

REF	CONTENT	Analyzer(s) on which <b>cobas c</b> pack(s) can be used
03183688 122	Albumin Gen.2 (300 tests)	System-ID 07 6592 9 COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	System-ID 07 3718 6
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	System-ID 07 7999 7
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6
12149443 160	Precipath U plus (10 × 3 mL, for USA)	System-ID 07 8000 6
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	System-ID 07 7469 3
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	System-ID 07 7470 7

**English****System information**

Test ALB2, test ID 0-592

**Intended use**

In vitro test for the quantitative determination of the albumin concentration in human serum and plasma on COBAS INTEGRA systems.

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

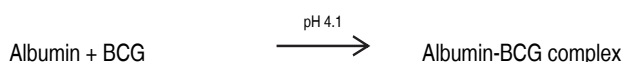
Albumin is a carbohydrate-free protein, which constitutes 55-65 % of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e.g. bilirubin, calcium and long-chain fatty acids. Furthermore albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL. Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

**Test principle<sup>3</sup>**

Colorimetric assay with endpoint method

At a pH of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromocresol green (BCG), an anionic dye, to form a blue-green complex.



The color intensity of the blue-green color is directly proportional to the albumin concentration in the sample. It is determined by monitoring the increase in absorbance at 583 nm.

**Reagents - working solutions**

**R1** Citrate buffer: 95 mmol/L, pH 4.1; preservatives; stabilizers

**SR** Citrate buffer: 95 mmol/L, pH 4.1; bromocresol green: 0.66 mmol/L; preservatives; stabilizers

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

**Precautions and warnings**

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

**Reagent handling**

Ready for use

**Storage and stability**

Shelf life at 15-25 °C See expiration date on **cobas c** pack label

COBAS INTEGRA 400 plus system

On-board in use at 10-15 °C 12 weeks

COBAS INTEGRA 800 system

On-board in use at 8 °C 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:

Serum

Plasma: Heparin (Li-, Na-, NH<sub>4</sub><sup>+</sup>) or EDTA (K<sub>2</sub>-, K<sub>3</sub>-) plasma.

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>4</sup> 2.5 months at 20-25 °C  
5 months at 4-8 °C  
4 months at -20 °C

**Materials provided**

See "Reagents – working solutions" section for reagents.

**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.

**Application for serum and plasma****COBAS INTEGRA 400 plus test definition**

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	583/512 nm
Calc. first/last	33/35
Unit	g/L

**Pipetting parameters**

		Diluent (H <sub>2</sub> O)
R1	100 µL	
Sample	2 µL	20 µL
SR	20 µL	10 µL
Total volume	152 µL	

**COBAS INTEGRA 800 test definition**

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	583/512 nm
Calc. first/last	44/46
Unit	g/L

**Pipetting parameters**

		Diluent (H <sub>2</sub> O)
R1	100 µL	
Sample	2 µL	20 µL
SR	20 µL	10 µL
Total volume	152 µL	

**Calibration**

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each cassette, every 4 weeks, and as required following quality control procedures

Traceability: This method has been standardized against the CRM 470 reference preparation.

**Quality control**

Reference range	Precinorm U, Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U, Precipath U plus or PreciControl ClinChem Multi 2
Control interval	24 hours recommended

Control sequence

User defined

Control after calibration

Recommended

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

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 INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factors:	g/L × 0.1 = g/dL
	g/dL × 10 = g/L
	g/L × 15.2 = µmol/L <sup>5</sup>

**Limitations - interference**

Criterion: Recovery within ± 10 % of initial value.

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 420 (approximate hemoglobin concentration: 261 µmol/L or 420 mg/dL).

Lipemia (Intralipid):<sup>6</sup> No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

γ-Globulin: No significant interference up to 3 g/dL.

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

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

Colorimetric methods used for the determination of albumin may lead to falsely elevated test results in patients suffering from renal failure or insufficiency due to interference with other proteins. Immunoturbidimetric assays are less affected.

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 INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

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

**Limits and ranges****Measuring range**

2-60 g/L (30.4-912 µmol/L or 0.2-6 g/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

**Lower limits of measurement**

Lower detection limit of the test:

2 g/L (30.4 µmol/L or 0.2 g/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 a zero sample (zero sample + 3 SD, repeatability, n = 21).

**Expected values**

Reference range study<sup>10</sup>

Adults	39.7-49.5 g/L	603-752 µmol/L	3.97-4.95 g/dL
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Consensus values<sup>11</sup>

Adults	35-52 g/L	532-790 µmol/L	3.5-5.2 g/dL
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Reference intervals according to Tietz<sup>12</sup>

## Newborns

0-4 days	28-44 g/L	426-669 µmol/L	2.8-4.4 g/dL
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## Children

4 days-14 years	38-54 g/L	578-821 µmol/L	3.8-5.4 g/dL
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14-18 years	32-45 g/L	486-684 µmol/L	3.2-4.5 g/dL
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Roche has not evaluated reference ranges in a pediatric population.

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 COBAS INTEGRA 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 (1 aliquot per run, 1 run per day, 21 days). The following results were obtained:

Repeatability	Level 1	Level 2
Mean	30.3 g/L (461 µmol/L or 3.03 g/dL)	31.4 g/L (477 µmol/L or 3.14 g/dL)
CV	1.9 %	1.9 %

Intermediate precision	Level 1	Level 2
Mean	30.3 g/L (461 µmol/L or 3.03 g/dL)	30.8 g/L (468 µmol/L or 3.08 g/dL)
CV	2.3 %	2.6 %

**Method comparison**

Albumin values for human serum and plasma samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Albumin Gen.2 reagent (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x) and to the previous reagent (ALB) on a COBAS INTEGRA 700 analyzer (x).

**Roche/Hitachi 917 analyzer**

Sample size (n) = 98

Passing/Bablok <sup>13</sup>	Linear regression
$y = 1.00x - 1.21 \text{ g/L}$	$y = 0.997x - 1.10 \text{ g/L}$
$r = 0.968$	$r = 0.999$
$SD(\text{md } 95) = 0.598$	$Sy.x = 0.335$

The sample concentrations were between 16.9 and 64.5 g/L (257-980 µmol/L and 1.69 to 6.45 g/dL).

**COBAS INTEGRA 700 analyzer**

Sample size (n) = 96

Passing/Bablok <sup>13</sup>	Linear regression
$y = 0.921x + 1.17 \text{ g/L}$	$y = 0.916x + 1.31 \text{ g/L}$
$r = 0.971$	$r = 0.998$
$SD(\text{md } 95) = 0.775$	$Sy.x = 0.415$

The sample concentrations were between 16.9 and 64.0 g/L (257-973 µmol/L and 1.69 to 6.40 g/dL).


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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

**Symbols**

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

<b>CONTENT</b>	Contents of kit
	Volume after reconstitution or mixing
<b>GTIN</b>	Global Trade Item Number

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# ALB2

Albumin Gen.2



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