Albumin in Urine/CSF FS* (Microalbumin)

Diagnostic reagent for quantitative in vitro determination of albumin in urine, CSF, serum or plasma on BioMajesty JCA-BM6010/C

Order information

Cat. No. 1 0242 99 10 964

R1: 6 x 100 tests
R2: 6 x 100 tests

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 and contamination is avoided. Do not freeze reagents! R1 and R2 must be protected from light.

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. In very rare cases, samples of patients with gammopathy might give falsified results [9].
4. The albumin concentration in serum samples is much higher than in urine/CSF samples. In order to avoid contaminations and carry over from serum samples into urine/CSF samples, cuvettes and other material must be cleaned thoroughly after being used for tests with serum.
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 trays.

Specimen

Urine, CSF, serum and heparin plasma

If contaminations are avoided the stability is [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

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration of the urine/CSF determination, the 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 the calibrators have been made traceable to the reference material ERM®-DA470k/IFCC.

For internal quality control of the urine/CSF 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
TruCal Albumin U/CSF (5 Level)	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
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

Performance Characteristics (Urine)

Measuring range up to 350 mg/L (5.32 µmol/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**	1 mg/L (0.0152 µmol/L) albumin
No prozone effect up to 60000 mg/L (912 µmol/L) albumin	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Hemoglobin up to 200 mg/dL
Conjugated bilirubin up to 10 mg/dL
Unconjugated bilirubin up to 20 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]	22.0	91.9	239
Mean [µmol/L]	0.34	1.40	3.63
Coefficient of variance [%]	2.21	1.11	0.86
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	23.8	93.7	241
Mean [µmol/L]	0.36	1.42	3.67
Coefficient of variance [%]	2.08	0.96	1.26

Method comparison (n=81)	
Test x	Competitor Microalbumin
Test y	DiaSys Albumin in Urine/CSF FS
Slope	1.06
Intercept	0.921 mg/L (0.014 µmol/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]

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Performance Characteristics (Serum)

Measuring range up to 110 g/L (1672 µmol/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***	1.0 g/L (15.2 µmol/L) albumin
No prozone effect up to 200 g/L (3040 µmol/L) albumin	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Hemoglobin up to 1000 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Lipemia (triglycerides) up to 2000 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 [g/L]	26.0	34.0	41.0
Mean [µmol/L]	396	517	622
Coefficient of variance [%]	1.11	1.87	1.44
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	25.8	34.6	41.5
Mean [µmol/L]	393	526	631
Coefficient of variance [%]	2.13	2.25	1.73

Method comparison (n=100)	
Test x	Competitor Microalbumin
Test y	DiaSys Albumin in Urine/CSF FS
Slope	1.0
Intercept	0.45 g/L (6.84 µmol/L)
Coefficient of correlation	0.9998

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

Conversion factor

Serum/plasma:
Albumin [g/L] x 15.2 = Albumin [µmol/L]
Albumin [g/dL] x 152 = Albumin [µmol/L]

Reference Range

Urine [3,4]:
Albumin excretion rate in urine:
< 30 mg/24 h (< 0.456 µmol/24 h)
Albumin concentration (early morning urine):
< 30 mg/L (< 0.456 µmol/L)
Albumin/creatinine ratio (first morning urine):
< 30 mg/g Creatinine (< 3.39 g/mol Creatinine)

CSF/Serum albumin ratio (RAlb) adults [5]**:**
$< 7 \times 10^{-3}$

Serum/plasma [6]**:**
35 – 53 g/L (3.5 – 5.3 g/dL)

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

IVD CE

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Albumin in Urine/CSF FS

Chemistry code 10 024

Application for serum and plasma 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.

Analytical Conditions	
R1 volume	125
R2e volume	0
R2 volume	25
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	MALBS
Digits	1
M-wave L.	571
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	With dil	No dil
Undil. sample vol.	5	0
Diluent volume	95	0
Diluent position	#	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1	With dil	5	95	#	9.999	-9.999
1	#	1	With dil	5	95	#	9.999	-9.999
2	#	1	With dil	5	95	#	9.999	-9.999
3	#	1	With dil	5	95	#	9.999	-9.999
4	#	1	With dil	5	95	#	9.999	-9.999
5	#	1	With dil	5	95	#	9.999	-9.999

entered by user

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Albumin in Urine/CSF FS

Chemistry code 10 024

Application for CSF and 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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	16
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	4
Sample vol (U)	4
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	MALBU
Digits	1
M-wave L.	410
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	4	4
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	4	No dil	0	0	0	9.999	-9.999
1	#	4	No dil	0	0	0	9.999	-9.999
2	#	4	No dil	0	0	0	9.999	-9.999
3	#	4	No dil	0	0	0	9.999	-9.999
4	#	4	No dil	0	0	0	9.999	-9.999
5	#	4	No dil	0	0	0	9.999	-9.999

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