


Albumin FS*

Order Information

Cat. No.

1 0220 99 10 923

Kit size

 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 an important binding and transport protein for various substances in plasma and the main contributor to the plasma osmotic pressure. Measurement of albumin in serum is used for diagnosis and monitoring of liver diseases, e.g. liver cirrhosis. Furthermore, albumin levels indicate the health and nutritional status of an individual and, therefore, are used for detecting malnutrition and for prognosis in elderly hospitalized patients. [1,2]

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 in-use stability of the reagent is 18 months.

Warnings and Precautions

- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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 [4]:

10 weeks	at	20 – 25°C
5 months	at	4 – 8°C
3 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. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 6 g/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.1 g/dL
Onboard stability	6 weeks
Calibration stability	5 weeks

Interfering substance	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
Hemoglobin	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 [5-7].

Precision			
Within run (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 [8]

Adults: 3.5 – 5.2 g/dL 507 – 756 µmol/L

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

Literature

1. Johnson AM, Rohlfis 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.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in February 2021. Published by AACCC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.
8. 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.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.



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* Fluid Stable

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

Technic	
Type:	End point
First reagent:[μ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
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 [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	0.1000
Concentration technical limits-Upper	6.0000
SERUM	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	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	>=3.50 <=5.20
URINE	
PLASMA	>=3.50 <=5.20
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