


Albumin in Urine/CSF FS* (Microalbumin)

Order Information

Cat. No.

1 0242 99 10 921

Kit size

 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human urine, cerebrospinal fluid (CSF), serum or heparin plasma on automated respons[®]920.

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

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		50 mmol/L
R2:	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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- 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.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.

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

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.

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/CSF 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.

Note: For serum determination, TruCal Protein has to be pre-diluted 1:20 with NaCl solution (9 g/L) and calibrator values have to be divided by 20.

	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

Urine

Measuring range up to 350 mg/L, depending on the concentration of the highest calibrator. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	2 mg/L
No prozone effect up to 60000 mg/L.	
Onboard stability	4 weeks
Calibration stability	4 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/L]
Bilirubin (conjugated)	25 mg/dL	85.1
Bilirubin (unconjugated)	25 mg/dL	98.1
Hemolysis	240 mg/dL	97.8
Urea	40 g/L	72.7

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]	20.3	34.1	106
CV [%]	3.01	1.55	0.567
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	20.8	35.0	110
CV [%]	3.46	2.91	1.94

Method comparison (n=92)	
Test x	DiaSys Albumin in Urine/CSF FS (Hitachi 911)
Test y	DiaSys Albumin in Urine/CSF FS (respons [®] 920)
Slope	0.935
Intercept	1.40 mg/L
Coefficient of correlation	0.999

Serum/Plasma

Measuring range up to 120 g/L, depending on the concentration of the highest calibrator. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.6 g/L
No prozone effect up to 220 g/L.	
Onboard stability	4 weeks
Calibration stability	4 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
Bilirubin (conjugated)	60 mg/dL	43.7
Bilirubin (unconjugated)	60 mg/dL	43.6
Hemolysis	1000 mg/dL	43.5
Lipemia (triglycerides)	2000 mg/dL	53.9

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]	38.2	57.5	67.9
CV [%]	2.04	1.81	2.25
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	41.4	60.5	71.8
CV [%]	2.32	2.73	2.52

Method comparison (n=116)	
Test x	DiaSys Albumin in Urine/CSF FS (Hitachi 911)
Test y	DiaSys Albumin in Urine/CSF FS (respons [®] 920)
Slope	1.07
Intercept	-0.857 g/L
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

Urine/CSF:

Albumin [mg/L] x 0.0152 = Albumin [µmol/L]

Urine:

Albumin [mg/g crea] x 0.113 = Albumin [g/mol crea]

Serum/plasma:

Albumin [g/L] x 15.2 = Albumin [µmol/L]

Albumin [g/dL] x 152 = Albumin [µmol/L]

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 ⁻³
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

- Johnson AM. Amino Acids, Peptides and Proteins. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. Elsevier Saunders, St. Louis, Mo., ©2006 p. 546-549.
- Fanali G, di Masi A, Trezza V, et al. Human serum albumin: from bench to bedside. Mol Aspects Med. 2012;33:209-90.
- Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2025 March 28] <https://www.clinical-laboratory-diagnostics.com>
- Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024;105(4S): S117–S314.
- Hegen H, Auer M, Zeileis A, et al. Upper reference limits for cerebrospinal fluid total protein and albumin quotient based on a large cohort of control patients: implications for increased clinical specificity. Clinical Chemistry and Laboratory Medicine (CCLM). 2016;54(2):285-292.
- Seeliger T, Gingele S, Emre GY, et al. Comparative analysis of albumin quotient and total CSF protein in immune-mediated neuropathies: a multicenter study on diagnostic implications. Frontiers in Neurology. 2024;14.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
- Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples, German United Society for Clinical Chemistry and Laboratory Medicine. 3rd ed; 2010.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
- Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in June 2024. Published by AACC Press and John Wiley and Sons, Inc.

respons[®]920

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.



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* Fluid Stable

Albumin in Urine/CSF FS

Application for urine and CSF

Test Details		Test Volumes		Reference Ranges	
Test	: UALBU			Auto Rerun	<input type="checkbox"/>
Report Name	: Albumin UCSF Urine application			Online Calibration	<input type="checkbox"/>
Unit	: mg/L	Decimal Places	: 2	Cuvette Washing	<input type="checkbox"/>
Wavelength-Primary	: 405	Secondary	: 700	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Point-To-Point	Reagent R1	: UALB R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: UALB R2
M2 Start	: 33	M2 End	: 33	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank /Level 0	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator 1	: **
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator 2	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator 3	: **
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator 5	: **
Y = aX + b	a= : 1.0000	b=	: 0.0000	Calibrator 6	: **

*Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

Test Details		Test Volumes		Reference Ranges																																			
Test	: UALBU																																						
Sample Type	: Urine																																						
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Test Details		Test Volumes		Reference Ranges																																			
Test	: UALBU																																						
Sample Type	: Urine																																						
Reference Range	: DEFAULT																																						
Category	: Male																																						
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Editable by user

Albumin in Urine/CSF FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: UALBS			Auto Rerun	<input type="checkbox"/>
Report Name	: Albumin UCSF serum application			Online Calibration	<input type="checkbox"/>
Unit	: g/L	Decimal Places	: 2	Cuvette Washing	<input type="checkbox"/>
Wavelength-Primary	: 578	Secondary	: 0	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Cubic spline	Reagent R1	: UALB R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: UALB R2
M2 Start	: 33	M2 End	: 33	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank /Level 0	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator 1	: **
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator 2	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator 3	: **
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator 5	: **
Y = aX + b	a = 1.0000	b = 0.0000		Calibrator 6	: **

*Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: MALBs				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 2.00 μL	Dilution Ratio	: 20 X		
Increase	: 5.00 μL	Dilution Ratio	: 20 X		
Decrease	: 2.00 μL	Dilution Ratio	: 40 X		
Standard Volume	: 2.00 μL				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 200 μL	R1 Stirrer Speed	: High		
RGT-2 Volume	: 40 μL	R2 Stirrer Speed	: High		
Sample Types					
<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other					

Test Details		Test Volumes		Reference Ranges	
Test	: MALBs				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit		
	(g/L)		(g/L)		
Normal	: #		: #		
Panic	: #		: #		
Sample Types					
<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other					

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