

Albumin in Urine/CSF FS* (Microalbumin)

Diagnostic reagent for quantitative in vitro determination of albumin in urine, CSF, serum or plasma on DiaSys respons[®]920

Order information

Cat. No. 1 0242 99 10 921

4 twin containers for 100 determinations each

Method

Immunturbidimetric 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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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 animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- 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, please use the automated washing steps which are specified in the system software. Please refer to the user manual of the instrument.
- 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 very rare cases, samples of patients with gammopathy might give falsified results [9].
- 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.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Urine, CSF, serum and heparin plasma

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators 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 determination in serum. The assigned values of TruCal Albumin U/CSF and TruCal Protein have been made traceable to the ERM[®]-DA470k/IFCC reference material. For internal quality control of the urine determination, DiaSys TruLab Albumin U/CSF control should be assayed. For internal quality control of serum determination, DiaSys TruLab Protein control should be assayed. 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 (5 levels)	1 9300 99 10 059	5 x 1 mL
TruCal Protein (5 levels)	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 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 up to 350 mg/L Albumin (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	2 mg/L Albumin
No prozone effect up to 60000 mg/L Albumin	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by	
Urea up to 40 g/L	
Hemoglobin up to 240 mg/dL	
Bilirubin up to 25 mg/dL	
For further information on interfering substances refer to Young DS [8].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	20.3	34.1	106
Coefficient of variance [%]	3.01	1.55	0.57
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	20.8	35.0	110
Coefficient of variance [%]	3.46	2.91	1.94

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

Performance Characteristics in Serum

Measuring range up to 120 g/L Albumin (in case of higher concentrations re-measure samples after manual dilution NaCl solution (9g/L) or use the rerun function).	
Limit of detection***	0.6 g/L Albumin
No prozone effect up to 200 g/L Albumin	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by	
Hemoglobin up to 1000 mg/dL	
Bilirubin up to 60 mg/dL	
Lipemia (triglycerides) up to 2000 mg/dL	
For further information on interfering substances refer to Young D. S. [8]	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	38.2	57.5	67.9
Coefficient of variance [%]	2.04	1.81	2.25
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/L]	41.4	60.5	71.8
Coefficient of variance [%]	2.32	2.73	2.52

Method comparison (n=116)	
Test x	DiaSys Alb in Urine/CSF FS (Hitachi 911)
Test y	DiaSys Alb in Urine/CSF FS (respons [®] 920)
Slope	1.065
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

Reference Range

Urine [3,4]:

Albumin excretion rate in urine: <30 mg/24 h
 Albumin concentration (early morning urine): <30 mg/L
 Albumin/creatinine ratio (first morning urine): <30 mg/g Creatinine

CSF/Serum albumin ratio (RAIb) adults [5]: <7 x 10⁻³
 Serum/Plasma [6]: 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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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				
Sample Volumes				Sample Types	
Normal	: 5.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input checked="" type="checkbox"/> Urine <input checked="" type="checkbox"/> CSF <input type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 20.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 5.00 μ L	Dilution Ratio	: 2 X		
Standard Volume	: 5.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 200 μ L	R1 Stirrer Speed	: High		
RGT-2 Volume	: 40 μ L	R2 Stirrer Speed	: Medium		

Test Details		Test Volumes		Reference Ranges	
Test	: UALBU				
Sample Type	: Urine				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit	<input checked="" type="checkbox"/> Serum <input checked="" type="checkbox"/> Urine <input checked="" type="checkbox"/> CSF <input type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
	(mg/L)		(mg/L)		
Normal	: 0.00		: 30.00		
Panic	: 0.00		: 0.00		

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		

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	: 35.00		: 53.00		
Panic	: 0.00		: 0.00		