

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[®]920.

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].
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- 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	6 weeks

Interfering substance	Interferences ≤ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	900 mg/dL
Lipemia (triglycerides)	500 mg/dL
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]	3.51	4.30	5.75
CV [%]	1.23	1.31	1.74
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.63	4.24	5.34
CV [%]	2.72	2.68	3.01

Method comparison (n=122)	
Test x	DiaSys Albumin FS (Hitachi 917)
Test y	DiaSys Albumin FS (respons [®] 920)
Slope	0.983
Intercept	0.142 g/dL
Coefficient of correlation	0.994

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

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, 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.
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 AACC 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, Biennvenu 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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www.diasys-diagnostics.com

* Fluid Stable

Albumin FS

Application for serum and plasma

Test Details	Test Volumes	Reference Ranges
Test : ALB		Auto Rerun <input type="checkbox"/>
Report Name : Albumin		Online Calibration <input type="checkbox"/>
Unit : g/dL	Decimal Places : 2	Cuvette Wash <input type="checkbox"/>
Wavelength-Primary : 578	Secondary : 700	Total Reagents : 1
Assay Type : 1-Point	Curve Type : Linear	Reagent R1 : ALB R1
M1 Start : 0	M1 End : 0	Reagent R2 :
M2 Start : 33	M2 End : 33	
Sample Replicates : 1	Standard Replicates : 3	Consumables/Calibrators:
Control Replicates : 1	Control Interval : 0	Blank /Level 0 : 0
Reaction Direction : Increasing	React. Abs. Limit : 0.0000	Calibrator 1 : *
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit % : 0	Delta Abs./Min. : 0.0000	
Technical Minimum : 0.1	Technical Maximum : 6.0	
Y = aX + b a= : 1.0000	b= : 0.0000	

* Enter calibrator value.

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