BioMajesty®

Albumin FS*

Order Information

Cat. No.	Kit size
1 0220 99 10 960	980 (4 x 245)
1 0220 99 10 967	1500 (6 x 250)

Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Albumin is synthesized and released by the liver and represents approximately 60% of the total plasma proteins. It is the main determinant of the plasmatic osmotic pressure and the most important factor for fluid distribution between body compartments [1,2]. Furthermore, albumin binds and transports a variety of substances like metal ions, bilirubin, free fatty acids, phospholipids, amino acids, hormones (steroid hormones, thyroid hormones) and drugs [2,3]. The healthy liver synthesizes 120 – 200 mg/kg body weight of albumin per day. Interestingly, the albumin synthesis rate fluctuates depending on the specific pathophysiological condition. For instance, in decompensated liver cirrhosis the synthesis may decrease to 30 – 50 % compared to healthy values while acute nephrosis leads to a strong increase in the synthesis rate of albumin [4]. On the other hand, hypoalbuminemia is prevalent in numerous diseases and results from different factors. Impaired hepatic synthesis and release (liver diseases, systemic inflammation), variations in the distribution of body fluids (edema, ascites), increased catabolism due to tissue damage (severe burns), protein-losing enteropathy (gastroenteritis) or increased degradation or loss through the urinary tract (nephrotic syndrome) lead to decreased plasmatic albumin concentrations [1,3-5,8]. Furthermore, hypoalbuminemia is common in heart failure and associated with further cardiac diseases, such as myocardial fibrosis [6,7]. A lowered serum concentration of albumin also serves as a rough indicator for the general health status of an individual, especially for elderly, chronically ill and hospitalized patients [3]. Additionally, decreased plasmatic albumin is a strong prognostic parameter in e.g. liver cirrhosis and heart failure patients [5-7].

Method

Photometric test using bromocresol green

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue.

Reagent

Components and Concentrations

Citrate buffer	pH 4.2	30 mmol/L
Bromocresol green		0.26 mmol/L

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [9].
2. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
3. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
4. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [10]:

2.5 months	at	20 – 25°C
5 months	at	4 – 8°C
4 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference material ERM-DA470. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 6 g/dL, linearity is given within ± 5%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.1 g/dL
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/dL]
Ascorbic acid	30 mg/dL	4.33
Bilirubin (conjugated)	60 mg/dL	4.31
Bilirubin (unconjugated)	60 mg/dL	4.31
Hemolysis	300 mg/dL	4.29
Lipemia (triglycerides)	1200 mg/dL	4.32

For further information on interfering substances, refer to the literature [11-13].

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Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.26	4.03	4.48
CV [%]	1.00	0.632	1.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.96	4.53	2.46
CV [%]	0.729	0.984	1.42

Method comparison (n=100)	
Test x	Competitor Albumin (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Albumin FS (BioMajesty® JCA-BM6010/C)
Slope	0.987
Intercept	0.168 g/dL
Coefficient of correlation	0.997

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
Albumin [g/dL] x 144.9 = Albumin [µmol/L]

Reference Range [3]

	[g/dL]	[µmol/L]
Adults		
≤ 60 years	3.5 – 5.3	507 – 753
> 60 years	3.4 – 4.8	492 – 695
> 70 years	3.3 – 4.7	478 – 681
> 80 years	3.1 – 4.5	449 – 652
> 90 years	3.0 – 4.5	434 – 652
Children		
Newborns	3.5 – 4.9	507 – 710
1st year	3.6 – 5.0	521 – 724
2–20 years	3.7 – 5.1	536 – 738

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

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Albumin FS

Chemistry code 10 022

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	90
R2e volume	0
R2 volume	0
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	3

Sub-analy. Conditions	
Name	ALB
Digits	1
M-wave L.	596
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	7
M-DET.P.n	9
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	3
Factor	3
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999