UMA CO., LTD.
2-19-6 Yokosuka
Matsudo, Chiba, Japan

MEASURE ALB

Reagent for determination of Albumin

Bromocresol Green Method

2 - 8°C	**IVD** *In vitro* Diagnostics	**QUALITY MANAGEMENT SYSTEM (BY TUV)**
DO NOT freeze	24 months/block from light	**ISO 13485:2016**

1. PURPOSE OF USE

Providing a quantitative in vitro assay for the Albumin (ALB) concentration in serum or plasma.

2. GENERAL INSTRUCTION

a. For in vitro diagnostics use only.

b. Diagnosis should be made in a comprehensive manner, in accordance with other related test results and clinical symptoms by the doctor in attendance.

c. For guaranteed results, usage of this product must comply with the instruction in this manual.

d. If you use automatic analyzers, follow their instructions carefully.

SUMMARY

Albumin is a natural colloid abundant in plasma (molecule weight 69 kDa). Commercially available strengths are 3.5% - 5%. Hyperoncotic albumin, 20% - 25%, is also available in some regions. There is normal translocation of albumin over the endothelium to the interstitium, and 60% of albumin is located extravascularly. Albumin is transported back to the circulation system via the lymphatic system. Albumin 5% expands plasma volume by 80% of the infused volume; infusion of 10 mL/kg albumin 5% increases serum albumin by 10% for 6 to 8 hours. In critically ill patients, there is increased leakage of albumin and supplementation of more albumin only contributes to peripheral edema (i.e., "albumin trapping"). Despite excellent volume expanding efficacy of albumin, randomized clinical trials have found no superiority over crystalloids.

3. MATERIALS REQUIRED BUT NOT INCLUDED

- Saline 0.9 % and high grade purified water

- Micropipet and other basic laboratory equipment.

- MEASURE Multi Calibrator and MEASURE Human Lyo L-1 and MEASURE Human Lyo L-2

4. REAGENT COMPOSITION & PREPARATION

- Reagent R-1: Bromocresol Green Sodium Salt.

Reagent R-1 is ready for use

- Once open, Reagent stored on board the instrument is stable for 30 days with Hitachi 7180 Analyzers.

- Applicable to various automated analyzers.

- Calibrator MEASURE Multi Calibrator (separately sold): Put 5 mL of purified water to the vials of Calibrator (MEASURE Multi Calibrator), leave at room temperature for 45 minutes and sometimes gently invert the vial before use. After reconstituting, Calibrator can be used without dilution.

- Controls MEASURE Human Lyo L-1 and MEASURE Human Lyo L-2 (separately sold): Put 5 mL of purified water to the vials of controls (Lyo L-1 and Lyo L-2); leave at room temperature for 45 minutes and sometimes gently invert the vial before use. After reconstituting, controls can be used without dilution.

5. SAMPLE PREPARATION & STORAGE

- Serum: Wait until the sample is completely coagulated. Take the supernatant to use as a specimen.

- Plasma: Treat blood sample by anticoagulant (Li-heparin and K2-EDTA); leave it to stand for 3 hours or centrifuge at 2000 rpm for 2 minutes; take the plasma layer (supernatant) and use as specimen.

- Analyze samples soon after collection. In case of storing sample 2 – 8°C, analyze within 7 days.

- Stability

- 3 days at 15 - 25°C
- 7 days at 2 - 8°C
- 6 months at < -20°C

- See interferences section for details about possible sample interferences.

6. MEASUREMENT PRINCIPLE

Albumin in patient samples binds with Bromocresol Green (BCG) and generates blue complex. Albumin concentration in patient samples can be determined by measuring absorbance of generated complex.

Albumin + *Bromocresol Green (BCG)*

→ *Albumin Bromocresol Green Complex*

7. ASSAY PROCEDURE

This product is compatible with various types of clinical analyzer. An example of the assay procedure is indicated below.

Sample	+	Reagent 1	$\xrightarrow[600s]{37^{\circ}C}$	Measurement Abs
2.0µL		200µL		(660/700nm)
			⟶	Concentration ALB

Perform the assay according to the instructions for operating the automated analyzer Hitachi models. Refer to the **13. INFORMATION FOR AUTOANALYZERS** for the details of the assay method. Contact **HUMA MEDICAL CO., LTD.** for information about the parameters for other automated analyzers.

8. CALCULATION & UNIT CONVERSION

Calculation

- Calculate ΔAbs of specimen & standards vs blank

- Plot a calibration curve ALB = f(ΔAbs)

- Calculate ALB in specimen using the curve

(doing same procedure for Controls)

Unit conversion

g/dL x 10 = g/L

9. PERFORMANCE & CORRELATION TEST

a. Measuring range

- The test is linear within a concentration range of 1 - 70 g/L.

- If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

b. Detection Limit

Limit of Blank (LoB)	=	0.5 g/L
Limit of Detection (LoD)	=	0.5 g/L
Limit of Quantitation (LoQ)	=	1.0 g/L

The LoB, LoD and LoQ were determined in accordance with CLSI EP17-A2 requirements.

The LoB is the highest apparent analyte concentration expected to be found when replicates of a blank sample containing no analyte are tested. The LoB corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

The LoD is determined based on the LoB and standard deviation of low concentration samples. The LoD corresponds to the lowest analyte concentration which can be detected (value above the LoB with a probability of 95%).

The LoQ is the lowest analyte concentration that can be reproducibly measured with a total error of 20%. It has been determined using low concentration samples.

c. Performance

- Sensitivity: Change in absorbance when measuring purified water ranges from 0.025 to 0.125 and when measuring samples of 40 g/L ranges from 0.07 to 0.35.

- Accuracy: When measuring a control sample, the result is within ±10% of assigned value.

d. Precision (on Biolis 30i / SK300)

Representative performance data on the analyzers are given below.

Results obtained in individual laboratories may differ.

Precision was determined using controls followed the CLSI Approved Guidline EP5-A2 with repeatability, reproducibility and total precison (1 aliquot per run, 2 run per day, 20 days).The following results were obtained.

Criterion: CV of Repeatability (aka. Within-run precision) is less than 1% and Total Precision is less than 3%.

Repeatability	*Mean* g/L	*SD* g/L	*CV* %
Control Lyo L-1	40.93	0.29	0.71
Control Lyo L-2	65.61	0.31	0.48

Reproducibility	*Mean* g/L	*SD* g/L	*CV* %
Control Lyo L-1	40.93	0.76	1.86
Control Lyo L-2	65.61	0.95	1.44

Total precision	*Mean* g/L	*SD* g/L	*CV* %
Control Lyo L-1	40.93	0.79	1.93
Control Lyo L-2	65.61	0.97	1.48

10. EXPECTED VALUES

41 - 51 g/L

Reference range should be established at each facility and judgement should base on measurement results in a comprehensive manner together with clinical symptoms and other measurement results.

11. INTERFERENCES

- Icterus: No significant interference of conjugated bilirubin concentration up to 20 mg/dL and free bilirubin concentration up to 20mg/dL.

- Hemolysis: No significant interference of hemoglobin concentration up to 500mg/dL.

- Lipemia (Intralipid): No significant interference triglycerides concentration up to 3000 FTU.

- Ascorbic Acid: No significant interference of ascorbic acid concentration up to 50 mg/dL.

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. Please use another methods if the result is affected by any factors.

12. HANDLING, USAGE & DISPOSAL

Handling

1. Specimen can be potentially positive for infectious agents including hepatitis B virus and HIV. Wear glove and goggle when needed.

2. In case reagents got into skin, eye or mouth by mistake, wash it immediately with plenty of water and consult the doctor if needed.

3. If reagents are spilled, dilute with water and wipe it out. If specimen is spilled, spray 80% of alcohol over the specimen and wipe it out.

Usage

1. Store reagents under specified condition. Do not use after expiration date.

2. Do not use the container and auxiliaries included in this kit for other purposes.

3. Do not mix reagents of different lot for use.

4. Do not add to the reagent being used even if it is the same lot number.

Disposal

1. All specimens, as well as all instruments (e.g. test tubes) that come in contact with the specimens, must be treated by the following methods, or they must be treated according to the manual for infectious medical waste provided in each facility.

- Sterilize with an autoclave, subjecting them to high pressure saturated steam at 121 °C for more than 20 minutes. Do not process waste containing sodium hypochlorite solution with an autoclave.

- Immerse at least one hour in sodium hypochlorite solution (active chloride concentration of over 1000 ppm).

2. This reagent contains sodium azide. Sodium azide can react with lead pipe and/or steel pipe and can generate explosive metal azide. Make sure to use plenty of water at disposal. Concentration of sodium azide in R-2 is 0.05%.

13. INFORMATION FOR AUTOANALYZERS

❖ **For Hitachi Model**

Calculation Method		One point
Temperature		37°C
Volume (µL)	Specimen	2.0
	R1	200
	-	-
Wavelength (nm)	Main	660
	Sub	700
Measurement (cycle)	Point 1	10
	Point 2	34
	Point 3	-
Calibration type		Linear
Unit		g/dL

14. OTHER INSTRUCTIONS AND CAUTION

- Results may differ depending on the sample/reagent ratio. Adjust parameters for different analyzer.

- Perform the QC procedure on the day of determination.

15. PACKING AND KIT CONFIGURATION

Code	Package	Test/Kit*	Test/Kit**
11A016A	R1 2x60mL	600	900
11A016A2	R1 4x60mL	1200	1800
11A016A3	R1 6x60mL	1800	2700
11A006A	R1 8x60mL	2400	3600
11A016	R1 2x90mL	900	1350
11A016-2	R1 4x90mL	1800	2700
11A006	R1 6x90mL	2700	4050

* For middle-scale automatic analyzers such as: SK300; BS series; BA200; BA400. Chemwell Series; Dirui Series; Biolyzer series, HumanStar 300, Erba Series; Bioelab Series, BX 3010; Pictus P500;...

** For large-scale automatic analyzers such as: CA800; CA400; Randox Imola; Randox Modena+; BM 6010; Biolis50i; SK500; AU Series; Pictus P700; C series; Ci series; HumanStar 600; Kenolab series ...

The above-mentioned test's number are calculated base on technical specifications of each analyzer. The real number of test per kit may higher than the calculation's number.

The above-mentioned test's number cover the loss of the dead volume of reagent bottles but not cover the loss of Calibrator and Control.

Please feel free to contact authorized distributor for further confirmation.

16. REFERENCES

1. Christer Svensén, Peter Rodhe, in Pharmacology and Physiology for Anesthesia, 2013
2. CLSI/NCCLS Evaluation of Precision Performance of Clinical Chemistry Devices, EP05-A2, 2004
3. CLSI EP17 · Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition, 2017
4. In house data, UMA Diagnostics

17. MANUFACTURER

UMA Co., Ltd.

2-19-6 Yokosuka, Matsudo City, Chiba

Prefecture 270-0031

TEL: 047-710-4871 (dial-in) **FAX: 047-710-4872**