respons®910

Albumin FS*

Order Information

Cat. No.	Kit size
1 0220 99 10 923	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human serum or heparin plasma on automated respons®910.

Summary

Albumin is synthesized and released by the liver and represents approximately 60% of the total plasma proteins. It is the main determinant of the plasmatic osmotic pressure and the most important factor for fluid distribution between body compartments [1,2]. Furthermore, albumin binds and transports a variety of substances like metal ions, bilirubin, free fatty acids, phospholipids, amino acids, hormones (steroid hormones, thyroid hormones) and drugs [2,3]. The healthy liver synthesizes 120 – 200 mg/kg body weight of albumin per day. Interestingly, the albumin synthesis rate fluctuates depending on the specific pathophysiological condition. For instance, in decompensated liver cirrhosis the synthesis may decrease to 30 – 50 % compared to healthy values while acute nephrosis leads to a strong increase in the synthesis rate of albumin [4]. On the other hand, hypoalbuminemia is prevalent in numerous diseases and results from different factors. Impaired hepatic synthesis and release (liver diseases, systemic inflammation), variations in the distribution of body fluids (edema, ascites), increased catabolism due to tissue damage (severe burns), protein-losing enteropathy (gastroenteritis) or increased degradation or loss through the urinary tract (nephrotic syndrome) lead to decreased plasmatic albumin concentrations [1,3-5,8]. Furthermore, hypoalbuminemia is common in heart failure and associated with further cardiac diseases, such as myocardial fibrosis [6,7]. A lowered serum concentration of albumin also serves as a rough indicator for the general health status of an individual, especially for elderly, chronically ill and hospitalized patients [3]. Additionally, decreased plasmatic albumin is a strong prognostic parameter in e.g. liver cirrhosis and heart failure patients [5-7].

Method

Photometric test using bromocresol green

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.

Reagent

Components and Concentrations

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

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [9].
2. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
3. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
4. Please refer to the safety data sheets (SDS) 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.
5. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [10]:

2.5 months	at	20 – 25°C
5 months	at	4 – 8°C
4 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference material ERM-DA470. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 from 0.07 g/dL up to 6 g/dL, linearity is given within ± 5%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.07 g/dL
Limit of quantitation**	0.07 g/dL
Onboard stability	6 weeks
Calibration stability	5 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/dL]
Ascorbic acid	30 mg/dL	3.31
Bilirubin (conjugated)	70 mg/dL	3.33
	70 mg/dL	5.15
Bilirubin (unconjugated)	70 mg/dL	3.35
	70 mg/dL	5.04
Hemolysis	500 mg/dL	3.57
	550 mg/dL	5.47
Lipemia (triglycerides)	800 mg/dL	3.25
	950 mg/dL	5.02

For further information on interfering substances, refer to the literature [11-13].

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Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.58	4.21	5.03
CV [%]	1.51	1.59	1.56
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.45	4.05	4.90
CV [%]	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 CLSI document EP17-A, Vol. 24, No. 34

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

Reference Range [3]

	[g/dL]	[µmol/L]
Adults		
≤ 60 years	3.5 – 5.3	507 – 753
> 60 years	3.4 – 4.8	492 – 695
> 70 years	3.3 – 4.7	478 – 681
> 80 years	3.1 – 4.5	449 – 652
> 90 years	3.0 – 4.5	434 – 652
Children		
Newborns	3.5 – 4.9	507 – 710
1st year	3.6 – 5.0	521 – 724
2–20 years	3.7 – 5.1	536 – 738

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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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

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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
Twin reaction:	No
Name:	ALB
Shortcut:	
Reagent barcode reference:	012
Host reference:	012

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	
Blank reagent	
Sensitive to light	
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 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	0.0700
Concentration technical limits-Upper	6.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	#
URINE	
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	0.025
Cal. 2	0.080
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value
# Editable by user