

### Kit Specifications:

	Reagent/Quantity	Storage
Cat. No.: <b>AB0011</b>	R.1: 6 x 50 ml total 300 ml	2-8°C
Cat. No.: <b>AB0017</b>	R.1: 5 x 60 ml total 300 ml	2-8°C

### Intended Use:

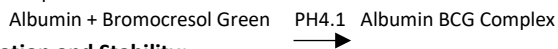
In Vitro Diagnostic reagent pack for the quantitative determination of Albumin in human serum on automated and semi-automated photometric systems.

### Summary and Explanation:

Albumin is an abundant protein in plasma. The 55 to 65 percent of total protein on blood. The essential role of this protein is to keep the osmotic pressure, transport and keep the many ligands that source of amino acids in body. Albumin is a simple protein without any carbohydrate which contain a poly peptide chain with 585 amino acids. Albumin daily synthesis from 9 to 12 grams in liver and deliver to blood stream. The albumin is relatively small molecule with high concentration therefore, in most of the human fluids such as vascular external fluids, CSF, urine and amniotic fluid in pregnancy period found. Furthermore, many materials such as bilirubin, calcium and fatty acids with long chain are transport by this protein. Albumin has an ability to absorb toxic, heavy metal and drugs. So by this ability the side effects of those were neutralized. The albumin in malabsorption, malnutrition liver diseases to repel abnormal. This protein is being low in kidney disease and bowl inflammation. The determination of albumin is critical in treatment of hyper glycaemia and kidney disease. Hypo albumin is found in many diseases such as liver disease, increase catabolism in albumin, tissue inflammation, mal absorption, mal nutrition, Crohn's disease, repel excessive water from kidney and digestive apparatus observed.

### Principle of the Method:

This method based on albumin exist on serum in acidic background by Bromocresol Green which make green / blue complex. The intensity of the color will have measured on 600-650 Nano meter wavelength which is correlate with the amount of Albumin on the sample.



### Reagent Preparation and Stability:

Reagent is ready for use.

Before use, mix reagent by gently inverting each bottle.

Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.

Do not use reagent over the expiration date.

Do not freeze and protect from light.

The reagent is transparent and dark green.

### Waste Management:

Refer to local legal requirements for chemical disposal regulations.

Warning: Handle waste as potentially biohazardous material.

Dispose of waste according to accepted laboratory instructions and procedures.

### Warnings and Precautions:

For In Vitro Diagnostics Use Only.

For Professional Use Only.

Carefully read instructions for use.

In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.

Take all necessary precautions required when handling laboratory reagents.

Do not use components past the expiry date stated on the Bottles.

Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

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.

### Type of Specimen:

Use fresh serum, non-hemolysis and heparinized or EDTA plasma Specimen must be completely cleared before assay.

It is recommended to follow CLSI procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.

### Stability:

Albumin stability in serum and plasma at 15-25°C 7 days, at 2-8°C 30 days and at -20°C will be 3 months.

If the garo closing in long term may should exit water from vein. So, the concentration of Albumin will be increased.

### Materials Required but not Supplied:

General chemistry calibrator from TKS or other valid calibrators.

General chemistry control Level 1 & 2 from TKS or other valid controls.

Saline solution 0.9 % NaCl

General laboratory equipments.

### Notes:

Carefully read instructions for use.

It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.

Use clean disposable pipette tips for its dispensation.

Disposable and glassware material used must be free of metals, ions and detergents.

### Performance Characteristics:

Performance results can vary with the instrument used.

Data obtained in each individual laboratory may differ from these values.

**Maximum determination in this assay is 6g/dl**

**LOQ: 0.5g/dl**

For samples with a higher concentration (6g/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

**Precision:**

**Intra Assay-Within run albumin**

Sample	n	Mean (µg/L)	SD (µg/L)	CV (%)
1	20	5.00	0.02	0.47
2	20	3.71	0.02	0.55

**Inter Assay-Between run albumin**

Sample	n	Mean (µg/L)	SD (µg/L)	CV (%)
1	20	4.56	0.28	6.20
2	20	3.07	0.18	5.90

### Accuracy:

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).

**Correlation coefficient (r): 0.9916**

**Regression equation: Y = 1.045 (X) + 0.028g/dl**

The results of the performance characteristics depend on the analyzer used.

### Interfering Substances:

No interferences were observed to:

<b>Haemolysis</b>	Less than 10% interference up to 5 g/L Hemoglobin
<b>Bilirubin (mixed isomer)</b>	Less than 10% interference up to 600 µmol/L Bilirubin
<b>Lipaemia</b>	Less than 10% interference up to 5 g/L Hemoglobin

### Reference Values:

<b>Serum/Plasma</b>	3.5-5.2 g/dl
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Each laboratory should establish its own expected values. The Albumin results should always be reviewed with the patient's medical examination and history.

### Assay Procedure:

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result.



**Assay conditions:**

600-650nm	Wavelengths
25 °C	Incubation Temperature
1 cm	Cuvette

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	Blank	
1000 µl	1000 µl	R1
5 µl	-	Control/Sample/Calibrator

Gently mix and incubate at 25°C for 10 minutes. The absorption of sample and calibrator against blank. The stability of color is 60 minutes. Do not expose to direct light.

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**Calculations:**

ΔAbs for each calibration should be prepared and calculate. The calibration curve should be prepared.

ΔAbs should be calculated for each sample. The related concentration should be determined by the calibration curve.

$$\text{Albumin (g/dl)} = \frac{\text{Abs. Sample} \times \text{Cal. Conc. (g/dl)}}{\text{Abs. Calibrator}}$$

**Conversion Factor:**

$$\text{Albumin (g/dl)} \times 144.9 = \text{Albumin}(\mu\text{mol/L})$$















TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

**References:**

- 1-Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft; 1998.p.652-6.
- 2-Doumas Watson W.A.; Clin.Chem. Acta, 31(1971)87.
- 3-Spencer D. et al., Anal. Clin. Biochem., 14 (1977)286.
- 4-Tietz N., Fundamentals of Clinical Chemistry Philadelphia W.B. Saunders 335-337,1976.
- 5-Gendler S. Uric acid. Kaplan A et al. Clin Chem the C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1268-1273 and 425.
- 6-Rodkey F L. Clin Chem. 1965; 11: 478-487.
- 7-Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACCPress, 1995

**Symbols:**

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

 In Vitro Diagnostics	 Contains sufficient for <n> tests
 Batch Code	 Temperature limit
 Catalogue No.	 Consult instruction for use
 Expiry Date	 Caution
 Date of Manufacture	 Keep dry
 Manufactured by	 This way up
 Biological Risks	 Keep away from sunlight