

**Prealbumin****Order information**

REF	CONTENT	Analyzer(s) on which <b>cobas c</b> pack(s) can be used
<b>20764655</b> 322	Prealbumin 100 tests	System-ID 07 6465 5
<b>03555941</b> 190	Calibrator f.a.s. PAC ( 3 x 1 mL)	Code 589
<b>04567021</b> 190	Prealbumin/Ceruloplasmin Control Set*	
	Precinorm PC (3 x 1 mL)	Code 102
	Precipath PC (3 x 1 mL)	Code 103
<b>05117003</b> 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391
<b>05947626</b> 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391
<b>05947626</b> 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 391
<b>05117216</b> 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392
<b>05947774</b> 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392
<b>05947774</b> 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 392
<b>04489357</b> 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3

\*Not for use in the US; US customers should use a suitable commercially available control.

**English****System information**

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

**PREA:** ACN 710

For **cobas c** 502 analyzer:

**PREA:** ACN 8710

**Intended use**

In vitro test for the quantitative determination of prealbumin in human serum and plasma on Roche/Hitachi **cobas c** systems.

**Summary**<sup>1,2,3,4</sup>

Prealbumin is a tryptophan-rich protein which is synthesized in hepatocytes and has a molar mass of 55000 daltons. At a pH of 8.6, an electrophoretic band appears prior to albumin in a relative amount of < 2.5 % due to its greater rate of diffusion to the anode. Its function is to bind and transport low molecular weight retinol-binding proteins (molar mass of less than 21000 daltons), preventing their glomerular filtration. 30-50 % of circulating prealbumin is complexed by retinol-binding protein. Furthermore, it binds and transports thyroxine (T<sub>4</sub>), nevertheless its affinity to this hormone is less than that of thyroxine-binding globulin.

Prealbumin has a short half-life of approximately 2 days. Accordingly, decreased hepatocellular synthesis caused by acute liver damage or dietary protein deficiency elicits a very rapid decrease in serum prealbumin levels. According to the literature, prealbumin can act as a negative acute phase reactant, with its concentration decreasing rapidly during inflammatory processes.

Various methods are available for the determination of prealbumin, such as radial immunodiffusion (RID), nephelometry and turbidimetry.

**Test principle**

Immunoturbidimetric assay.

Human prealbumin forms a precipitate with a specific antiserum which is determined turbidimetrically.

**Reagents - working solutions****R1** Accelerator

Polyethylene glycol (PEG): 50 g/L; phosphate buffer; preservative

**R2** Anti-prealbumin T antiserum (rabbit) specific for human prealbumin: > 0.25 g/L; phosphate buffer; preservative

R1 is in position B and R2 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.

**Reagent handling**

Ready for use

**Storage and stability****PREA**

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and 8 weeks

refrigerated on the analyzer:

**Diluent NaCl 9 %**

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and 12 weeks

refrigerated on the analyzer:

**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<sub>2</sub>-EDTA plasma.

The use of Li-heparin plasma may lead to approximately 6 % lower values.

The use of K<sub>2</sub>-EDTA plasma may lead to approximately 5 % lower values.

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.

Stability:<sup>5</sup> 3 days 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 serum

### cobas c 311 test definition

Assay type	2-Point End		
Reaction time/Assay points	10 / 6-25		
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	90 μL	–	
R2	10 μL	20 μL	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	12 μL	15 μL	135 μL
Decreased	12 μL	5 μL	145 μL
Increased	12 μL	15 μL	135 μL

### cobas c 501 test definition

Assay type	2-Point End		
Reaction time/Assay points	10 / 10-36		
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	90 μL	–	
R2	10 μL	20 μL	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	12 μL	15 μL	135 μL
Decreased	12 μL	5 μL	145 μL
Increased	12 μL	15 μL	135 μL

### cobas c 502 test definition

Assay type	2-Point End		
Reaction time/Assay points	10 / 10-36		
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	90 μL	–	
R2	10 μL	20 μL	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	12 μL	15 μL	135 μL
Decreased	12 μL	5 μL	145 μL
Increased	12 μL	20 μL	80 μL

### Calibration

Calibrators	S1: H <sub>2</sub> O
	S2-S6: C.f.a.s. PAC

Multiply the lot-specific C.f.a.s. PAC calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:

S2: 0.200	S5: 1.75
S3: 0.400	S6: 2.75
S4: 0.800	

Calibration mode	RCM2
Calibration frequency	Full calibration
	• after reagent lot change
	• 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 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.

Drug concentrations of the controls have been verified by GC/MS.

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:	mg/dL x 0.01 = g/L	g/L x 18.2 = μmol/L
	g/L x 100 = mg/dL	mg/dL x 0.182 = μmol/L

### Limitations - interference

Criterion: Recovery within ± 10 % of the initial value at a prealbumin concentration of 0.4 g/L (7.28 μmol/L, 40 mg/dL).

Icterus:<sup>6</sup> 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:<sup>6</sup> No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 μmol/L or 1000 mg/dL).

Lipemia (Intralipid):<sup>6</sup> No significant interference up to an L index of 100. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors up to 400 IU/mL do not interfere.

High dose hook-effect: No false result occurs up to a prealbumin concentration of 2.5 g/L (45.5 μmol/L, 250 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.<sup>7, 8</sup>

Exception: Intralipid causes artificially high prealbumin results.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.<sup>9</sup>

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/Multiclean/SCCS or 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 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

0.03-0.8 g/L (0.55-14.6 µmol/L, 3-80 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

### Lower limits of measurement

#### Lower detection limit of the test

0.03 g/L (0.55 µmol/L, 3 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

### Expected values<sup>10,11</sup>

0.2-0.4 g/L (3.64-7.28 µmol/L or 20.0-40.0 mg/dL)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

### Specific performance data

Representative performance data on the 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:

Repeatability	Mean	SD	CV
	g/L	g/L	%
	(µmol/L, mg/dL)	(µmol/L, mg/dL)	
Precinorm Protein	0.201 (3.66, 20.1)	0.003 (0.05, 0.3)	1.2
Precipath Protein	0.207 (3.78, 20.7)	0.003 (0.05, 0.3)	1.4
Human serum 1	0.189 (3.44, 18.9)	0.004 (0.07, 0.4)	2.2
Human serum 2	0.216 (3.93, 21.6)	0.002 (0.04, 0.2)	1.1
Intermediate precision	Mean	SD	CV
	g/L	g/L	%
	(µmol/L, mg/dL)	(µmol/L, mg/dL)	
Precinorm Protein	0.198 (3.60, 19.8)	0.004 (0.07, 0.4)	1.9
Precipath Protein	0.203 (3.69, 20.3)	0.004 (0.07, 0.4)	1.9
Human serum 3	0.194 (3.53, 19.4)	0.004 (0.07, 0.4)	2.2
Human serum 4	0.252 (4.59, 25.2)	0.005 (0.09, 0.5)	2.1

### Method comparison

Prealbumin values for human serum 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) = 260

Passing/Bablok <sup>12</sup>	Linear regression
y = 0.989x + 0.016 g/L	y = 0.955x + 0.027 g/L
τ = 0.907	r = 0.989

The sample concentrations were between 0.019 and 0.743 g/L (0.346 and 13.5 µmol/L, 1.9 and 74.3 mg/dL).

### References

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- 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.
- Burtis CA, Ashwood ER, Bruns DE (eds.). Tietz Fundamentals of Clinical Chemistry, 6th ed., Saunders Elsevier 2008:297.
- 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

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