respons®910

Albumin FS*

Diagnostic reagent for quantitative in vitro determination of albumin in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 0220 99 10 923
4 containers for 200 tests each

Method

Photometric test using bromocresol green

Principle

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue.

Reagents

Components and Concentrations

Citrate buffer	pH 4.2	30 mmol/L
Bromocresol green		0.26 mmol/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 25 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results.
2. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:
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, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference material ERM -DA470. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 6 g/dL albumin (in case of higher concentrations re-measure samples after manual dilution or use rerun function).	
Limit of detection**	0.1 g/dL albumin
On-board stability	6 weeks
Calibration stability	5 weeks

Interfering substance	Interferences < 10%	Albumin [g/dL]
Ascorbate	up to 30 mg/dL	3.31
Hemoglobin	up to 500 mg/dL	3.57
	up to 550 mg/dL	5.47
Bilirubin, conjugated	up to 70 mg/dL	3.33
	up to 70 mg/dL	5.15
Bilirubin, unconjugated	up to 70 mg/dL	3.35
	up to 70 mg/dL	5.04
Lipemia (triglycerides)	up to 800 mg/dL	3.25
	up to 950 mg/dL	5.02
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.58	4.21	5.03
Coefficient of variation [%]	1.51	1.59	1.56
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.45	4.05	4.90
Coefficient of variation [%]	3.88	1.83	2.92

Method comparison (n=100)	
Test x	DiaSys Albumin FS (Hitachi 917)
Test y	DiaSys Albumin FS (respons®910)
Slope	0.992
Intercept	0.072 g/dL
Coefficient of correlation	0.997

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

Conversion factor

Albumin [g/dL] x 144.9 = Albumin [µmol/L]

Reference Range [3]

Adults: 3.5 – 5.2 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

1. Guder WG. Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
2. 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.
3. Dati F. Schumann G. Thomas L. Aguzzi F. Baudner S. Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
4. Johnson AM. Rohlfs EM. Silverman LM. Proteins. In: Burtis CA. Ashwood ER. editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p. 477-540.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.

Manufacturer

IVD   CE   DiaSys Diagnostic Systems GmbH
Alte Strasse 9   65558 Holzheim   Germany

respons®910

Albumin FS

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

Identification	
This method is usable for analysis:	Yes
Name:	ALB
Shortcut:	
Reagent barcode reference:	012
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	
Blanc correction	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(-00:12)
Last reading time [min:sec]	03:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.100
Concentration technical limits-Upper	6.00
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	4
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=3.50 <=5.20
URINE	
PLASMA	>=3.50 <=5.20
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details		
Calibrator list		**Concentration**
Cal. 1		0
Cal. 2		*
Cal. 3		*
Cal. 4		*
Cal. 5		*
Cal. 6		*
	Max delta abs.	
Cal. 1	0.100	
Cal. 2	0.080	
Cal. 3		
Cal. 4		
Cal. 5		
Cal. 6		
Drift limit [%]	0.8	
Calculations		
Model		X degree
Degree		1

* Enter calibrator value