

# ALBT2

## Tina-quant Albumin Gen.2

### Order information

REF	CONTENT	Analyzer(s) on which <b>cobas c</b> pack(s) can be used
04469658 190	Tina-quant Albumin Gen.2 100 tests	System-ID 07 6743 3 Roche/Hitachi <b>cobas c</b> 311, <b>cobas c</b> 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<sup>1,2,3,4,5,6,7,8,9,10</sup>

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<sup>1</sup>

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 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.<sup>11,12</sup>

#### 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 %

Shelf life at 2-8 °C:

See expiration date on **cobas c** pack label.

# ALBT2

## Tina-quant Albumin Gen.2



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<sub>2</sub>-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.

### CSF

Stability: <sup>13</sup>	up to 3 days	at 2-8 °C
	6 months	at (-15)-(-25) °C
	indefinitely	at (-60)-(-80) °C

### Serum, plasma

Stability: <sup>14</sup>	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: <sup>14</sup>	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 <sub>2</sub> O)	
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 <sub>2</sub> O)	
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 <sub>2</sub> O)	
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	
Reaction time / Assay points	10 / 6-18	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	g/L (μmol/L, mg/dL)	

# ALBT2

## Tina-quant Albumin Gen.2



Reagent pipetting	Diluent (H <sub>2</sub> O)
-------------------	----------------------------

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 <sub>2</sub> O)
-------------------	----------------------------

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 <sub>2</sub> O)
-------------------	----------------------------

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 <sub>2</sub> O)
-------------------	----------------------------

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 <sub>2</sub> O)
-------------------	----------------------------

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 <sub>2</sub> O)
-------------------	----------------------------

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	12.0 µL	10 µL	110 µL

# ALBT2

Tina-quant Albumin Gen.2

cobas®

## Calibration

Calibrators S1: H<sub>2</sub>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 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 Full calibration  
frequency - after reagent lot change  
- and as required following quality control procedures

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.

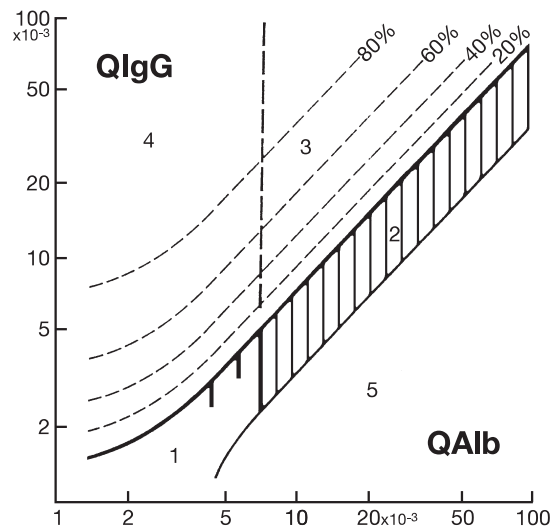
Follow the applicable government regulations and local guidelines for quality control.

## 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 =  $\mu$ mol/L  
mg/L x 0.1 = mg/dL  
mg/L x 0.0152 =  $\mu$ mol/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)<sup>15</sup> are plotted.



1. Reference range. 2. Blood brain barrier functional disorder without local IgG-synthesis in the CNS. 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  $\pm 10\%$  of initial value at an albumin concentration of 20 mg/L (0.30  $\mu$ mol/L, 2 mg/dL).

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

Hemolysis: No significant interference up to a hemoglobin concentration of 248  $\mu$ mol/L or 400 mg/dL.

No interference by acetone  $\leq 60$  mmol/L, ammonia chloride  $\leq 0.11$  mol/L, calcium  $\leq 40$  mmol/L, creatinine  $\leq 0.18$  mol/L,  $\gamma$ -globulin  $\leq 500$  mg/L, glucose  $\leq 0.19$  mol/L, urea  $\leq 0.8$  mol/L, uric acid  $\leq 5.95$  mmol/L and urobilinogen  $\leq 378$   $\mu$ mol/L.

Drugs: No interference was found at therapeutic concentrations using common drug panels.<sup>16</sup>

High dose hook-effect: Using the prozone check, no false result without a flag was observed up to an albumin concentration of 40000 mg/L (608  $\mu$ mol/L, 4000 mg/dL).

### Serum/plasma

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

Icterus:<sup>17</sup> No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026  $\mu$ mol/L or 60 mg/dL).

Hemolysis:<sup>17</sup> No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621  $\mu$ mol/L or 1000 mg/dL).

Lipemia (Intralipid):<sup>17</sup> 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  $\leq 1200$  IU/mL do not interfere.

Drugs: No interference was found at therapeutic concentrations using common drug panels.<sup>18,16</sup>

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.<sup>19</sup>

### CSF

Criterion: Recovery within  $\pm 10\%$  of initial value at an albumin concentration of 240 mg/L (3.65  $\mu$ mol/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, 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 NaOH/SMS/Multiclean/SCCS or the NaOH/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 not required.

**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 (LoB) and Limit of Detection (LoD)*

###### *Urine*

LoB = 2 mg/L

LoD = 3 mg/L

###### *Serum, plasma*

LoB = 1 g/L

LoD = 2 g/L

###### *CSF*

LoB = 20 mg/L

LoD = 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 95<sup>th</sup> 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 ( $\leq 3$  mg/L (urine);  $\leq 3$  g/L (serum, plasma);  $\leq 36$  mg/L (CSF)) will not be flagged by the instrument.

#### **Expected values**

##### *Urine*

###### 2nd morning urine:<sup>5</sup>

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

Children (3-5 years):<sup>20</sup> < 20 mg/L (0.304 µmol/L, 2 mg/dL) albumin  
< 37 mg albumin/g creatinine

24-hour urine:<sup>21</sup> < 20 mg/L (0.304 µmol/L, 2 mg/dL)  
< 30 mg/24 h (0.456 µmol/24 h)

##### *Serum/plasma*

###### Reference Range Study:<sup>22</sup>

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

###### Consensus values:<sup>23</sup>

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

###### Reference intervals according to Tietz:<sup>24</sup>

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)

Children 14-18 yr: 3.2-4.5 g/dL (32-45 g/L; 486-684 µmol/L)

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

Adults: <sup>6</sup>	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*

<i>Repeatability</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	<i>mg/L (µmol/L, mg/dL)</i>	<i>mg/L (µmol/L, mg/dL)</i>	<i>%</i>
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

<i>Intermediate precision</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	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*

<i>Repeatability</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	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

<i>Intermediate precision</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	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*

<i>Repeatability</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	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

<i>Intermediate precision</i>	<i>Mean</i>	<i>SD</i>	<i>CV</i>
	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 same reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 129

Passing/Bablok <sup>25</sup>	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 <sup>25</sup>	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 <sup>25</sup>	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**

- Multicenter study of Tina-quant Albumin in urine and β-N-acetylglucosaminidase (β-NAG) in urine. Workshop Munich, November 29-30, 1990 Wien Klin Wschr 1991;103 Suppl.189:1-64.
- Greiling H, Gressner AM, eds. Lehrbuch der Klinischen Chemie und Pathobiochemie, 3rd ed. Stuttgart/New York: Schattauer Verlag 1995:749-750.
- Rothschild MA, Oratz M, Schreiber SS. Serum albumin. Hepatology 1988;8(2):385-401.
- Schäufelberger H, Caduff F, Engler F, et al. Evaluation eines Streifentests (Micral-Test) zur semiquantitativen Erfassung der Mikroalbuminurie in der Praxis. Schweiz Med Wschr 1992;122:576-581.
- Hofmann W, Guder WG. A diagnostic program for quantitative analysis of proteinuria. J Clin Chem Clin Biochem 1989;27:589-600.
- Reiber H. External Quality Assessment in Clinical Neurochemistry: Survey of Analysis for Cerebrospinal Fluid (CSF) Proteins based on CSF/Serum Quotients. Clin Chem 1995;41:256-263.
- Reiber H, Felgenhauer K. Protein transfer of the blood cerebrospinal fluid barrier and the quantitation of the humoral immune response within the central nervous system. Clin Chim Acta 1987;163(3):319-328.
- Reiber H. Die diagnostische Bedeutung neuroimmunologischer Reaktionsmuster im Liquor cerebrospinalis. Lab med 1995;19:444-462.
- Zimmermann K, Marr U, Linke E. Liquordiagnostik, MTA 1996;11:258-260.
- Reiber H. Flow rate of cerebrospinal fluid (CSF) – a concept common to normal blood-CSF barrier function and to dysfunction in neurological diseases. J Neurol Sci 1994;122:189-203.
- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
- Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders Company 1995;24.
- Use of Anticoagulants in Diagnostic Laboratory Investigations. WHO Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
- Reiber H. The hyperbolic function: a mathematical solution of the protein flux/CSF flow model for blood-CSF barrier function. J Neurol Sci 1994;126:243-245.

- 16 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.
- 17 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. *Clin Chem* 1986;32:470-475.
- 18 Breuer J. Report on the Symposium "Drug effects in Clinical Chemistry Methods". *Eur J Clin Chem Clin Biochem* 1996;34:385-386.
- 19 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *Clin Chem Lab Med* 2007;45(9):1240-1243.
- 20 Hubbuch A. Results of a multicenter study of provisional reference ranges for albumin in urine of children and adults. Roche publication.
- 21 Hasslacher C. Diagnostische Überwachung und Therapie in den Stadien der diabetischen Nierenerkrankung. *Akt Endokr Stoffw* 1989;10:60-63.
- 22 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.
- 23 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.
- 24 Burtis CA, Ashwood ER, Bruns DE (eds.). *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 4th ed. St Louis, Missouri; Elsevier Saunders 2006;549.
- 25 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

COBAS, COBAS C, PRECINORM, PRECIPATH, PRECICONTROL and TINA-QUANT are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Significant additions or changes are indicated by a change bar in the margin.

© 2013, Roche Diagnostics



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

