Albumin Gen.2

Order information

COBAS INTEGRA Albumin Gen.2	300 Tests	Cat. No. **03183688** 122 System-ID 07 6592 9
Calibrator f.a.s.	12 × 3 mL	Cat. No. **10759350** 190
Calibrator f.a.s. (for USA)	12 × 3 mL	Cat. No. **10759350** 360 System-ID 07 3718 6
Precinorm U	20 × 5 mL	Cat. No. **10171743** 122 System-ID 07 7997 0
Precipath U	20 × 5 mL	Cat. No. **10171778** 122 System-ID 07 7998 9
Precinorm U plus	10 × 3 mL	Cat. No. **12149435** 122
Precinorm U plus (for USA)	10 × 3 mL	Cat. No. **12149435** 160 System-ID 07 7999 7
Precipath U plus	10 × 3 mL	Cat. No. **12149443** 122
Precipath U plus (for USA)	10 × 3 mL	Cat. No. **12149443** 160 System-ID 07 8000 6
PreciControl ClinChem Multi 1	20 × 5 mL	Cat. No. **05117003** 190
PreciControl ClinChem Multi 1 (for USA)	4 × 5 mL	Cat. No. **05947626** 160 System-ID 07 7469 3
PreciControl ClinChem Multi 2	20 × 5 mL	Cat. No. **05117216** 190
PreciControl ClinChem Multi 2 (for USA)	4 × 5 mL	Cat. No. **05947774** 160 System-ID 07 7470 7

● Indicates analyzer(s) on which **cobas c** pack can be used

COBAS INTEGRA 400/400 plus	COBAS INTEGRA 800
●	●

System information
COBAS INTEGRA Albumin Gen.2 (ALB2)
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[1,2]
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[3]
Colorimetric assay with endpoint method
At a pH of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromcresol green (BCG), an anionic dye, to form a blue-green complex.

$$\text{Albumin + BCG} \xrightarrow{pH\ 4.1} \text{Albumin-BCG complex}$$

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

Components	Concentrations			
	R1	R2 = SR	Test	
Citrate	95	95	75	mmol/L
Bromcresol green		0.66	0.087	mmol/L
pH	4.1	4.1		

The reagent contains a nonreactive stabilizer and a surfactant.

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

Reagent handling
Ready for use.

Storage and stability

Shelf life at 15 to 25 °C	See expiration date on **cobas c** pack label
COBAS INTEGRA 400/400 plus systems	
On-board in use at 10 to 15 °C	12 weeks
COBAS INTEGRA 800 systems	
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_4^+-) or EDTA (K_2-, K_3-) 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.

Stability:[4] 2.5 months at 15-25 °C
5 months at 2-8 °C
4 months at -20 °C

Centrifuge samples containing precipitates before performing the assay.

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 400/400 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_2O)
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_2O)
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 or Precinorm U plus
Pathological range	Precipath U or Precipath U plus
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. Other suitable control material can be used in addition.
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 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 400/400 plus/800 analyzers).

Conversion factors: g/L × 0.1 = g/dL
g/dL × 10 = g/L
g/L × 15.2 = µmol/L[5]

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Serum, plasma

Icterus[6]	No significant interference for both conjugated and unconjugated bilirubin.
Hemolysis[6]	No significant interference up to an H index of 420 (approximate hemoglobin concentration: 420 mg/dL or 261 µmol/L).
Lipemia[6]	No significant interference.
γ-Globulin	No significant interference.
Drugs	No interference was found at therapeutic concentrations using common drug panels.[7,8]
Other	In very rare cases gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.

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 Method Manual, Introduction, Extra Wash Cycles for further instructions. **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 by 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 detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying three standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 21).

Expected values

Reference range study[9]

Adults	39.7-49.5 g/L (603-752 µmol/L or 3.97-4.95 g/dL)

Consensus values[10]

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

Reference intervals according to Tietz[11]

Newborns	0-4 d	28-44 g/L (426-669 µmol/L or 2.8-4.4 g/dL)
Children	4 d-14 y	38-54 g/L (578-821 µmol/L or 3.8-5.4 g/dL)
Children	14-18 y	32-45 g/L (486-684 µmol/L or 3.2-4.5 g/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 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[a] (n = 21) and intermediate precision[b] (1 aliquot per run, 1 run per day, 21 days).
The following results were obtained:

	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 repeatability[a]	1.9 %	1.9 %
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 intermediate precision[b]	2.3 %	2.6 %

a) repeatability = within-run precision
b) intermediate precision = total precision / between-run precision / between-day precision

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 to those determined with the the same 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[12]	Linear regression
$y = 1.00x - 1.21$ g/L	$y = 0.997x - 1.10$ g/L
$\tau = 0.968$	r = 0.999
SD (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[12]	Linear regression
$y = 0.921x + 1.17$ g/L	$y = 0.916x + 1.31$ g/L
$\tau = 0.971$	r = 0.998
SD (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).

References

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