respons®910

Albumin in Urine/CSF FS* (Microalbumin)

Diagnostic reagent for quantitative in vitro determination of albumin in urine and CSF on DiaSys respons®910

Order information

Cat. No. 1 0242 99 10 921

4 twin containers for 100 tests each

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. DiaSys respons containers provide protection from light. Do not freeze 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. Albumin concentration in serum is much higher than in urine. To avoid carryover contamination, pipette needle should be rinsed, if previously worked with serum. We recommend analyzing urines as batch. Please refer to user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [9].
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. The bottles are placed directly into the reagent rotor.

Specimen

Urine, CSF

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal Albumin U/CSF calibrator set is recommended for calibration. The assigned values of the calibrators have been made traceable to the Reference Material ERM-DA470k/IFCC. DiaSys TruLab Albumin U/CSF should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Albumin U/CSF (5 levels)	1 9300 99 10 059	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

Performance Characteristics in Urine

Measuring range from 20 to 350 mg/L Albumin (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 Albumin
No prozone effect up to 60000 mg/L Albumin	
On-board stability	14 days
Calibration stability	7 days

Interfering substance	**Interferences < 10%**	**Albumine [mg/L]**
Hemoglobin	up to 300 mg/dL	110
Bilirubin, conjugated	up to 3 mg/dL	24.2
	up to 3 mg/dL	42.5
Urea	up to 50 g/L	66.9
	up to 55 g/L	275
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]	24.6	57.5	114
Coefficient of variance [%]	3.76	1.84	1.30
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	22.4	55.6	96.7
Coefficient of variance [%]	2.76	2.34	3.12

Method comparison (n=125)	
Test x	DiaSys Alb in Urine/CSF FS (Hitachi 917)
Test y	DiaSys Alb in Urine/CSF FS (respons®910)
Slope	0.932
Intercept	–0.675 mg/L
Coefficient of correlation	0.9997

** according to NCCLS document EP17-A, vol. 24, no. 34

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

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5, 50-1, 54-5.
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3. Dati F, Metzmann E. Proteins-Laboratory testing and clinical use. 1st ed. Holzheim: DiaSys Diagnostic Systems; 2005: p. 93.
4. Sacks DB, Bruns DE, Goldstein DE, Mac Laren NK, Mc Donald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2002; 48: 459-62.
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8. 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.
9. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

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respons®910

Albumin in Urine/CSF FS Urine Application

Application for urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	MALBu
Shortcut:	
Reagent barcode reference:	700
Host reference:	700

Technic	
Type:	End point
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	350.0000
SERUM	
Normal volume [µL]	10.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	10.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	10.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	10.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	10.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	10.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	10.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	10.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	10.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	10.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	
URINE	>= <=30.0
PLASMA	
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	0.0200
Drift limit [%]	2.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value