Albumin in Urine/CSF FS *(Microalbumin)

Reagent for quantitative in vitro determination of albumin in urine, CSF, serum or plasma on photometric systems

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
5 9200 99 10 037		3 x	1 mL	TruCal Protein high		
5 9200 99 10 039		5 x	1 mL	TruCal Protein:		
	Calibrator set with 5 different levels					
1 9300 99 10 037		3 x	1 mL	TruCal Albumin U/CSF high		
1 9300 99 10 059		5 x	1 mL	TruCal Albumin U/CSF:		
	Calibrator set with 5 different levels					

Summary [1,2]

Albumin is the main plasma protein in terms of quantity (> 50%). It serves as a transport and binding protein for substances having low water solubility, such as free fatty acids, bilirubin, hormones, vitamins, trace elements and medicaments and it contributes decisively towards maintaining the colloidal osmotic pressure. It is synthesized exclusively by the liver parenchymal cells at a rate of 14 g/day. Increased urine albumin concentrations indicate bleedings in the lower urinary tract (ureter, bladder) or infections of the renal pelvis. A small abnormal albumin excretion is known as Microalbuminuria and serves as an indicator for temporary overload of the glomerular filtration (fever, excessive sports) or chronic injury of the glomeruli (Diabetes). The determination of the CSF/serum albumin ratio (RAlb) serves to judge the integrity of the blood-brain barrier and is necessary for the preparation of immunoglobulin ratio diagrams used in CSF diagnostics.

Method

Immunoturbidimetric test

Principle

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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

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 animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. The albumin concentration in serum samples is much higher than in urine samples. In order to avoid contaminations and carry over 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 [8].
5. Please refer to the safety data sheets 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.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Urine, CSF, heparin plasma and serum
If contaminations are avoided, stability is [3]:

in urine:	7 days	at	20 – 25°C
	1 month	at	4 – 8°C
	6 months	at	–20°C
in CSF:	1 day	at	20 – 25°C
	2 months	at	4 – 8°C
	1 year	at	–20°C
in serum/plasma:	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 for Analyzers

Application sheets for automated systems are available on request.

Basic parameters for Hitachi 704

Urine determination

Wavelength	700/415 nm (bi-chromatic)
Temperature	37°C
Measurement	2-Point-Test (fixed time kinetics)
Sample/Calibrator	20 µL
Reagent 1	350 µL
Reagent 2	70 µL
Addition Reagent 2	Cycle 17 (340 s)
Absorbance 1	Cycle 15 (300 s)
Absorbance 2	Cycle 32 (640 s)
Calibration	spline

Serum determination

All samples, calibrators and controls have to be pre-diluted 1:20 with NaCl solution (9 g/L)!

Wavelength	570 nm
Temperature	37°C
Measurement	2-Point-Test
Sample/Calibrator	3 µL
Reagent 1	350 µL
Reagent 2	70 µL
Addition Reagent 2	Cycle 17 (340 s)
Absorbance1	Cycle 15 (300 s)
Absorbance 2	Cycle 32 (640 s)
Calibration	spline

Note: For manual procedures the volumes of sample, calibrator and reagents have to be calculated appropriately and the timing has to be kept exactly.

Calculation

The Albumin concentration of unknown samples is derived from the 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.
Stability of calibration: 4 weeks.

Calibrator and controls

For calibration of the urine determination, DiaSys Albumin U/CSF calibrator set is recommended, whereas the DiaSys Calibrator set TruCal Protein is recommended for the determination in serum.
The assigned values of the calibrators have been made traceable to the reference material ERM®-DA470k/IFCC. For internal quality control of the urine determination, DiaSys TruLab Albumin U/CSF control should be assayed. For internal quality control of the serum determination, DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
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 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 in urine

Measuring range

The test has been developed to determine albumin concentrations from 3 - 350 mg/L (0.003 – 0.35 g/L) – the exact values depend on the actual calibrator lot. When values exceed this range samples should be diluted 1 + 3 with NaCl solution (9 g/L) and the result multiplied by 4.

Prozone Limit

No prozone effect was observed up to Albumin values of 60000 mg/L (60.0 g/L)

Specificity/Interferences

DiaSys Albumin in Urine/CSF is specific for human albumin given by the antibodies chosen. No interference was observed in urine by conjugated and unconjugated bilirubin up to 25 mg/dL, hemoglobin up to 250 mg/dL and urea up to 40 g/L. For further information on interfering substances refer to Young DS [7].

Sensitivity/Limit of Detection

The lower limit of detection is 3 mg/L (0.003 g/L)

Precision (Hitachi 704)

Intra-assay n = 20	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	18.8	0.38	2.03
Sample 2	27.5	0.27	0.99
Sample 3	94.9	0.87	0.92

Inter-assay n = 20	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	19.6	0.69	3.50
Sample 2	34.1	1.37	4.00
Sample 3	94.3	1.24	1.30

Total precision according to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards):

Total precision n = 80	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	25.6	1.79	6.98
Sample2	104	4.40	4.23

Method comparison

A comparison of DiaSys Albumin Urine/CSF FS (y) with a nephelometric test (x) using 123 samples gave following results:
Y = 1.01 x – 0.30 mg/L ; r = 0.998.
A comparison of DiaSys Albumin in Urine/CSF FS (y) with an immunoturbidimetric test (x) using 139 samples gave following results: y = 1.23 x + 0.61 mg/L; r = 0.994.

Performance characteristics in serum

Measuring range

The test has been developed to determine albumin concentrations from 0.6 – 120 g/L – depending on the highest calibrator. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to albumin values of 200 g/L.

Specificity/Interferences

DiaSys Albumin in Urine/CSF is specific for human Albumin given by the antibodies chosen. No interference was observed in serum by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [7].

Sensitivity/Limit of Detection

The lower limit of detection is 0.6 g/L.

Precision (Hitachi 704)

Intra-assay n = 20	Mean [g/L]	SD [g/L]	CV [%]
Sample 1	40.7	1.17	2.88
Sample 2	51.2	1.25	2.44
Sample 3	59.5	1.45	2.43

Inter-assay n = 20	Mean [g/L]	SD [g/L]	CV [%]
Sample 1	40.5	0.66	1.63
Sample 2	52.8	1.19	2.25
Sample 3	60.8	1.11	1.83

Total precision according to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards):

Total precision n = 80	Mean [g/L]	SD [g/L]	CV [%]
Sample 1	52.4	1.01	1.93
Sample 2	61.4	1.68	2.73

Method comparison

A comparison of DiaSys Albumin in Urine/CSF FS (y) with a nephelometric test (x) using 97 samples gave following results:
y = 0.99 x – 0.34 g/L; r = 0.989
A comparison of DiaSys Albumin in urine/CSF FS (y) with an immunoturbidimetric test (x) using 97 samples gave following results:
y = 1.11 x – 0.91 g/L; r = 0.993

Reference range

Urine [5]:
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 (RAlb) adults [6]: $< 7 \times 10^{-3}$
Serum/Plasma [1]: 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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Manufacturer

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