.9 (0.03, 0.19)	2.4
Human CSF A	113 (1.72, 11.3)	2.3 (0.03, 0.23)	2.0
Human CSF B	496 (7.54, 49.6)	3.3 (0.05, 0.33)	0.7
Human CSF C	4327 (65.8, 433)	69.3 (1.0, 6.93)	1.6

<i>Intermediate precision</i>	<i>Mean</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>SD</i> mg/L ($\mu\text{mol/L}$, mg/dL)	<i>CV</i> %
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

Results for intermediate precision were obtained on the **cobas c 501** analyzer.

Method comparison

Albumin values for human serum, plasma, urine and CSF samples obtained on a **cobas c 701** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Serum/plasma

Sample size (n) = 103

Passing/Bablok ³⁰	Linear regression
$y = 1.011x + 0.395 \text{ g/L}$	$y = 1.021x + 0.286 \text{ g/L}$
$\tau = 0.966$	$r = 0.998$

The sample concentrations were between 1.20 and 86.3 g/L (18.2 and 1312 $\mu\text{mol/L}$, 120 and 8630 mg/dL).

Urine

Sample size (n) = 103

Passing/Bablok ³⁰	Linear regression
$y = 0.973x + 0.308 \text{ mg/L}$	$y = 0.969x + 0.851 \text{ mg/L}$
$\tau = 0.983$	$r = 0.999$

The sample concentrations were between 3.50 and 374 mg/L (0.053 and 5.68 $\mu\text{mol/L}$, 0.350 and 37.4 mg/dL).

CSF

Sample size (n) = 85

Passing/Bablok ³⁰	Linear regression
$y = 0.963x - 0.369 \text{ mg/L}$	$y = 0.935x + 9.31 \text{ mg/L}$
$\tau = 0.973$	$r = 0.999$

The sample concentrations were between 53.3 and 4701 mg/L (0.810 and 71.5 $\mu\text{mol/L}$, 5.33 and 470 mg/dL).

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ALBT2

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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):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number



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