BioMajesty®

# Albumin FS*

## Order Information

| Cat. No. | Kit size |
|---|---|
| 1 0220 99 10 960 | Σ 980 (4 x 245) |
| 1 0220 99 10 967 | Σ 1500 (6 x 250) |

## Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human serum or heparin plasma on automated BioMajesty®-JCA BM6010/C.

## 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

1. In very rare cases, samples of patients with gammopathy might give falsified results [3].
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 [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.<br>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** | 300 mg/dL |
| **Lipemia** (triglycerides) | 1200 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] | 3.26 | 4.03 | 4.48 |
| CV [%] | 1.00 | 0.63 | 1.02 |
| **Between day (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [g/dL] | 3.96 | 4.53 | 2.46 |
| CV [%] | 0.73 | 0.98 | 1.42 |

| **Method comparison (n=100)** | |
|---|---|
| Test x | Competitor Albumin |
| Test y | DiaSys Albumin FS |
| Slope | 0.987 |
| Intercept | 0.168 g/dL |
| 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**

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

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## 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 Assocation 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, 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.

IVD CE


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* Fluid Stable

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# Albumin FS

### Chemistry code 10 022

## 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 | 90 |
| R2e volume | 0 |
| R2 volume | 0 |
| 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 | 3 |

| Sub-analy. Conditions | |
|---|---|
| Name | ALB |
| Digits | 1 |
| M-wave L. | 596 |
| S-wave.L | 694 |
| Analy.mthd. | EPA |
| Calc.mthd. | STD |
| Qualit. judge | No |

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

# entered by user

| Endpoint method | |
|---|---|
| Re.absorb (u) | 9.999 |
| Re. Absorb (d) | -9.999 |

| Calculation Method Setting | |
|---|---|
| M-DET.P.I | 0 |
| M-DET.P.m | 7 |
| M-DET.P.n | 9 |
| S-DET.P.p | 0 |
| S-DET.P.r | 0 |
| Check D.P.I. | 0 |
| Limit value | 0.003 |
| Variance | 10 |
| Reac.type | Inc |

| Reaction Rate Method | |
|---|---|
| Cycle | 3 |
| Factor | 3 |
| E2 corre | Not do |
| Blank (u) | 9.999 |
| Blank (d) | -9.999 |
| Sample (u) | 9.999 |
| Sample (d) | -9.999 |

| Standards Setting | |
|---|---|
| FV | # |
| BLK H | 9.999 |
| BLK L | -9.999 |
| STD H | 9.999 |
| STD L | -9.999 |