

# Albumin FS\*

## Order Information

Cat. No.	Kit size	
1 0220 99 10 021	6 x	25 mL
1 0220 99 10 026	6 x	100 mL
1 0220 99 10 023	1 x	1000 mL
1 0220 99 10 704	8 x	50 mL
1 0220 99 10 917	10 x	60 mL

Kits for use in conjunction with DiaSys CE applications.

## Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human serum or heparin plasma on automated photometric systems.

## 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

- In very rare cases, samples of patients with gammopathy might give falsified results [9].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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.

## 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.

## Assay Procedure

### Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	596/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent	90 µL
Addition reagent	Cycle 19 (286 s)
Absorbance	Cycle 7/9 (95 s/122 s)
Calibration	Linear

## Calculation

### With calibrator

$$\text{Albumin [g/dL]} = \frac{A_{\text{Sample}}}{A_{\text{Cal}}} \times \text{Conc. Cal. [g/dL]}$$

### Conversion Factor

$$\text{Albumin [g/dL]} \times 144.9 = \text{Albumin [µmol/L]}$$

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference material ERM-DA470. Albumin Standard FS may be used alternatively for calibration. 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
Albumin Standard FS	1 0200 99 10 030	6 x 3 mL

## Performance Characteristics

### Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 6 g/dL, linearity is given within $\pm 5\%$ . When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	0.1 g/dL

Interference by	Interferences $\leq 10\%$ 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].

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.

## Reference Range [3]

	[g/dL]	[ $\mu\text{mol/L}$ ]
<b>Adults</b>		
$\leq 60$ 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
<b>Children</b>		
Newborns	3.5 – 4.9	507 – 710
1 <sup>st</sup> 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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\* Fluid Stable