

# Albumin in Urine/CSF FS\* (Microalbumin)

## Order Information

Cat. No.	Kit size		
1 0242 99 10 021	R1 5 x 25 mL	+	R2 1 x 25 mL
1 0242 99 10 023	R1 1 x 1000 mL	+	R2 1 x 200 mL
1 0242 99 10 930	R1 4 x 20 mL	+	R2 2 x 8 mL
1 0242 99 10 935	R1 2 x 20 mL	+	R2 1 x 8 mL

Kits for use in conjunction with DiaSys CE applications.

## Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human urine, cerebrospinal fluid (CSF), serum or heparin plasma on automated photometric systems.

## Summary

Albumin is a carbohydrate-free protein that constitutes a major part of total plasma proteins, accounting for approximately 60% of the total protein content in blood [1]. It is primarily synthesized in the liver at a rate of 12-25 g/day and is distributed in plasma, interstitial fluid, and various body compartments [2]. The main physiological role of albumin is to maintain oncotic pressure, facilitate the transport of various substances (such as hormones, fatty acids, and drugs), and serve as a source of amino acids [2,3]. Due to its size and charge, albumin is normally retained in the bloodstream, with only minimal amounts present in urine or cerebrospinal fluid (CSF). Any significant deviation from normal albumin levels in these fluids can indicate underlying pathological conditions [1,3]. The determination of albumin in urine is crucial in assessing renal function and detecting early-stage kidney diseases [4]. Even a slight increase in urinary albumin (microalbuminuria) serves as an early marker of diabetic nephropathy and hypertensive kidney damage, while higher levels of albumin in urine indicate more severe glomerular dysfunction [3,4]. In contrast, albumin measurement in CSF primarily assesses the integrity of the blood-brain barrier (BBB). Increased CSF albumin levels suggest BBB impairment, which can be associated with neurological disorders such as multiple sclerosis, meningitis, and traumatic brain injury [5]. Additionally, the CSF/serum albumin ratio is a valuable parameter for evaluating the degree of BBB dysfunction [6].

## Method

Immunoturbidimetric test

Determination of the albumin concentration via photometric measurement of antigen-antibody-reaction among antibodies against albumin and albumin present in the sample.

## Reagents

### Components and Concentrations

<b>R1:</b>	TRIS	pH 7.5	100 mmol/L
	NaCl		50 mmol/L
<b>R2:</b>	TRIS	pH 8.0	83 mmol/L
	NaCl		165 mmol/L
	Antibodies (goat) against human albumin		< 1%

## Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°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. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. The albumin concentration in serum samples is much higher than in urine samples. In order to avoid contaminations and carryover from serum samples into urine samples, cuvettes and other glassware must be cleaned thoroughly after being used for tests with serum.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.

6. 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.
7. 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.
8. 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 reagents are ready to use.

## Materials Required

General laboratory equipment

## Specimen

Human urine, CSF, serum and heparin plasma

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

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

Stability in urine [8]:

7 days	at	20 – 25°C
1 month	at	4 – 8°C
6 months	at	-20°C

Stability in CSF [8]:

1 day	at	20 – 25°C
2 months	at	4 – 8°C
1 year	at	-20°C

Stability in serum/plasma [8]:

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

Only freeze once. Discard contaminated specimens.

## Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

### Urine/CSF

<b>Wavelength</b>	410/805 nm
<b>Temperature</b>	37°C
<b>Measurement</b>	Endpoint
<b>Sample/Calibrator</b>	4.0 µL
<b>Reagent 1</b>	80 µL
<b>Reagent 2</b>	16 µL
<b>Addition reagent 2</b>	Cycle 19 (286 s)
<b>Absorbance 1</b>	Cycle 17/18 (231 s/244 s)
<b>Absorbance 2</b>	Cycle 41/42 (586 s/600 s)
<b>Calibration</b>	Spline

### Serum/Plasma

<b>Wavelength</b>	571/805 nm
<b>Temperature</b>	37°C
<b>Measurement</b>	Endpoint
<b>Sample/Calibrator</b>	1.0 µL
<b>Reagent 1</b>	125 µL
<b>Reagent 2</b>	25 µL
<b>Addition reagent 2</b>	Cycle 19 (286 s)
<b>Absorbance 1</b>	Cycle 17/18 (231 s/244 s)
<b>Absorbance 2</b>	Cycle 41/42 (586 s/600 s)
<b>Calibration</b>	Spline

## Calculation

The albumin concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log or spline. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

### Conversion Factor

Urine/CSF:

$$\text{Albumin [mg/L]} \times 0.0152 = \text{Albumin [\mu mol/L]}$$

Urine:

$$\text{Albumin [mg/g crea]} \times 0.113 = \text{Albumin [g/mol crea]}$$

Serum/plasma:

$$\text{Albumin [g/L]} \times 15.2 = \text{Albumin [\mu mol/L]}$$

$$\text{Albumin [g/dL]} \times 152 = \text{Albumin [\mu mol/L]}$$

## Calibrators and Controls

DiaSys TruCal Albumin U/CSF is recommended for calibration of urine/CSF determination. DiaSys TruCal Albumin U/CSF high may be used alternatively for calibration. DiaSys TruCal Protein is recommended for calibration of serum/plasma determination. The calibrator values have been made traceable to the reference material ERM®-DA470/IFCC. Use DiaSys TruLab Albumin U/CSF Level 1 and Level 2 for internal quality control of urine/CSF determination. TruLab Urine Level 1 and Level 2 may be used alternatively for internal quality control of urine determination. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control of serum/plasma determination. 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 Albumin U/CSF	1 9300 99 10 059	5 x 1 mL
TruCal Albumin U/CSF high	1 9300 99 10 037	3 x 1 mL
TruCal Protein	5 9200 99 10 039	5 x 1 mL
TruLab Albumin U/CSF Level 1	5 9710 99 10 046	3 x 1 mL
TruLab Albumin U/CSF Level 2	5 9720 99 10 046	3 x 1 mL
TruLab Urine Level 1	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
TruLab Urine Level 2	5 9180 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

## Performance Characteristics

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

#### Urine

Measuring range up to 350 mg/L, depending on the concentration of the highest calibrator. Linearity is given within ± 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**	1 mg/L
No prozone effect up to 60000 mg/L.	

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/L]
Bilirubin (conjugated)	10 mg/dL	30.2
Bilirubin (unconjugated)	20 mg/dL	28.2
Hemolysis	200 mg/dL	27.1
For further information on interfering substances, refer to the literature [9,10].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	22.0	91.9	239
CV [%]	2.21	1.11	0.858
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	23.8	93.7	241
CV [%]	2.08	0.963	1.26

Method comparison (n=81)	
Test x	Competitor Albumin in Urine/CSF (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Albumin in Urine/CSF FS (BioMajesty® JCA-BM6010/C)
Slope	1.06
Intercept	0.921 mg/L
Coefficient of correlation	0.997

#### Serum/Plasma

Measuring range up to 110 g/L, depending on the concentration of the highest calibrator. Linearity is given within ± 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**	1 g/L
No prozone effect up to 200 g/L.	

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
Bilirubin (conjugated)	60 mg/dL	40.5
Bilirubin (unconjugated)	60 mg/dL	40.4
Hemolysis	1000 mg/dL	40.1
Lipemia (triglycerides)	2000 mg/dL	40.3
For further information on interfering substances, refer to the literature [9,10].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	26.0	34.0	41.0
CV [%]	1.11	1.87	1.44
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	25.8	34.6	41.5
CV [%]	2.13	2.25	1.73

Method comparison (n=100)	
Test x	Competitor Albumin in Urine/CSF (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Albumin in Urine/CSF FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	0.450 g/L
Coefficient of correlation	0.999

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

## Reference Range

Urine [3]:

Albumin excretion rate in urine:	< 30 mg/24 h
Albumin concentration (early morning urine):	< 30 mg/L
Albumin/creatinine ratio (early morning urine):	< 30 mg/g Creatinine
CSF/Serum albumin ratio (RAIb) adults [3]:	(5 – 8) x 10 <sup>-3</sup>
Serum/Plasma, adults ≤ 60 years [3]:	35 – 53 g/L

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